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SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

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

MONDAY, 6 FEBRUARY 2006

SYDNEY

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SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Monday, 6 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, Robert Ray, Siewert, Watson, Webber and Wong

Senators in attendance: Senators Adams, Barnett, Fielding, Heffernan, Humphries, Moore, Nash, Polley and Webber

Terms of reference for the inquiry:

Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005

WITNESSES

Committee met at 8.33 am

CHAIR (Senator Humphries)—I call together this meeting of the Senate Community Affairs Legislation Committee. The committee is continuing its inquiry today on 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 remove responsibility for approval for RU486 from the Minister for Health and Ageing and to move that responsibility to the Therapeutic Goods Administration. The inquiry will focus on the terms of the bill by seeking evidence on the issues that are relevant to the bill in order to inform the Senate in its deliberations on the bill.

To enable the committee to hear from as many witnesses as possible, the program has been arranged with groups of witnesses in each timeslot during the day. A representative of each group will be invited to make a short opening statement and the committee members will ask questions of those representatives. I would ask committee members to bear in mind the time constraints imposed by today's program and, given the number of senators likely to appear today, to keep questions succinct and to the point. We have had a request from the media to record the proceedings. Is there any objection to that taking place? There being no objection, it is agreed that the media will have access to the proceedings on the usual terms.

[8.34 am]

FISHER, Most Reverend Professor Anthony Colin Joseph, Member, Bishops Committee for Family and Life, Australian Catholic Bishops Conference

RIORDAN, Ms Marcia, Executive Officer, Respect Life Office, Catholic Archdiocese of Melbourne

VOUT, Dr Brigid Mary, Executive Officer, Life Office, Catholic Archdiocese of Sydney

CHAIR—I now welcome Bishop Fisher and representatives of the Catholic Archdiocese of Sydney and the Catholic Archdiocese of Melbourne. Thank you for being here. You have been provided with information on parliamentary privilege and the protection of witnesses and evidence. We have your submissions, numbered 628, 1111, and 720. Thank you very much for them. I now invite you to make an opening statement before we proceed to ask you questions.

Dr Vout—Good morning. I am a qualified medical doctor and bioethicist appearing on behalf of the Catholic Archdiocese of Sydney. With me this morning is Bishop Anthony Fisher, appearing on behalf of the Australian Catholic Bishops Conference Committee for the Family and for Life, and Ms Marcia Riordan, from the Respect Life Office of the Catholic Archdiocese of Melbourne. I will make a brief opening statement. Bishop Fisher and Ms Riordan and I will then welcome your questions and, if it is acceptable to the chair, Bishop Fisher would like to make a short concluding statement.

The Catholic Church has a long and ongoing tradition of directly caring for the health of women and their children as well as advocating for social policy that seeks to promote and protect the life and health of every member of the human family. We sponsor the oldest and the largest network of health care institutions in the world and are the largest non-government provider of health care in Australia. As Australian Catholics in a pluralist society, we recognise our responsibility to actively engage in public discussion about important and sensitive life issues in order to contribute to a robust Australian democracy. So, too, we recognise the responsibilities that democracy entrusts to the elected members of the government, particularly in deciding matters of social and ethical importance.

The Therapeutic Goods Amendment (Repeal of Ministerial Approval of RU486) Bill 2005 is essentially about who should decide whether drugs like RU486 should be available in Australia for use as abortifacients. Should these decisions remain with an elected community representative or should they be delegated to unelected specialist bureaucrats? We contend that this must remain a ministerial decision for the following reasons. Firstly, substances like RU486 are not conventional therapeutic goods. A substance is therapeutic if it relates to the treatment or curing of disease. However, drugs like RU486 are not administered to women with the intention of treating or curing a disease. Abortifacients are administered with the intention of ending the life of a human embryo or foetus.

Secondly, abortion is an important and sensitive ethical and social issue in Australia. In particular there is widespread and deep unease about the high incidence of abortion in Australia. Recent research into Australians' attitudes to abortion has found that, although

supportive of legal access to abortion, Australians are deeply ambivalent about the morality of abortion and, apart from hard cases involving danger to the mother's health or foetal disability, fewer than one in four Australians think that abortion is morally justified. This study reveals that 87 per cent of Australians believe that it would be a good thing if the number of abortions was reduced without restricting access.

This committee has received over 1,000 submissions and another thousand form letter submissions arguing against this bill and/or any move to introduce RU486 into Australia. An additional 2,000 letters protesting against moves to introduce RU486 into Australia have been written to senators. Two hundred Catholic doctors in Queensland are reconsidering their membership of the Australian Medical Association and the Royal Australian College of General Practitioners owing to a growing concern over the lack of consultation of views in relation to this issue. Research and recent experience both show, therefore, that the community is significantly concerned about the broader ethical and social issues surrounding abortion generally as well as specific concerns about RU486. The Australian community wants to see fewer abortions not more methods of abortion.

Thirdly, while there is currently no discernible consensus that the availability of abortifacients increases or decreases a nation's overall abortion rates, it is hard to see how access to chemical abortion will do anything to address the public concern about the high incidence of abortion in Australia. Prima facie, the more methods of abortion and the greater the access, the more mainstream abortion may seem and the more likely the abortion rate is to increase. Certainly social arguments in favour of abortifacient use in Australia on the grounds that women should have a choice of abortion methods would seem to only support the current culture of high abortion rates. Practically, what is required is not another method of abortion but positive strategies which address the social circumstances that cause women to choose abortion in the first place.

Each of these points highlights the fact that drugs such as RU486 do not only carry the usual measure of medical risks associated with therapeutic goods. Because they are designed to end very young human lives, allowing or disallowing access to abortifacients also has serious ethical and social implications. The Therapeutic Goods Administration might possess the medical knowledge and the expertise to conduct the evaluation of RU486 and other abortifacients for quality, safety and efficacy, as it does with therapeutic goods; however, the TGA does not have the knowledge, the expertise or the mandate to make a judgment about the ethical and social impact of abortifacient drugs. Judgments and decisions about abortifacients call for an additional level of scrutiny and accountability by elected community representatives.

So who should decide whether or not abortifacient drugs are to be allowed in Australia? We submit that there are important ethical and social concerns surrounding abortifacient drugs which make them unsuitable for evaluation within the same framework as therapeutic goods. Accordingly, it is the Minister for Health and Ageing and not the Therapeutic Goods Administration who should retain ultimate responsibility for decisions in relation to the importation, trial, registration and listing of RU486 and other abortifacients in order to ensure appropriate scrutiny and accountability by elected community representatives. Thank you for your attention. We will be pleased to discuss these matters further with the committee.

CHAIR—Thank you very much. Have you made that statement on behalf of all three members of the panel?

Dr Vout—Yes.

CHAIR—Could I start by asking you about the sorts of issues that a government or minister for health should consider, beyond the technical questions about the medical efficacy of a drug, that you have described as needing to be considered at government level? What kinds of issues should a government take into account when it is making a decision about a drug like RU486? Should it take into account those technical questions or should it leave those to a body like the Therapeutic Goods Administration and, if so, what are the issues that a government ought to consider when deciding whether to approve a drug like that for use in Australia?

Bishop Fisher—A number would immediately occur to me. One is clearly the medical range of issues, and the TGA would be one place certainly that you would expect a government or a minister to turn to for advice. It might not be the only one, but it certainly would be a logical one to be included. But there is a range of other issues, such as legal issues, issues of social policy—whether we want to encourage more or fewer methods of abortion and what as a community we want our direction to be in this area—and issues of ethics and morality with respect to the protection of the unborn or of women. You would expect an elected leader to take that range of issues into account, and that is a much broader range than you could ask a group like the TGA to consider. Of course, I should mention that there would also be financial issues, which again a government would perhaps be concerned about with respect to a whole new direction but which would not necessarily be the concern of the TGA.

Senator MOORE—There are similar questions at all the hearings. Hearing your evidence again this morning after reading the submissions, I think there is so much on which people can agree, but that probably will not be reflected in the process. The argument in this process is looking at a specific clause in a bill that looks at assessment of a drug, and yet the debate is about the wider issue of abortion in Australia. I would really like to hear, following on from Senator Humphries' question, about the methodology of the debate. If the intent is to have the debate about the ethical questions—the questions you have just raised, Bishop, about the wider area—why use a clause about therapeutic goods to have that debate? Why, from your perspective, when your argument is based on the role of government, use a very short clause in the therapeutic goods amendment about assessment to raise what you state—and quite rightly, I agree—is a much wider area which crosses the whole of government? Specifically in this case we are looking at the specific legality or otherwise in the Australian Constitution of termination as at the state level. I would like to have on record the response to that question.

Bishop Fisher—It strikes me that issues of this kind of social import, such as taking a major new direction in the way we might do at least some of our abortions in the future—and that might have an impact on numbers but certainly will have an impact on the women affected, their children and their broader families—are the sorts of issues that you would want our elected leaders to be considering. The bill presently before the parliament would take that responsibility that presently is with a minister and, therefore, ultimately cabinet and parliament away from him or her and put it in the hands of some people whose specific task is purely to look at the medical efficacy and safety and not at the broader range of issues.

What we are saying is that this is at present a responsibility of our elected leaders, and given the huge importance and the complexity of it beyond medical considerations, we would want it to continue to be a responsibility of our elected leaders. The bill proposes to remove not just RU486 but a whole range of drugs from that category of goods that are not treated as therapeutic goods but as goods that require ministerial approval before they can be imported. The reason we think that they should be regarded as quite different is that whether they are therapeutic or not is very much at issue; and they have a much broader range of implications, socially and ethically, than an ordinary medical drug would have.

Dr Vout—Much of the answer lies in the fact that these drugs are like no other drug. I suppose that is why we went to lengths to distinguish between them and therapeutic goods by saying that we actually believe that the classification of RU486 and other abortifacients as restricted goods is appropriate. It reflects the fact that these drugs are like no other drug. They are designed to cause an abortion, and that in itself raises a whole range of additional ethical and social issues—and a whole range of different health issues—when we are considering the effects of these drugs upon women. As a first step in our argument, I think that is an important one: these are not therapeutic goods.

Senator FIELDING—The federal parliament decided in 1996 that decisions about abortion drugs were too important to be made by unelected, unaccountable bureaucrats. Do you believe that anything has changed since 1996, in the last 10 years, that means we should now allow unelected bureaucrats to make these decisions?

Bishop Fisher—My own opinion is that, as a matter of principle, nothing has changed. This remains an issue of enormous importance to women, to unborn children, to the family, and to the whole community. It is as true today as it was a decade ago when the view was taken that a drug with these sorts of implications should be permitted only with the authority of our elected leaders.

It does strike me that one important thing has changed, and that is the growing ambivalence towards the abortion rates in this country. Study after study is now suggesting that while Australians do not want to see new criminal sanctions on abortion, they do want governments and others—including ourselves as churches—to take a lead in trying to give women real alternatives and to try to decrease the amount of abortion in this country. At the moment our rate is something like double that of Britain, for instance. That is a change in the meantime, but it is a change that would point us in the direction of being very wary of adopting another means of abortion in this community or shifting the responsibility to unelected officials.

Dr Vout—Tied in with that, another thing that has changed is a growing awareness in the community of the harm that abortion causes to women—the physical and, perhaps more importantly, the psychological after-effects of abortion. As Bishop Fisher pointed out, while from our perspective the ethical issues surrounding this have not changed, I think we have grown an awareness of the wider harm that abortion causes to women, to fathers, to families, to the wider community, to our health professionals and to our institutions. Perhaps that is what is being reflected in the growing unease about the high rates of abortion in this country. This is something that we were all too afraid to speak about too often, particularly from the perspective of women, and women are now beginning to speak about how this impacts upon their lives, the lives of their families and their communities. We welcome that.

While our submission and my presentation today did not focus on the physical and psychological after-effects of abortion on women, we are pleased that there has been so much community discussion around that fact as this issue has come to light. There is a growing awareness that abortion, certainly from our perspective, kills a very young human life but it often also causes great harm to women.

Ms Riordan—Many of the women we speak to through our work, who come to regret this decision, insist that at the time they were not given other options—they did not feel that they had other options—and that they were just steered into this path. They later came to regret it because it has become so common. Many of them are now saying that they want to help other women make sure that they are not steered in that direction. They would like to see other women given real options and the community find new ways of helping women when they are faced with such a decision—that they are not just steered in that direction and that abortion is the only option they are given.

Senator FIELDING—What I have heard of your perspective is that nothing has changed in the last 10 years—that the current system allows the elected and accountable people to make that decision and that you are suggesting that research and other pieces are saying that people actually feel uncomfortable with the number of abortions. I am wondering whether the change is that we have a handful of politicians, including some who have personally attacked the health minister, who have decided that unelected bureaucrats should now be responsible for making policy decisions.

CHAIR—What is the question, exactly?

Senator FIELDING—I am just making a statement based on what I have heard.

CHAIR—If you want to respond to that, you may. If not, we will have further questions.

Senator BARNETT—Thank you very much for your submission. I am interested in two aspects: the view that you have that the definition of 'therapeutic' is related to the treatment or curing of disease, and then you go on to say:

Abortifacients are administered with the intention of ending the life of a human embryo or fetus.

Is this one of the key reasons that you see this drug as different from all other drugs? It has been put to us at the inquiry that it should be treated like all other drugs. Why should RU486 with prostaglandin, which is required in terms of abortion, be treated separately? There are other drugs for treating and curing diseases; different types of drugs—a full gamut which, as a senator and lawyer, I am not totally familiar with—but why should this be treated so separately and distinctly?

Dr Vout—Certainly doctors—I speak here as a medical practitioner—and, I think, women, even women who are facing pregnancy in difficult circumstances, do not regard pregnancy, however difficult and traumatic it may be, as a disease. It is regarded as a very particular situation that brings with it a whole host of other considerations. I have noticed in the public debate that even some doctors have at times been talking about pregnancy as a disease. There was a report on the ABC last week about pregnancy—that it is a common gynaecological condition that women suffer. I submit that pregnancy is not a disease and that any woman could tell the committee that.

Senator BARNETT—I think that all of those around this table would certainly agree with your views on that. Can you list or outline to us the nature and reasons—you said 'for a whole list of reasons'—why this is a different drug and should be treated and assessed differently?

Dr Vout—Pregnancy is not a disease. Although there may be a whole host of health problems that accompany a pregnancy which certainly need to be addressed and treated, we do not actually treat a pregnant woman. We do not treat pregnancy; we care for the woman who is pregnant. Whereas a therapeutic good is designed to cure or to treat a disease, abortifacients are designed to end a human life. I think that is a very important distinction between the two, which is why I believe that the designation of abortifacients, including RU486, as restricted goods reflects their true nature; it reflects what they are.

Senator BARNETT—You go on to say:

The TGA does not have the knowledge, expertise or the mandate, to make a judgment about the ethical and social impact of abortifacient drugs.

Can you expand on that, particularly with regard to the ethical and social impact, and help the committee to understand your views that the TGA does not have the wherewithal to make this assessment by itself?

Dr Vout—Government, and I think the community, recognise that the TGA has been established to make judgments about the safety and efficacy of therapeutic goods. It is a very important role, and one which they seek to fulfil. This is not a therapeutic good, though, as I have said. This drug is an abortifacient. It ends very early human lives, which obviously has an implication upon the life of the embryo or foetus and, because this is not an ordinary medical decision, a potentially profound impact upon the women who have received the drug and upon the communities that surround these women. It is not the same as trying to treat or cure a standard disease. When we consider the broader ethical and social issues—I think Bishop Fisher outlined some of them before—abortion impacts upon women, upon their families and upon communities. Australians are showing deep unease about that. I think we are starting to now experience the after-effect of abortion and realise just how it does ripple out into our community.

Bishop Fisher—On some other issues where we seek to have an ethical judgment made—for instance, on some research projects—we would ensure that the body making such decisions had people with expertise in ethics, perhaps people with expertise in sociology with an eye to the social impact, and people with a broader range of expertise than we quite properly require of the TGA. Its members have a very particular task, and they are chosen with that in mind. We do not choose TGA members on the basis of, for instance, their having done degrees in bioethics or having experience in sociological research and the like.

Senator BARNETT—And, to your knowledge, those people that you refer to are not part of the TGA and are not on the assessment panel?

Bishop Fisher—To my knowledge, no. It is certainly not the basis on which they are chosen. Occasionally, accidentally as it were, a person could be on the TGA who had such experience and background, but that is not the basis on which they are chosen, and it would be unusual, I would think.

Senator BARNETT—You referred a number of times during your submission to abortifacient drugs that are on the restricted goods list. I think up until this inquiry started most people thought that we were talking about just RU486, whereas of course we are talking about eight separate abortifacient drugs that are listed as substances subject to import controls in addition to human chorionic gonadotrophin vaccines—is that right?

Bishop Fisher—This was also news to us. The way it has been explained to the general public, and indeed to the parliament, is that the inquiry is on RU486. That is the very name of the inquiry, and all the public debate has been about that one drug. We learnt only much later, on examining the legislation, that it affects a range of drugs. I think that is right.

Senator BARNETT—Do you have an understanding of or details on the various drugs that are referred to on this list? No doubt we can come to that as a committee but, if you have any evidence about the nature of these drugs and their objectives, that would be of interest.

Dr Vout—No, we have nothing further to add. We are not pretending to stand here as medical experts today, but as I am a doctor I would add that in fact very little is known about many of those drugs.

Senator BARNETT—In regard to the protocols and guidelines that would, hypothetically, be established if the TGA did approve the drug, do you have any confidence that the protocols would be comprehensive and adequate to ensure the safety and efficacy, let alone deal with the ethical and social impacts of applying and using RU486 or another abortifacient drug?

Bishop Fisher—With respect to the last part of that, no, I do not have confidence that they will address the social and ethical implications of the drug, because it is not part of the TGA's role to do that. So it would be surprising if they sought to in their protocols were they to be given the task of doing this. Even on the medical matter, concerns have been raised in the community about the limited resourcing and mandate of the TGA. It does very little in the way of monitoring beyond the granting of the initial permission to see the effects on people and the adverse effects. The TGA unavoidably relies, as I understand it, very heavily on what the manufacturers provide by way of information and such published studies as there may be from time to time. As you have raised already, there are a number of drugs affected by this bill, and for some of these there has been little published research. In these cases the TGA would be relying I would guess almost entirely on the manufacturer's information. Even for RU486 people would say there is very contradictory research. The TGA, in terms of any follow-up on the effects of RU486 on our community, especially on the women and children affected but also the whole community, has a limited ability to do that and a limited mandate.

Senator POLLEY—We have had endless evidence put before this committee and, as has been alluded to this morning, we have been inundated with emails and other forms of communication. One of the areas of concern to me is that we had representatives of university students who believe—and others have raised the issue—that this is about choice. So if you are pro-choice on abortion, you want another option. They also view it as a quick, easy and cheaper option. Do you have a view on that? The other area of major concern to me was that there was an emphasis that this really was a procedure that is no worse than women's monthly menstruation. I have concerns for the community when people who are pushing for this change would see such a destructive act as such a short-term, quick-fix solution. There is also

the other theory that this is a drug that has been pushed by the pharmaceutical lobbyists as a quick fix—another easy solution to fix another female problem. Would any of you like to share your views on that?

Senator MOORE—Chair, before we go further, I think it is important for the record that it is the university students and nobody else that I am aware of have used the word 'quick fix' in relation to this particular process. I think it is important to have that on the record straightaway.

CHAIR—That view is noted. Are there any responses to Senator Polley's question?

Bishop Fisher—On the question of choice, if people in the community do see this as helping to multiply women's choices, our own view would be that it is not beginning to address the issue of women's choice. So many women feel pressured by financial, emotional and other circumstances into abortion and possibly regret it for years thereafter—or at least have ambivalence about it. Just multiplying the methods does not begin to address the issue of the lack of choices that women really have. There we have to look at things like workplaces, family attitudes, cultural attitudes to pregnancy and a whole range of things which are limiting women's choices enormously. I think just to offer another method certainly is not multiplying choice; it is leaving women as lacking in choice. I know that Marcia has done some work on this and might like to say some more.

The other thing I would add is that, if there is an impression out there that this is a quick fix, that this is quicker and easier than a surgical abortion—and that impression may be out in the community because it has been called in some places 'a home abortion', so you do not have to go to an institution; it sounds easy and it sounds simple—we know in fact it is far from that. In many ways, it is more complex and dangerous.

So if that impression is out there, it only gives us more cause for concern. People might think: 'I don't need continuing medical supervision. I don't need to take the second drug. I don't need to have a follow-up to check that it's actually worked and I've not been left with parts of my unborn child or with infection.' If that is out there—and I think you are right to suggest that some people think that, whether they have made submissions or not; I have seen it suggested in the media—it is neither multiplying women's choices nor giving them a quicker or easier way.

Ms Riordan—I think that instead of addressing the real needs of women, in some ways it is treating them with disrespect. It is not really addressing the issues that are driving them to seek an abortion in the first place—the lack of support, the lack of opportunities. It is just saying, 'Here is another option for you,' rather than looking at what they might really be seeking, what they might really be wanting and what might really be in their long-term best interests. That is the way I see it.

Senator HEFFERNAN—I was pretty traumatised when I saw you this morning, Bishop Fisher. You are far too young to be a bishop. I must be far too old to be a politician. I have a different perspective in these hearings. The cover argument I have heard, and I have not participated in this debate before, is that this is all about who should make the decision—in other words, this argument is purer than the driven snow, which of course is rubbish. This is an inseparable issue about where we go from here. I am not qualified to talk about the ins and

outs of it, even though I come from a long line of large families and I am a failure because I only have four kids. I would like to go into the long-term impacts of what this is all about rather than the merits of the medical side or the non-medical side. The AMA recently said in regional New South Wales that RU486 is a safer option for rural women because it is safer than childbirth. What do you think about that?

Dr Vout—I am not sure how to interpret that statement. I think it is important that when we are looking at the safety of this drug the right comparisons are made. I think that the right comparison to be made about the safety of RU486 is between the complications, the danger, of surgical abortion up to seven weeks versus the complications, the danger, of chemical abortion up to seven weeks.

Senator HEFFERNAN—I actually think it is about positioning the debate. I want to just say that I think that parenthood is the world's greatest vocation. Parenthood often involves sacrifice, inconvenience and frustration, probably verging on insanity at times. It was not designed to be a ship of convenience. I want to talk to you about the long-term impacts, that the world's greatest vocation may become just a matter of social convenience. I do not think this debate has really looked at the 50-year impact of all of these decisions. If you are looking at the clear-felling of a forest, you have to look at what happens in 50 or 100 years to the forest or where the forest was. China's one-child policy was something that looked pretty smart at the time. It is now going to turn into a nightmare for China. Climate change is another thing.

We have all been going around ignoring climate change and the world has almost decided that it is too late now. And so it is with euthanasia. I recall the debate on euthanasia. Now, in Holland, 50 per cent of all people who are euthanased are euthanased without their consent or knowledge. It has got a long way from the original debate. I want to talk about where this is going to go in 50 years and how the urge of social convenience will overpower the great vocation of parenthood, which will be more affected in countries with higher standards of living than lower standards of living, and what the long-term impact of that will be socially right around the globe. Would you like to comment on that?

Bishop Fisher—Those are huge questions.

Senator HEFFERNAN—The world is your oyster.

Bishop Fisher—I think you are right to say these are bigger questions than just an issue of medical risk. That is because we know that some major changes in social policy have very significant family impacts and demographic impacts. If they have significant impacts on family and on demography, in turn they will affect culture, society, economy and polity in all sorts of ways. If, for instance, we face some real issues with demographic decline in Australia, if that is a concern for the community—and it is raised periodically—or if we have real issues with the pressures on families at the moment, the umpteen pressures against child-rearing, then you will want to ask, with a major new approach to abortion being proposed: 'What are the impacts likely to be on the family or on the demography and therefore in turn on culture and economy and so on?'

I think you are right to raise those issues. It is true that not a lot of serious thinking has been done about that—at least not that has been published in the media and other places. If,

for instance, we were to at least continue with the present abortion rates, and possibly increase them by mainstreaming another method of abortion which might increase them, if that is a possibility, is that helpful to us as a community? What will the effects of that be? We are in a situation at the moment where attitudes to fertility, to the unborn, to children, raise all sorts of important social questions. We have got an inquiry at the moment that is trying to report very quickly and to vote very quickly. To so quickly go in a whole new direction on abortion when it could have such major impacts on family life and demography and so on seems to me imprudent, to say the least. You would want to say of social policies such as this: 'We want to think through very hard what will be the impacts on family, on women, on demography and so on.'

Senator HEFFERNAN—You say that if the authority to decide social policy issues is removed from ministers there will be an adverse impact on the process of government. I would like you to illustrate an example of that in a minute. Before you do that, I want to further explore the power of the bureaucracy to make social decisions. I know that this is a long way from why we are allegedly here today, but film censorship is a really good example of this. Film censorship allegedly reflects community standards, yet film censorship has allowed recently on TV full frontal nudity, people playing with themselves et cetera.

Senator NASH—I have a point of order, Chair. Could you perhaps bring the senator back to the terms of reference?

Senator HEFFERNAN—This is to illustrate—

CHAIR—It would be useful, with great respect—

Senator HEFFERNAN—I know it is getting a bit wide; I will come back. That is to illustrate a bureaucratic decision. Bishop Fisher, could you give us an example of such a situation of taking it away from the process of government, or giving it from the minister to government?

Bishop Fisher—I think we could point to a number of situations where governments have found it convenient perhaps not to address an issue themselves and so put it onto somebody else, or where this has happened without perhaps the elected leaders even adverting to how the decision making has shifted to some other body. Another matter which you will have to consider as a parliament in the near future is the recent Lockhart report which, amongst other things, suggests that whole areas of new biotechnology should no longer come before the elected representatives but should be simply decided by the NHMRC or some other body. That might be new forms of cloning or animal-human hybridisation or whatever. The proposal there is to take that out of the purview of the elected leaders of the country and give it to some bureaucrat.

One can only presume people propose that because they think they will get what they want more easily by not having to go through the process of public debate and public accountability. I think that, were we to trawl through the last few years and reflect on at what times decisions of major social impact have been made by the bureaucracy rather than by our elected representatives, we would find that a common theme is that either they were chosen deliberately because someone did not want to face the issue or parliamentarians did not realise the shift of power that was going on towards somebody else.

Senator HEFFERNAN—That is, political convenience. If the TGA is not the appropriate body, who is?

Bishop Fisher—I think the appropriate body for making major decisions of social and ethical import in a democracy is the elected leaders. At the moment we have the minister, who is accountable to the cabinet, which is accountable to the parliament. You might argue that it should be a broader range of political leaders, but it seems to me fairly straightforward that on a matter of this import it should be our political leaders rather than a group little known and not elected.

Senator HEFFERNAN—Why don't you consider it to be good social policy for there to be, if need be, an increase in abortions?

Bishop Fisher—There are a whole range of reasons why we would not think it a good thing for there to be an increase in abortions, and that is not even something peculiar to the Catholic Church. Our concern for the lives that are lost in abortion, a very important concern, is well known. But we also recognise increasingly the impacts of abortion on women and on the wider family—the men and others in the family—the demographic impacts, the impacts on people who increasingly find it impossible to adopt and the impacts on the economy, the culture and the polity of having more and more of our children never see the light of day. Any proposal that was likely to at least continue this situation and very possibly make it worse would have to be of concern not just, I would think, to the churches but to the general community. That is reflected in the recent polling that shows that eight out of 10 people say, 'Whatever of abortion laws and regulation, what's clear to us is that 90,000 a year, one in four pregnancies, is just too many.'

Ms Riordan—If I could add to that last question, the bishop mentioned the dramatic social impact, and we are starting to see that as well in relationship breakdown. Many couples where there has been an abortion are unable to maintain that relationship subsequently. That could have all kinds of social impacts that we might want to be thinking about as well. As we know, Australia has a high rate of relationship and marriage breakdown. Abortion can have wide spectrum of impacts.

Senator NASH—I do not think there is any disagreement around this table that there should be fewer abortions and more done on prevention and education. I have been on record many times as having said that. Certainly one of the points that is coming through from what you have said today is your concern that introducing another method of termination would possibly increase the abortion rate. We are certainly saying that the TGA should be able to assess it; we are not making any comment on whether they would approve it or not. On that, do you have any evidence at all that having another method of termination would increase the overall abortion rate?

Dr Vout—It is a very interesting question. It is difficult to answer at the moment. Certainly if we look at the experience in countries where RU486 has been available, some have shown a slight increase in their overall abortion rate; some have shown a slight fall. In the countries that have been studied the most extensively the abortion rate has remained stable. So I do not think from just looking at the research at the moment we can clearly say that. We argue—and I think this view would be shared generally by the community—that another method of

abortion will do nothing to bring down the abortion rate in the way the community would like to see it come down.

Senator NASH—But certainly any comment on it potentially increasing the abortion rate is purely speculation and assumption.

Bishop Fisher—That is why we preface it with 'potentially'. What we do know from experience is that there is plenty of evidence that demand for abortion has followed supply. As abortions become easier and safer, people have been more willing to contemplate that as a possibility. The abortion rate in Australia has spiralled as it has become more easily available. Also, we know that mainstreaming an activity has a cultural effect. It affects people's values, it affects their first intuition of what to do in the face of a crisis. The more abortion appears easy or readily available, just one of the options out there, the more likely it is that someone may choose it. But you are quite right to say that at the moment we do not have the solid research base. We have not had the experience of RU486 in enough countries over enough time to know what will be the impacts. But no-one whom I have heard of suggests that to multiply the number of methods available would decrease the abortion rate.

Senator NASH—You mentioned that with the increasing availability of abortions there has been an increase in the number of abortions. I think it was on Friday the committee took some evidence that the rate of abortion had actually decreased prior to it becoming lawful. Given the contradiction there, would you provide to the committee the evidence on which you base your link between the availability of abortion and an increase in the abortion rate? It does not have to be now, but as soon as possible.

Bishop Fisher—I would be very happy to do that. We can look, for instance, at the published figures for South Australia, which are collected each year. The rise has been very significant.

Senator NASH—Whatever you looked at to come to your premise today we can compare with the previous evidence.

Senator POLLEY—Evidence has been given to us—and I would be most interested in your views—as to whether there is likely to be an increase in the number of abortions if women choose a medical procedure over a surgical procedure. A percentage of women would have to go through a surgical procedure following the failure of the medical procedure. I have had doctors approach me who are pro-choice but who have concerns that this is going to increase the health budget and cause more problems.

Dr Vout—You are right; that is the case. Figures vary, but up to eight per cent of women who have used RU486 will need a surgical procedure to either end bleeding or to complete the abortion. It is hard to see how that is going to play out in the way that you suggest. The most concerning aspect of those sorts of figures is the issue of safety it raises for women who may be isolated geographically and socially. Despite the very best of medical supervision—and I am not calling into question that doctors would do their very best to see that this process is managed as safely as possible—there would be a group of vulnerable women who may not be in the position to seek that emergency medical help if it were needed.

Senator POLLEY—Could there not be an increase in the psychological impact on those women—choosing to take medication, believing that was going to be a better option for them

than going through a surgical procedure, and then having to go through a second procedure? That is likely to increase the psychological impact on those women and their families.

Dr Vout—I certainly think so. To go back to the question you raised earlier, unfortunately, if we are just talking about the introduction of RU486 as providing another choice then there is a danger that people will not see beyond that rhetoric, so to speak, to really understand what chemical abortion is about.

Ms Riordan—It would seem to me that, again, we are selling abortion as a solution to a problem, by whichever way women would be choosing to have it done. Again, we would have concerns about that. We think we should be addressing why it is that they are in this situation, what it is they need that could help them get through this without an abortion, what social supports they need and what career options they need. All those things are not being addressed just by looking at giving them another method of doing it.

Senator WEBBER—I have two questions I would like to raise. The committee received evidence on Friday about the full range of uses of the drug RU486, because it is possible to use it for things other than terminations, which is what we are talking about. In fact, a good friend of mine, the late Peter Cook, was hoping to use it in his cancer treatment, but getting access to that drug is pretty complicated in this country at the moment. Would it be your view that the TGA should be allowed to assess the use of RU486 for cancer treatments and other things to determine its safety?

Bishop Fisher—My understanding is that there is already provision for the import of these drugs for particular uses such as the one that you have pointed to and for very particular trials in those areas. What the current legislation does is prohibit the general import for a use such as abortion. I do not pretend to have a view on the particulars of that procedure of allowing the import of a drug for something such as cancer, whether that is too hard or easy at the moment or whether that could properly be made easier. Clearly if the drug does have genuinely therapeutic uses then putting it on the restricted list was not intended to inhibit those. It was intended to inhibit it being used for something such as a broadly available abortifacient.

Senator WEBBER—So it would not trouble you if it was referred to the TGA purely to look at the safety of using that drug for cancer treatment in an Australian context?

Bishop Fisher—I presume that if the drug—

Senator WEBBER—Moving away from the abortion argument

Bishop Fisher—If there is a licence granted, as is possible at the moment, for the drug to be imported for some other use, I presume that that would go to the TGA for assessment. I cannot see any problem with that. The problem would be if that were used as some kind of cover for making the drug available for other uses, but I am sure that is not in your mind.

Senator WEBBER—I understand. That is a natural caveat from your position. As I understand it, the current position is that it does not rest with elected representatives as such; it rests with the minister for health. Whoever the minister for health is is the choosing of the Prime Minister of the day. So if we have a different minister for health who had a different moral and ethical view then there would be nothing to stop this drug being referred to the

TGA as it stands. So, if we had a different minister for health, whose advice do you think that minister for health should take in terms of looking at this drug? Should they go to the TGA or should they take wider advice?

Bishop Fisher—I think the reason we have a minister responsible for a situation like this is that we know they will have to look beyond just their private opinions, to the views at least of the cabinet. The cabinet in turn is accountable to the parliament. The parliament could, for instance, change this law as it stands. That is exactly what is before you at the moment—a proposal to change this law. The minister is answerable to a broader group than just the group the TGA is answerable to. That he might take advice from the TGA seems to me perfectly reasonable, as he might take advice from a number of places and/or, if we had a new minister, she might take advice from a number of places. That would be because it is appreciated that this is more than just an issue of medical efficacy and safety.

CHAIR—Senator Fielding, do you have a follow-up question?

Senator FIELDING—My party, Family First, is concerned that we increasingly live in a society that appears to not value children and sees them as a cost and a commodity. Bishop Fisher, what do you think that says about Australian society that here we are talking about another option—a do-it-yourself abortion at home option—when people are concerned about the increasing number of abortions?

Bishop Fisher—I think this points to what you might call a certain ambivalence or contradiction, not just in particular women who feel deeply ambivalent in the face of pregnancy or about abortion before or after it but in the whole community. On the one hand we love our children when we have them and we do a great deal to look after them and try to protect them and nurture them, and perhaps we are better at that than ever before in some ways, but on the other hand so many are lost every year by abortion and so many suffer from family breakdown and in other ways in our community. I think we have a paradox at the moment where we as a community and as individuals are pulled in two directions where other things are priorities for us and children often will lose out in the face of that. But at the same time we do care about children and we are ashamed and sorry when they are let down in some way by us or by the community.

In the face of that kind of tug of war that is going on in us individually and as a community at the moment, one more abortion method does not begin to address that. In fact, it probably just adds to the tension. Women may ask: 'Should I choose that now there are more methods, what methods should I choose or should I go the abortion way or not?' That tension that is already in us I think is only multiplied, particularly if this is all that is being offered at the moment as a response to the issue of abortion, as a new way forward. The only thing on offer that is being proposed at the moment is another method by referring it to another authority.

Senator FIELDING—The Catholic Church is the largest non-government provider of welfare and health services in Australia. Do your services encounter many women who have had abortions? What are your concerns about RU486?

Bishop Fisher—Yes, they certainly do, but because I know that Marcia has done a lot of work on this I might hand over to her.

Ms Riordan—Increasingly, we are hearing from many women who have had an abortion at some stage in their life, even women in their 80s who have been quite traumatised by it, who often had one when they were 17 and have never got over it. So we would be deeply concerned about anything that might encourage women to have abortions. We know many of these women have been left deeply traumatised. Some of them have turned to alcohol and drugs to try to numb this grief and pain that they have been suffering. Again, because society often does not acknowledge that there can be problems after abortion, they are often left with nowhere to go. So for all these reasons we would not like to see parliament just pass this off, not begin to address all the social issues around abortion and continue to allow it to go on.

Many women now are needing help and we are now developing new ministries to help women, with other women, get through this terrible trauma that they have suffered. Many of these women would say that they would do anything to help other women have choices. They do not want anyone else to go through what they have been through.

Senator FIELDING—We heard on Friday from Dr Cannold that politicians should stay out of medical issues. What is your response to that and that politicians have no role to play on this abortion issue or any other medical issue like cloning?

Bishop Fisher—My own view is that politicians are unavoidably concerned about medical issues because they are concerned about the common good. The good of our community requires that we have a good health system. If politicians wash their hands of concern of medical issues, we would not have Medicare, for instance, we would not have public hospitals, we would not have universities to train our health professionals and so on. It is very important, given the importance of health care for our community's health and welfare, that our leaders take very seriously the whole area of health care and welfare for people. For politicians to say, 'This is not our issue,' would be disastrous for our community.

The particulars of an issue like abortion, or cloning, which is another one on the horizon for you, of course have very big social and ethical implications. So, to say, 'We should leave that to some expert somewhere,' whether it is an academic like Dr Cannold or whether it is a bureaucrat, is really to trivialise the issue, which is one of such big social import. We would say, 'Of course our leaders must accept their responsibility for this'—which is not to put it all on your shoulders; I think the whole community has to take responsibility in these matters. But, certainly, part of why we have elected leaders is to address exactly these sorts of issues that so affect the common good and the future of the community.

Senator MOORE—I will fall into the temptation of asking a question outside this bill, which is about the assessment process, because each of you has raised in your submission the issue of giving appropriate counselling and information to people who are facing such a decision. I am interested in that because we have heard that from a few places. Should a woman come to one of the endorsed counselling authorities that are around and want full information on all the choices that she has, would any of the counselling areas that you are involved in refer her on, if she wanted to go through the process of termination? Also, you have raised very important information about post-surgery counselling, which I think we all agree on—one of the aspects of this issue that we have talked about is appropriate sex education and the development of awareness and knowledge of all the issues around people's sexuality. I am interested also in the issue of effective contraception, because this argument

has come up consistently in this inquiry. If we are as a committee looking at ensuring that, whatever comes out of this particular process, there is ongoing work around those areas in terms of funding for information and counselling, would there be an acceptance that the whole range of choices would be available, with information on all the things that people are concerned about, taking into account religious differences and different processes—ensuring that that core element of information about what is available is given in the counselling and the follow-up?

Bishop Fisher—That not being part of the responsibility of this inquiry, I have not addressed my mind to what counselling services we have and exactly what they do.

Senator MOORE—It was in the submission.

Bishop Fisher—But I think when we do propose there should be counselling, as there should be in this area generally, we would say that it should be medically accurate counselling and it should give women a whole range of options. We clearly would not be referring people for abortions, because we think abortion is wrong and is bad for them, but we know full well that women will make their own decisions. If a woman, after coming to a church based counselling agency, said, 'Thank you for that; I am happy to have had those options and that advice given to me,' she will go her own way anyway. If that happens and if a woman has an abortion, she will still be welcomed back by us to help her with the healing afterwards. More and more, we have women coming to us because there is nowhere else really available for post-abortion healing. So they will often come to the churches, even though they know the churches will not necessarily agree with the original decision. I think they will find that they are treated very compassionately there and assisted with healing. So, while of course you will not get a Catholic Church based agency referring people for abortion, we will give accurate information and we will give compassionate care—

Senator MOORE—About the options available.

Bishop Fisher—before and after abortion.

Senator MOORE—Ms Riordan, I am interested in your input, as your submission did mention the process from the perspective of the Melbourne diocese and generally—and in particular the issue of contraception.

Ms Riordan—As Bishop Fisher said, obviously we would point out to women our concerns about the long-term effects of abortion that they are risking. We are certainly doing a lot more now as a church to warn women of these consequences and especially to assist women who have already been there. There are many women now coming forward to receive care and help, and we are very delighted to be able to assist them in this. Many women have not been able to talk about it except to maybe one or two people in their life, and they often feel they are being rejected or told, 'Well, you've had it now; just get on with your life,' and that people do not want to hear that they are not coping. I would also have to say that many of these women had been on contraception and it failed, and that is part of the reason they got into this situation in the first place.

Senator POLLEY—The committee has heard a lot of evidence in relation to the benefits that this medication would bring to women who live in rural and regional Australia. I have concerns about that. When we talk about the policy, surely the TGA is not the authority that

should be making the policy decision when it comes down to issues of how this medication works and how long it takes for the baby to die. Reportedly, after taking RU486, it takes three days before the baby dies, and you then have to go through the process. Do you have a view on how this is supposed to help rural and regional women, who already lack access to medical practitioners?

Dr Vout—I think if it is a situation where a woman living in a rural area generally does have lack of access to medical practitioners, then unfortunately these are precisely the women who we would not want to be taking RU486 because they would not have access to that backup. I would hope that if women approached doctors and they were aware that they were not able to provide that emergency backup, they would not give women this drug, because to do so would seriously endanger the women.

Ms Riordan—I would also have concerns that the procedure being longer and more drawn out is likely to have more dramatic psychological consequences. I cannot be sure of that, but I would certainly have concerns about that.

Senator BARNETT—My question is a follow-up to Senator Webber's question about the TGA and the implication that it cannot assess the drug RU486 for cancer and related diseases. Are you aware of this answer by the government to a question on notice? I will read it and then you can respond:

The Government is aware that mifepristone can be used as a treatment in some tumours. There have been several instances since June 1996 where mifepristone (RU486) has been used for the treatment of brain tumours and serious endocrine conditions. In these cases, the drug was obtained under the Special Access Scheme arrangements for supply of unregistered drugs for use in lifethreatening conditions. Because the RU486 was not being used as an abortifacient, Ministerial approval for importation of the drug was not required. The Special Access Scheme is administered by the TGA.

I do not have the exact day when that answer was provided. I hope that dispels any queries or misunderstandings about the TGA's approval process.

CHAIR—There is no need for a response to that, is there?

Senator MOORE—Do you have a view on that?

Senator BARNETT—I could have taken a point of order, Senator Moore, but I wanted to put that on the record so that you know what the facts are.

CHAIR—Okay, it is on the record now. I think we should proceed, in light of the time, and draw this part of the proceedings to a close. I invite Bishop Fisher to make a closing comment.

Bishop Fisher—Thank you, Chair and senators, for the welcome we have received and for hearing us today with such courtesy. The advocacy of the Catholic Church for protecting the unborn and women from abortion is well known. I am very heartened to see our leaders taking such serious matters so seriously and seeking to treat them with fairness and with compassion. From our point of view, the move to chemical abortion, or what has been called in the media home abortion, is a new development of major social and ethical import, not merely a pharmacological matter. We have explored today in the short time we have had together just some of the social issues and ethical issues that this new direction raises.

Australians are deeply concerned that the abortion rate is already too high, and clearly this new direction will not help to decrease abortion. The public clearly would like to see rates decreased and therefore looks to our leaders for ways to bring that about. Above all, they should be looking to ensure that women are offered real alternatives to abortion rather than alternative methods of abortion.

Respectfully, I think that will require of you, and all of our political leaders that you represent, a certain courage, a willingness to lead at the moment, because the temptation would be very strong to pass this to somebody else—to some bureaucrat or to some group such as the TGA—to worry about. We look to you to continue to operate with the seriousness you have demonstrated today. Thank you for your courage this day.

CHAIR—Thank you, Bishop, Dr Vout and Ms Riordan for your testimony today and for the submissions. Thank you very much.

[9.51 am]

CROZIER, Ms Denele, Executive Officer, Women's Health New South Wales

KIRKBY, Ms Margaret Anne, Coordinator, Bessie Smyth Foundation; and Activist Member, Women's Abortion Action Campaign

McCLELLAND, Ms Sue, Coordinator, Bankstown Women's Health Centre

PERKS, Ms Jo, Clinical Nurse Consultant, Women's Health, Leichhardt Women's Community Health Centre

POTTER, Ms Isabelle, Manager, Leichhardt Women's Community Health Centre

CHAIR—Welcome. Thank you very much for your appearance today. I understand that information on parliamentary privilege and the protection of witnesses and evidence has been provided to you, so you have that background in those matters. We have received submissions from the five organisations represented before us, and we thank you for those submissions. I invite each of you representing an organisation to make a short opening statement, and then we will proceed to ask you some questions.

Ms Crozier—I have prepared an opening statement, and I would like to thank you for asking us to participate in this Senate committee. We have been operating since 1981 and represent 23 community based feminist women's health services in New South Wales. Six of these services are special purpose services, such as the New South Wales Rape Crisis Centre, and 17 are generalist women's health services. They have predominantly been operating since the 1970s. I would like to talk about the principles of how they provide care. They are based on the principles of social justice and an understanding of a gendered approach to health or health within a social context. This has been endorsed by governments throughout Australia. The original endorsement of this was through the national women's health policy in 1989 entitled Advancing Women's Health in Australia and subsequently in various state and territory broader policy frameworks for health priorities that have a gender view of health, such as the Women's Health Outcomes Framework 2002 and Gender Equity in Health 2000, developed by the New South Wales Department of Health.

The Australian government endorsed a social view of health back in 1993 through the Australian Health Minister's Advisory Council with a policy position that stated:

> The advancement of women's health requires that promotion of physical, mental and social well-being ...

This follows the broad definition adopted by the World Health Organisation back in 1936. The principles of women's health care recognise that health is determined by a broad range of social, environmental, economic and biological factors. Differences in health status and health objectives are linked to gender, age, socioeconomic status, ethnicity, disability, location, environment, racism, sexual stereotyping, gender inequity and discrimination, ageism, sexuality and sexual preferences; that health promotion, disease prevention, equity of access to appropriate and affordable services and strengthening the primary health care system are necessary along with high-quality illness treatment services; and that information,

consultation, advocacy and community development are important elements of the health process.

In accordance with these principles, feminist women's health centres provide a service which reflect women's various roles in the Australian community, not just their reproductive role; promote the participation of women in debate and decision making about health issues and their own health care; recognise women's rights as health care consumers to be treated with dignity in an environment which provides for privacy, informed consent, confidentiality and safety; acknowledge that informed decisions about health and health care require accessible information which is appropriately targeted for different socioeconomic, educational and cultural groups; use existing data research and policy concerning women's health as well as incorporating women's views about their own health and the best strategies to address their health needs; ensure equity and accessibility of services without financial, cultural, geographic and/or other barriers; and provide a broad range of strategies within a preventive and holistic framework.

In conclusion, we think women's health centres address women's expressed and perceived health care within a framework that recognises the complex factors affecting women's health. We strive to improve the quality of women's lives through a model of primary health care that stresses education, prevention, informed decision making, early intervention, referral, follow-up and emotional support. With 30 years experience in direct service provision using these principles, we understand that, in the provision of health care, the most important factor is that each woman's experience and need will be different. A decision a woman will make regarding any surgical or therapeutic intervention will be based on the individual circumstances, needs and values of the woman seeking care.

We also believe that there is mounting evidence from Australian, international and world health bodies, particularly the World Health Organisation, that supports the availability of RU486. Accordingly, we do support the proposed Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005, which would allow an impartial evidence based investigation of RU486 by the Therapeutic Goods Administration. Should such an investigation propose the availability and use of RU486 in Australia, for some women, it would be a very meaningful choice.

Ms Kirkby—I am wearing my cap as the coordinator of the Bessie Smyth Foundation. Firstly, I would like to say thanks for asking us to present to the inquiry. We are very pleased to present and glad that you are willing to hear us. I will provide background for committee members about the Bessie Smyth Foundation. Our organisation was established in July 1977. We opened what was Australia's first feminist abortion service. We ran a termination of pregnancy service from 1977 until August 2002, when we sold our clinic. We no longer have a termination of pregnancy clinic. We now provide a state wide pregnancy options service. As a pregnancy options service we have developed quite a range of resources for women who call our service, such as a values clarification and pregnancy decision-making guide, a wide range of information and resources for women who have resolved to continue their pregnancy, and a wide range of information for women who resolve to terminate their pregnancy.

With regard to this inquiry, we believe that the appropriately qualified organisation to evaluate this drug is the Therapeutic Goods Administration. We believe the committee should

recommend endorsement of this bill. We in the Bessie Smyth Foundation further believe that, if approved, RU486 should be available across Australia within appropriate protocols.

Senator BARNETT—I would like to clarify something, Chair: is Ms Margaret Kirkby speaking for the Women's Abortion Action Campaign as well?

Ms Kirkby—Yes, I am.

Ms Potter—Thank you very much for inviting us here today. Leichhardt and Bankstown are two non-government women's health centres in Sydney's South West Area Health Service. The majority of our clients live within the boundaries of this health service. We have been delivering no-cost and low-cost health services and a wide range of physical and emotional health issues to women for over 30 years. We aim to support women in a safe environment, providing them with sufficient information so they feel empowered in making their own informed decisions. Our service includes general practitioners and women health nurse clinics, generalist counselling, alcohol and other drug counselling, assessment and referral, child sexual abuse counselling, naturopathy and acupuncture, and a group education and support program.

The centre specifically targets women experiencing disadvantage, be they on low income, older, homeless, lesbians, survivors of violence, or from non-English-speaking backgrounds. As such, our client group is often culturally and linguistically diverse and from new and emerging communities. In the last financial year over 80 per cent of the women attending our centres indicated that they had an income of $20,000 per annum or less, and almost half were from non-English-speaking backgrounds. Both services have a focus on the particular issues affecting women including sexual health, which covers a wide range of issues such as pap smears, breast checks, contraceptive advice, pregnancy counselling, antenatal care, childbirth groups, postnatal care, menopause, sexually transmitted infections, thrush and incontinence. Other areas we deal with regularly are mental and emotional health issues including eating issues, depression and anxiety, stress, and of course the health effects of violence.

The strong ethos of our organisations is to provide women with extensive health information, looking at the individual woman's circumstances and supporting women in a non-directive, non-judgmental manner which would assist her to make an informed decision about her health care. It is for this reason that we strongly support the lifting of the current restriction on RU486. It is not appropriate that this drug be made an exception to the accepted protocols where the Therapeutic Goods Administration has responsibility for regulating standards and availability of medications to Australians. One use of RU486 is to procure a medical abortion. We support a woman's right to access a non-surgical abortion as an option when required. There would be many circumstances where a medical abortion would be an appropriate option for a woman. For example, many of our clients have experienced sexual violence. This may have been child sexual abuse, rape, sexual assault or domestic violence. For survivors of violence, having control over their bodies and their lives is a key element in the ongoing process of healing. A surgical abortion requires some form of anaesthetic, which could leave the woman feeling vulnerable and certainly not in control of her body. To then have a surgical procedure performed on her body and on a particularly vulnerable area in her body could constitute a violation for this woman.

Some recently arrived migrant women are fleeing from persecution in their country of origin. Their experiences of trauma or torture in their own country can make any invasive health procedure, even a part test, extremely difficult. Again, these women may feel that to have a surgical procedure carried out on their bodies is equivalent to the experience that prompted their relocation.

It is a fundamental belief of our practitioners to provide non-judgmental health care that respects individual decisions in relation to that care. All doctors, nurses and other health care practitioners work on that presumption. Medical decisions should be made on the basis of up-to-date medical evidence. In Australia, the Therapeutic Goods Administration is an appropriate body to monitor usage and standards of medication; we feel that RU486 should not be made an exception.

CHAIR—Do you want to make a statement, Ms McClelland?

Ms McClelland—No, thank you. Ms Potter's statement was made on my behalf also.

Ms Kirkby—I would also make an opening statement for Women's Abortion Action Campaign.

CHAIR—Please proceed.

Ms Kirkby—Again, we thank the committee members for inviting us to present to this, your third public hearing. As a longstanding women's health activist organisation, we are honoured to be asked to be present here. At the outset we would also like to acknowledge that a number of the members of this committee strongly disagree with the views of our organisation. We wish to state that we respect their right to their views, as we ask for respect for our right to our views.

As was mentioned in our submission, we were established in August 1972. We have never received any government funding. Members of our organisation do all of their work voluntarily. We have organised rallies, pickets and so on. We are a member of the international organisation called the Women's Global Network for Reproductive Rights, which is based in Amsterdam and operates as a global network for grassroots women's health activists and organisations around the world. One of the strengths of Women's Abortion Action Campaign is the fact that we listen to women and place addressing their needs at the top of our agenda; thus we also have as strong an interest in abortion methodology issues and abortion service delivery issues as we have in the politics of abortion.

In regard to the specific matter which this committee is inquiring into—that is, the Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005—we unequivocally support the bill and urge that the committee recommend that the federal parliament support the bill and thereby allow the TGA to scientifically evaluate and decide whether to list this drug rather than for the minister to have the responsibility. Our recommendation is based not on our having a blind faith in the TGA but rather on the fact that the TGA is, as Dr Sharman Stone outlined in her submission to the inquiry, a WHO collaborating centre and an internationally respected body capable of evidence based on research and evaluation. The federal government should utilise this organisation for the work that it is obviously designated to undertake and, more importantly, is internationally recognised as being able to undertake. If the TGA can have the

responsibility of evaluating and listing all non-abortifacient drugs, it should also have the responsibility of evaluating and monitoring abortifacient drugs.

This bill offers federal parliament the opportunity to reverse what has been an aberration of international practice since 1996. It also offers federal parliament the opportunity to acknowledge that the international evidence on abortifacient drugs and, in particular, RU486 has widened and grown considerably since the decision of 1996. As those of you who have had the time to read our submission and the attachments would have noted, we as an organisation have followed the development of this drug in our magazine *Right to Choose* since 1982, when RU486 was first being developed as a birth control pill—and you would have read that we were somewhat sceptical about it. But, as the evidence on the drug became more extensive and as women's voices began to be heard about their experiences with the drug, we became less sceptical about RU486.

Abortifacient drugs, such as RU486, merely offer an alternative abortion methodology. They are not going to replace suction curettage and they will only be used for a number of Australian women—those who realise early enough that they are pregnant; who are still within the quite narrow window period within which RU486 most efficaciously works; who have access, if they wish, to non-judgmental and non-directive pregnancy counselling; who have resolved, after that counselling if they decided to seek it, that they wish to terminate their pregnancy; who then have access to comprehensive yet non-directive comparative information as to abortion methodology; and, finally, who subsequently also resolve to terminate using a chemical method as opposed to suction curettage. There are many steps that women will have to go through before they decide to use this drug, if it becomes available.

Australian women know what they want and they know that they have been duped by the federal parliament since the decision in 1996 to introduce ministerial responsibility for this drug. Given the size of the majority in the Australian population who support the continued availability of abortion, they will not forget this decision of parliament, whichever way it goes. Again, we support the Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005.

CHAIR—Thank you very much to each of you for those opening statements. We will proceed now to ask questions.

Senator MOORE—Each of you has provided a submission in support of this particular bill, which is about the assessment process, and are aware that the debate has ranged wide on the wider issues of abortion. I would be interested in comment from your organisations about the quality of the debate and, in particular, the labelling of this particular drug as 'do-it-yourself', 'quick fix', 'do it at home'—those kinds of labels, which now have come into the public debate—and regarding information that has come from women's health clinics, particularly from you, Ms Kirkby, with your 30-year experience and involvement in the process. I am asking for something to be placed on the record about how you see that labelling and perhaps a little about the media involvement in this process. I am not sure who would like to go first.

Ms Kirkby—As was said in the Women's Abortion Action Campaign submission, an abortion is an abortion is an abortion. Whether it is done chemically or by suction curettage,

the issues are the same for women regarding their decision-making process; but the issues are the same for any doctor deciding to prescribe this drug. The drug would not be made available unless certain protocols were in place. The TGA quite commonly releases drugs as being only suitable in A, B and C conditions but not in D, E and F conditions. The Therapeutic Goods Administration is the appropriate body to deal with it. Looking at the protocols from New Zealand, the UK and Europe, it definitely would not be an at-home abortion option, a quick fix, cheaper or any of those things. It definitely would have to be administered under appropriate protocols and with sufficient medical backup for the woman at all times.

Ms Crozier—The Australian medical profession have consistently found the whole illusion or concept of at-home medicine quite an insult to the practice that both rural and city doctors adhere to in the whole process of having ultrasounds and medical checkups available. People who practise medicine in Australia practise it well, and there are regulations in place for those who do not. Australia's performance of medical practice, with its ethics and standards, is world best, and I do not see that this will be any different. There have been suggestions that a medical practitioner might use this drug in an inappropriate manner, but I would submit that we have a considered approach to surgical abortion and I think those considerations will carry over. It is misleading to see it only as an at-home do-it-yourself procedure, when clearly it is a drug that needs medical supervision.

Ms McClelland—If we look at how this is played out in the media, and from women's stories, we are being told quite often that women are insulted that people do not think they are able to make their own decisions. I think that should be remembered: women are very good at making decisions about their own bodies, about their own lives, and about what they need to do. This drug should be considered only in consultation with a health professional. It is a woman's choice with her health professional. RU486 is not going to make a difference in reality to abortion. Abortion is there and it is available at the moment. What we are debating today is who makes the decision about whether RU486 is available or not available.

Senator POLLEY—We have heard a lot of evidence for and against whether this legislation should be supported, but overwhelmingly the view that has been expressed to me is that the elected representatives and, in this case, the minister, have the ultimate responsibility for policy direction. This is a huge step forward. I take note of some comments that were made in the introduction this morning: an abortion is an abortion is an abortion. I am a feminist, and I have a different view about what constitutes a good, safe abortion, and I have heard enough evidence to suggest that RU486 certainly is not a safe option. I would have thought that any woman who chooses to make the decision to have an abortion would want to make it in their best interests and in the safest way, and I would not have thought that allowing a baby to take three days to die would be.

I am most interested in hearing why women's action groups are so intent on pushing for a drug that is already in the USA being revisited as to whether or not it is a safe option. Just in the last week or so, Italy has banned the drug. For me, this is not an issue about whether you are pro-choice; it is about whether or not this is in the long-term interests of women's health. Surely an abortion should take place as quickly as possible.

Ms Crozier—What we are pushing for is an impartial, evidence based examination of current international literature that has been 10 years in the making. We would like the

Therapeutic Goods Administration to have a chance to look at that evidence based on Australian standards. I think there is quite conflicting information. We are getting information that it is quite safe and you are getting information that consistently says it is not safe. It is the contradictions that are a problem when the matter is not in the hands of the delegated authority to investigate. That is really the issue for us at the moment.

Senator POLLEY—But the responsibility of the TGA is to administer therapeutic goods. I have not seen any evidence or any explanation that this drug fits into that, so therefore it is beyond the scope of that authority to even investigate it for use in abortion.

Ms Crozier—I understand that any drug that claims to have an action is considered under therapeutic goods, and therefore RU486 would clearly fall into that jurisdiction.

Senator POLLEY—This drug is to kill; it is not there to enhance. Pregnancy is not a disease.

Ms Crozier—We would not agree with the way you have framed those questions. We understand that 81 per cent of Australians believe in a woman's right to choose and a woman's right to have access to abortion.

Ms Kirkby—I understand where you are coming from, Senator Polley, but, in the end, I can respond to what you said when you asked the question by saying that I do not agree and I think XYZ. It comes down to us stating our personal view on the basis of our understanding as it is at the moment of the evidence around RU486. At the end of the day, there is delegated authority in the Therapeutic Goods Administration act allowing the TGA to evaluate on a scientific basis the evidence around drugs. I feel that that is the appropriate body to look into this. You or I could write submissions to the TGA, if this bill got through and the TGA did evaluate it, and state our different points of view. Whether the TGA would take any notice of us would be another thing.

The other comment I would make about what you said is that, at the end of the day, it is for women to decide. As I said, it is just another abortion method. What women need, as well as non-directive, non-judgmental counselling, is non-directive information on a comparative basis about methods. For example, sometimes when I talk to women some of them say, 'Ugh! I'd hate to have a chemical abortion; that sounds terrible,' and others say the reverse and think it is really great. You cannot anticipate how every woman is going to feel about this alternative method. We should ask the TGA to evaluate it and we could see what came out of the TGA evaluation and then take it one step at a time.

Senator POLLEY—Considering that RU486 is there to abort and kill a baby, surely that does not warrant the TGA's investigation for that purpose. It goes outside that it; it is a social issue. Whether we like it or not, this still revolves abortion and it is such a draconian method to put any woman through. It takes three days for a baby to die and then the woman has to expel it. Surely that is not in the interests of women's health, and it is certainly not in the interests of that child. A surgical procedure, which takes a matter of minutes, would be a safer option and would hopefully have less traumatic effects on that woman.

Ms Crozier—Again, I think how one presents the issue speaks to their own personal view and I concur with Ms Kirkby in that every woman would have a different reaction to the whole idea of surgery versus chemical abortion depending on their needs and their

circumstances. Also, we are talking about a procedure that is legal in Australia. Abortion is a legal procedure in Australia. Some women are allergic to anaesthetics. Some, as we have pointed out, have come from other countries and have experienced torture with medical instruments. We have referred to women who have been sexually assaulted wanting more control over their lives. For them, a chemical abortion feels very comfortable. I do not think we can say in every circumstance chemical abortion is horrible and unsafe. It is a very personal decision.

Senator POLLEY—To follow up, you do not actually have to have anaesthetic to have a surgical procedure. The other issue is the fact that there have been reported deaths and further investigations are still to take place in America. Does not the loss of life for those women and the medical complications cause any concern for your organisations?

Ms Crozier—What we are asking for is an examination of that evidence by the appropriate body. There are many circumstances surrounding any medication of any kind, and quite a few of the medicines we have available now are life threatening. It is putting any form of medication in its appropriate medical context in Australia that is most important here. I think we have a very good track record on how we approach health care in Australia, and I would presume that would continue with RU486.

Senator BARNETT—Are you the author of the Women's Health New South Wales submission?

Ms Crozier—I would have to say no. You have probably received quite a few submissions that are similar, so what is the point of your question in particular?

Senator BARNETT—I would just like to know who is behind the submission. Do you know who authored it?

Ms Crozier—We used a pro-forma that was available on the internet. Because of the time frame that was offered, we did not have time to research the range of information, but we clearly wanted to at least support the position that we think women in the community would like us to support.

Senator BARNETT—So you stand behind the pro-forma submission that you have put to our Senate committee and believe it is credible?

Ms Crozier—Yes, I do.

Senator BARNETT—Can I ask you some questions about your submission?

Ms Crozier—Go on.

Senator BARNETT—What is the drug Claratyne used for?

Ms Crozier—I understand it is an antihistamine.

Senator BARNETT—What is an example of an adverse event following the use of the over-the-counter drug Claratyne?

Ms Crozier—Probably sleepiness, a dry mouth, which can be extreme. There can be hair loss. There are a range of different adverse effects.

Senator BARNETT—You have specifically compared the adverse events from the use of RU486 to the use of Claratyne. Can you describe to us some of the adverse events from the use of RU486?

Ms Crozier—The whole point of that comparison was clearly to point out that there are a lot of drugs on the market that have adverse effects that far exceed the claims of the adverse effects of RU486. It was not intended to be anything more than that—

Senator BARNETT—You have claimed that the adverse event rate for the use of Claratyne is 87 times higher than that of RU486. Is that correct?

Ms Crozier—I presume it is correct, yes, since I have respect—

Senator BARNETT—What does 'presume' mean?

Ms Crozier—I have told you I have respect for the group that presented this for my use.

Senator BARNETT—Do you know who that group is? Can you name them?

Ms Crozier—Yes, it is on the internet.

Senator BARNETT—Who is it?

Ms Crozier—It is Reproductive Choice Australia.

Senator BARNETT—Adverse events from RU486 include hospitalisation, but, as you indicated with respect to Claratyne, includes things like dry mouth, headache and nausea. I have looked at the research and I have found that the reported adverse event rate for Claratyne for headache is six per cent, dry mouth is eight per cent and nausea is two per cent. For RU486, according to the FDA—I am not looking at the hospitalisation rates; I am looking at the similar aspects of headache and nausea—the rate for nausea is 61 per cent and for headache it is 31 per cent. You have said in your submission that the adverse event rate, even comparing the more mild effects, is 87 times greater when you use Claratyne compared to RU486. Would you like to make any observation in regard to that?

Ms Crozier—The point was to point out that there are many drugs that have adverse effects, and that consistently dismissing RU486 because it is an unsafe drug clearly—

Senator BARNETT—Is it a fair comparison?

Ms Crozier—On the way you are presenting it, I would say no, and I accept that—

Senator BARNETT—I asked the same question of the Public Health Association in Melbourne, and they said what you said. They said it was not an appropriate comparison. I appreciate your feedback. There are two other aspects of your submission, which is obviously based on a pro-forma submission, because we have received a number of them, including from the National Union of Students. On page 3 you state, in reference to Dr Greene—it is Dr Michael Greene; your submission says Dr Robert Greene:

> The overall mortality rate associated with medical abortion is ... 1:100,000 ... and no different to that posed by surgical abortion.

And yet before our committee we have had tabled Dr Michael Greene's actual journal article of December last year. He says:

> The risk of death from infection is less than 1 per 100,000.

It is 1 per 100,000 for medical abortions and 0.1 per 100,000 for surgical abortions. That is a difference of 10. How do you respond to that?

Ms Crozier—I can only presume that you are quoting directly from the article and an error has been made. My point would be that there is quite a lot of inconsistent evidence around, which really speaks back to the issue of the need for Australia to conduct its own investigation of the drug and its use.

Senator BARNETT—The third issue I would bring to your attention is your point—which seems to be a direct lift from the Public Health Association or based on a pro-forma submission, because it is the same in many submissions we have received—which says:

The US FDA recently affirmed the safety of medical abortion for American women and authorised its continued use.

In the evidence I have seen, the FDA November fact sheet information, the FDA does not affirm the safety of medical abortion. It does not affirm or reaffirm it. In fact, it has some provisos in it regarding four recent deaths in the USA and highlights the concerns that they have in that regard. Can I draw that to your attention as well and hopefully that can be noted?

Ms Crozier—Okay.

Senator BARNETT—Are you aware that the restricted goods that the bill refers to relate not just to RU486?

Ms Crozier—I believe it is the whole therapeutic goods act that the bill refers to. What in particular would you like to draw to my attention?

Senator BARNETT—The definition of 'restricted goods' includes in fact not just RU486 but eight separate abortifacient drugs and also includes some vaccines. Has your organisation or anybody at the table had an opportunity to look at those eight abortifacient drugs and do you have a view that you would like to put to the committee as to whether they should also be removed from ministerial discretion, or are your views to this committee only in regard to referring to RU486?

Ms Kirkby—I can comment. I was aware that 'restricted goods' was not only about RU486. Our argument would still be the same—that the Therapeutic Goods Administration is the appropriate body to scientifically evaluate what literature there is on the various abortifacient drugs that come under the restricted goods definition.

Senator BARNETT—Ms Crozier, did you want to respond?

Ms Crozier—At the moment there is more international evidence in relation to RU486. That is why there has been such a focus on the investigation of that drug. That is all I could comment on.

Senator BARNETT—Ms Crozier, in light of my earlier questions, would you feel it appropriate to get back to Reproductive Health Australia and alert them to what is on the *Hansard* and the discussions we have had today so that they could then perhaps come back to the committee with some corrections to their submission or to the pro- forma submission? Would you be willing to do that?

Ms Crozier—I am happy to do that.

Senator BARNETT—Ms Kirkby, you have referred on the last page of your submission to the fact that RU486 will not make abortion cheaper for women and you have indicated you wanted another special Medicare item number for RU486. Can you give us an indication of the level of cost of RU486?

Ms Kirkby—No, I have no idea. It has not been available, so I do not know what the cost is.

Senator BARNETT—You said it will not be cheaper?

Ms Kirkby—No, because when you are looking at—

Senator BARNETT—On what basis do you say that? Can you give us some evidence to back up your claim that it will not be cheaper?

Ms Kirkby—I was the manager of Bessie Smyth Foundation's Powell Street Clinic for the three years before we sold it. If you are doing the right thing by women in terms of having counselling staff, nurses and doctors there as a backup for the small percentage of women who will require suction curettage after administration of RU486, those staff cost money and it is not going to be cheaper at all. If you are administering RU486, you must run your facility on the basis, potentially, that every woman is going to have a complication. Obviously the literature shows that that is not going to be the case, but in terms of following appropriate protocols and making sure you have adequate backup and support for women who have been administered the drug, when you look at those staffing costs, it is not going to end up cheaper.

Senator BARNETT—I will make this my last question. According to the evidence I have, in New Zealand it costs around $1,000—but I am happy for that to be clarified or to take evidence to confirm what the costs are—and in the US it costs approximately twice as much as a suction abortion. Does that sound about right to you?

Ms Kirkby—The circumstance of termination of pregnancy service provision in New Zealand and in the United States is quite different to here. In New Zealand the majority of the terminations, whether with RU486 or suction curettage, are through the public hospital system, whereas in Australia, overwhelmingly, I would say that abortions being done in the private sector are now hitting about 95 to 98 per cent of all abortions.

Senator BARNETT—Do you know the cost?

Ms Kirkby—In New South Wales, there is a problem, because the Health Insurance Commission has ruled that abortion providers can no longer bulk-bill. So if your pregnancy is under 12 weeks you are looking at about $530 upfront and you will perhaps get about $245 or $250 back from Medicare.

Senator BARNETT—What if it is over 12 weeks?

Ms Kirkby—It depends on the number of weeks. It goes up on a weekly basis.

Senator BARNETT—Say 20 weeks?

Ms Kirkby—Up to 20 weeks you are looking at an upfront cost of about $1,800. But that is no comparison, because you cannot use RU486.

Senator BARNETT—I am just getting a feel for the cost. So at 20 weeks it is about $1,800.

Ms Kirkby—In New South Wales. I am not saying that is across Australia.

Senator ADAMS—Thank you all for your submissions; they are very practical. I am a midwife and come from a rural area and I have worked throughout Western Australia as a midwife, so I really do appreciate the practicality of your submissions. I am very interested in the counselling service, perhaps with both your submissions—with your two hats. I note here that all federal government funding around pregnancy counselling so far that has been made available since this government came in has been directed towards services which are anti-abortion in their outlook. Is that a fact?

Ms Kirkby—Yes, but it depends on perspective. I know that the federal government argues that, because they also provide some—minuscule, in my opinion—funding to sexual health and family planning, they count that in as funds towards pregnancy counselling. But the raison d'etre of sexual health and family planning is contraception. They do some pregnancy counselling and some decision making counselling in New South Wales. I am not sure about every state. Because Jo is familiar with FPA Health, she might know. The raison d'etre of family planning organisations is contraception, not so much pregnancy and/or termination of pregnancy. The overwhelming majority of funding since 1996 that is going to organisations that call themselves pregnancy support or pregnancy help is all going to the anti-abortion ones. We were sitting in on the Catholic Church representation. As you heard, they will not refer or give information about termination of pregnancy services.

Senator ADAMS—Since you have changed your practice, having sold the clinic, have you received any federal government funding for counselling services?

Ms Kirkby—No. We sent a submission to the health minister, Mr Tony Abbott, seeking information about the guidelines relating to pregnancy counselling services and a direction on who we write to within the health department. We were sent back a reply that funding goes to family planning and pregnancy support services and there was no information about how one applies to the federal government for that funding. So it is clear to us that the funding is only for services that are anti-abortion and that they will not refer for termination of pregnancy.

Senator ADAMS—I notice now that you provide a state-wide telephone pregnancy option service with counselling information, referral and advocacy. Could you give me an indication of the sorts of calls you are getting from people outside the metropolitan areas?

Ms Kirkby—There are quite a lot. The women are often distressed because they have probably gone through about six phone numbers before they can get an answer to their questions. It is very problematic for women in rural areas. I grew up in the country so I have some understanding of it. My father still lives in the country and he needs to go to various medical appointments, so I have a lot of understanding of what is involved. It is about logistics. If the women have children, it is about having somebody look after their children. It is also about coming up with a story as to why they are leaving the town, so that their privacy is not breached, travel costs and possible overnight accommodation if they are coming to Sydney. There are a lot of problems for women in rural areas if they decide to terminate their pregnancy. Similarly, even if they decide to continue with their pregnancy, there are still major problems in rural areas in having adequate access to good quality antenatal care and a range of birthing options. The women come to us usually in a state of distress. They hit us

after about their sixth phone call to different organisations, all of which say, 'We can't tell you the answer to that.' We spend a lot of time. The average call that we undertake is usually around 30 to 40 minutes. For women from rural areas, in particular, you have to allow as much time as they need to have all their questions answered.

Senator ADAMS—Where do you get your funding from to keep the organisation going?

Ms Kirkby—From funds left over from the sale of our clinic. We have done a submission to NSW Health for ongoing funding, and at the moment we are lobbying for that. We have not received any government funding.

Senator ADAMS—A number of constituents have written to me regarding the *Yellow Pages*. I have written to the minister for communications on this; I think it is a communications issue. It was put to me that if you are going to get paving done or bitumen or something like that you would look in the *Yellow Pages* for bitumen specialists, paving specialists or whatever. Do you feel there should be some definition there to list the different services that are available from each of the organisations? As you have just said, women may have gone through six phone calls before they get to you. This is of concern to me; I have not had a letter back from the minister as yet. You have really told me, but I would just like you to—

Ms Kirkby—There is a problem in that when antiabortion services are listed under pregnancy termination there is no designation clearly stating that they are antiabortion and will not refer, so that is a waste of a call and a waste of time for the women. The other issue is that if you are going to run a help line—I do not care whether it is an antiabortion one or one that will provide an option—you must have some professionalism and a willingness to be transparent and accountable. For example, the Bessie Smyth Foundation is a member of the TISCA organisation, which is called the Telephone Information Support and Counselling Association. We follow its protocols about making it well know what our service is about so that women who, for example, are very strongly opposed to abortion and think they are going to be talked into it—which they will not, but you can understand that a person may gain the wrong impression—will not waste their time calling us. It is very important that what any help line will do is transparent. As TISCA has said in its best practice guidelines, there is actually no monitoring of help lines in Australia at the moment, either federally or state based. Services can open up and call themselves a help line but no professional practice is being followed and there is no proper training other than perhaps a two-hour training session of people who call themselves counsellors. It is an area that needs to be looked at—the way they are designated in the *Yellow Pages*, in particular.

Senator ADAMS—Who do you think should be in charge of that monitoring, seeing that it is a national problem?

Ms Kirkby—I am not sufficiently aware.

Ms Crozier—I think any organisation that is funded. Usually there is a range of funding guidelines. For women's health centres, we have to go through accreditation processes and seek accreditation by external accepted principles of care. I think any phone-in that is funded should also have to adhere to some form of quality assurance that is external from its own organisation. That is the way we judge best practice in Australia now, whether it is a hospital,

clinic or otherwise. Since those standards do exist and have been accepted as best practice, that would be a reasonable condition of funding.

Senator ADAMS—So you think it should be the role of the funder as part of the guidelines?

Ms Crozier—That you show within a period of time that you have gone through a process—it may not be an accreditation process but aiming towards accreditation, or a quality improvement process by a recognised authority whose standards have been recognised in Australia, who represents registered quality improvement. I think that is a pretty good standard for quality assurance at the moment.

CHAIR—Senator Polley, do you have a follow-up question?

Senator POLLEY—You made a comment on the lack of access to options for surgical abortions in rural and regional Australia. I concur that there are major concerns for women's health for many within rural and regional areas. Therefore it begs the question: using RU486 surely would not be prudent in those areas when in fact all the evidence that has come before us indicates that, if this drug were to be introduced into Australia, there would need to be critical backup facilities available because of haemorrhaging and other complications. I have some concerns, then, as to why we would see such a push at this point in time when already we are facing a massive shortage of doctors and health services in rural and regional Australia. Surely that has got to be of major concern. The other issue that you raised was in relation to privacy. Surely if a woman is going to expel a baby in public, whether she is picking up her children at school, at home or wherever, there needs to be that critical care.

Ms Kirkby—I do have a lot of faith in the medical profession, even though I am at the same time critical of the Western medical profession. I read the Rural Doctors Association submission from the 15 December hearing. No doctor is going to be stupid enough, quite frankly, in today's medical negligence environment to administer RU486 without appropriate backup. Their insurer would just click their fingers and say: 'No way. You're not going to get cover for it.' A lot of things at the moment in the abortion field and in other forms of surgery are insurance driven. It is a real brake on what doctors feel confident they can do. I would imagine that a rural doctor would think very carefully before they would be willing to administer or prescribe RU486 unless they had a proper backup system in place.

The other main issue that has not been aired before this committee is: if you are prescribing RU486 as a doctor, whether you like it or not, you are therefore an abortion provider. Therefore you are also opening yourself up to protests by anti-abortion activists, to the possibility of people demonstrating outside your surgery and hassling women as they go in. Since the murder of the security guard at a Melbourne clinic in July of 2001, there is a whole range of security mechanisms that abortion providers must have in place. That is the same whether you are administering and prescribing RU486 or whether you are doing suction curettage.

I know that those on this committee who are opposed to abortion would not endorse violence against an abortion provider or a woman approaching a clinic, but you cannot guarantee what is going to happen—as was the case with the man who killed the security guard—with people out there who say they support your cause. No doctor is going to be

stupid enough to prescribe RU486 without having security mechanisms in place. They cost money—I can tell you they do. It cost us money after 2001, when we still had the Powell Street Clinic. After the murder of the security guard it cost every abortion clinic across Australia substantial sums of money. There is an enormous range of practicalities around this, even if this bill is endorsed and RU486 is referred to the TGA.

Senator FIELDING—Ms Crozier, are you aware that women with the following conditions have been kept out of tests on RU486 for fear that the drug could be dangerous or deadly for them? This is out of the *New England Journal of Medicine*. Here are the conditions: first, the presence of cardiovascular risks, including high blood pressure, obesity, cigarette smoking and diabetes; second, asthma or bronchitis; third, aged over 35 or under 18; fourth, anaemia or blood-clotting disorders; fifth, menstrual integrity, fibroids or endometriosis; and sixth, use of oral contraceptive or IUD less than three months prior to conception. Are you aware of those?

Ms Crozier—I presume you are talking about specific trials. Trials under ethical committees often have a group because they have a particular purpose. I think what we are asking for is that the mounting evidence of all use internationally be open to investigation by the Therapeutic Goods Administration.

Senator FIELDING—The question was: are you aware of those?

Ms Crozier—No.

Senator FIELDING—Thank you. Do you believe abortion in Australia is a community issue as well as a moral and ethical issue?

Ms Crozier—It always depends on whom you are talking to, but I understand that 81 per cent of Australians still support the right for women to seek abortion.

Senator FIELDING—Given that this issue has become one of a conscience vote, given the number of submissions, given the complexities that we have heard and given the research we have seen about people's concerns on the number of abortions, do you agree that publicly elected members are the ones that should set policy rather than bureaucrats?

Ms Crozier—I think having a concern about what is happening in Australia is different to regulated law. It always depends on whom you are talking to as to what their perceptions are. In relation to abortion in Australia, it is a legal procedure. We are asking that the chemical version of that procedure be allowed to be investigated. For us, that is the issue at this stage.

Senator FIELDING—Are you concerned that women will have to expel their own foetuses in their home and dispose of their own foetuses? Do you not think that will bother them?

Ms Crozier—I think women are very used to a whole range of menstrual experiences. Truly, when working with women and explaining whether it is a medical or surgical process, each woman will decide what is appropriate for her. Each woman knows what she is comfortable with. So, in that regard, I still believe appropriate medical practice, appropriate counselling and the relationship between the health care provider and the woman are the most important parts of a health care process.

Senator FIELDING—In 1996 both houses of parliament decided that this issue was a responsibility of the elected members, the parliament itself. What do you believe has changed since 1996 that it should now be given to the unelected bureaucrats to decide?

Ms Crozier—I personally think that possibly it was a political decision back in 1996. I do not see that any additional investigations on safety were made at that time, but we have 10 years worth of international medical evidence that I think warrants investigation. I think 10 years experience is what has made the difference.

Senator FIELDING—And are you concerned about the level of abortions in Australia?

Ms Crozier—I am concerned about the lack of funding to good-quality life decisions and the lack of funding to good contraception. I am concerned about the lack of funding to the health system per se. I am concerned about a whole range of things.

Senator FIELDING—But not about the number of abortions in Australia? You are not concerned about that?

Ms Crozier—Because I believe that that will be taken out of context, I will not answer it in the way that you want me to. I am concerned about the medical health of women and the whole community in their access to good medical care.

Senator FIELDING—What are your thoughts about the unborn child and the rights of the unborn?

Ms Crozier—I think that is probably going a little bit too far in relation to the terms of reference of this committee, so I choose not to answer that.

CHAIR—We are running very short of time, so do you have a brief comment that you want to make, Ms Kirkby?

Ms Kirkby—Senator Fielding was raising the issue about elected politicians. The conscience vote has been in the Liberal Party of Australia and the Australian Labor Party since the year dot. There has never been an Australian Labor Party government or a Liberal Party government which has run specifically on a policy that it will implement decisions to restrict the availability of abortion. I do not believe that the 1996 decision was made on the basis of any kind of mandate whatsoever. It has been mentioned by the health minister that, as the politicians are the elected people, they are the ones who will be held accountable. But the reality—when you look at the problems within the Liberal Party and the ALP in regard to preselection processes, factionalism and so on—is that there is not a lot of accountability.

I think that, if you actually took a referendum of members of the ALP and members of the Liberal Party, you would be very surprised to find that an overwhelming majority in both parties supports the availability of abortifacient drugs and supports the availability of abortion. But the leadership of both parties will not take such a referendum because it does not suit them.

The other issue that I guess any politician who is strongly opposed to abortion has to think about is the fact that you are there as a representative. It has been overwhelmingly shown that the majority of the Australian population supports the continued availability of abortion. I can understand it if, out of the strength of one's personal views, one cannot in good conscience vote for such a bill, but you are not being representative when you do that. You are imposing

your own personal view upon your representative position. I am not making any judgment about that, because it is a conscience vote as things stand in most of the political parties—not the Democrats and not the Greens, and in the Family First Party it would obviously not be a conscience issue. I understand where people are coming from, but there is still a fundamental issue that people need to look at in terms of how representative what they are doing is, given the opinion polls.

Senator FIELDING—The issue, I think, is who should set policy versus who should implement policy. Obviously the TGA should advise and implement policy, whereas elected members in the community should be the ones to set policy.

Ms Kirkby—And ignore what the majority of the Australian population thinks—that is what you are saying with that factor.

Senator FIELDING—No, there is general, overwhelming concern about the level of abortions, and—

Ms Kirkby—No, you are saying that you are happy to ignore the majority of the Australians.

Senator FIELDING—and once people hear about the draft—

CHAIR—I do not think we are allowed to have a debate across the table.

Ms Kirkby—Sorry.

Senator FIELDING—do-it-yourself abortions at home are a concern.

CHAIR—Okay, I think that is where we will leave those questions. Thank you, Senator Fielding.

Senator NASH—I have a question following on from Senator Fielding's concerns about the physical process of medical abortion for women. Would I be right in assuming that if—and I stress 'if'—this were to be approved by the TGA, and a woman had the process explained to her and was comfortable with it, she would choose the medical abortion? Is that your experience with women?

Ms Crozier—Definitely.

Senator NASH—I am also concerned about some of the comments that have been made about women perhaps not following through with the two-part process for a medical abortion. There has been a lot of comment that they would not follow the process properly. Again, in your experience with women, do you have any reason not to believe that a woman would be able to follow a process knowing that she is well aware of the process and the reason she is undergoing it?

Ms McClelland—I guess that is what I was alluding to earlier in my statements about women being insulted. Women within our community and women who use our services are saying, 'Can't we make our own decisions? Don't they trust that we can make our own decisions about our own bodies?' That is part of it—assuming that women do not do this or cannot do this. Women make decisions about a whole range of issues throughout their lifespan, this being one of them. To assume that women would not follow through a process is just ridiculous. It is laughable, almost.

Ms Crozier—Some of the examples given in the rural settings have been a bit of an insult to the rural medical profession. In the examples given of remote communities without medical backup I cannot see medical practitioners using this drug in those circumstances. Another example was given where people could not understand English. There was concern about the northern Aboriginal community. I cannot see doctors prescribing this whole procedure in a circumstance that was not appropriate. The Australian medical profession have good standing. I support them in the decisions they make. In relation to how it would help women in the rural setting, there are rural settings now that clearly do have the support and back-up and the medical structure and the hospitals that would allow the use of RU486 and where currently there are no private abortion clinics in that town that have the support. So in some regards it will be of great benefit to those settings that have the structures in place now. That would be some improvement. But I cannot see the medical profession using this drug in the examples given.

Senator WEBBER—Before pursuing the rural and regional issue I want to return first to the role of the TGA, because we seem to have got lost there somehow, the drugs that they look at assessing and their definition of 'therapeutic'. It would seem to me that their definition is a bit wider than our standard dictionary definition of 'therapeutic'. It would be correct to say that in sending RU486 to the TGA—if we decide that that is appropriate—that is the same body that has evaluated the use of oral contraception in Australia. We accept that pregnancy is not a disease. Pregnancy tests and a whole range of other things have been accepted as safe for use in Australian conditions. So this will be treating that drug the same way that we treat a whole lot of things to do with women's physiology. Nodding is not picked up by *Hansard*. I need someone to say yes.

Ms Potter—Yes.

Ms Crozier—Yes.

Ms McClelland—Yes.

Senator WEBBER—I just wanted to get that point of clarification on the record. A lot has been made—as Senator Nash pursued—of the potential dangers to women of having a medical termination. Senator Adams has greater experience of this than I do. As she says, she is a country midwife and she still lives in country Western Australia, which has greater concerns with isolation than anywhere else—and people get tired of hearing us talk about that. My understanding of the medical profession in Western Australia is that most country doctors have extensive training in how to deal with miscarriages, which is essentially what this drug—if it is deemed to be safe, which we do not know because the TGA has not looked at it, and if it is used—would produce. Most of them have training in dealing with the outcomes of miscarriage. But what country doctors in Western Australia do not have training in is how to actually create a surgical termination. Therefore country women could be assured of having adequate medical backup for a miscarriage or a medically induced termination but not of actually procuring and having the surgery some thousands of kilometres away from Perth. Would the case be the same in New South Wales?

Ms Potter—My understanding is that it would. However, for a doctor to get professional indemnity insurance and to prescribe the drug, they would need to have access to a doctor that was able to do curettage.

Senator ADAMS—As far as the surgical backup goes, I have a submission here from six doctors in Broome and they are asking that this drug be available to them. They do have surgical backup everywhere. They are fully aware of the guidelines. It would be available. I can say, from the rural doctors' submission and the people that I have talked to quite extensively on this issue, that no-one would be using this drug, if it were approved, without surgical backup. D and C and suction are used very often. As they say in this particular submission, it is one in four women in the Kimberley. These are the six doctors that are with the Broome Regional Aboriginal Medical Service. They are fully aware of what the drug does, what the necessary procedure is if someone does retain products. Speaking for rural Western Australia: most people do have access, and their doctors have access, to surgical procedures. They would not be doing anything other than what they should be doing if they were to use this drug. That is just to clarify.

Senator POLLEY—In relation to the figures, various people on either side of the debate come forward and tell us how the majority of Australians actually support abortion. I wonder whether or not, if you were to truly explain the process of how RU486 works, the result would be the same. There is another issue I just want to query. I have been a member of the Labor Party for some 32 years and I would not dare to presume that I could speak on behalf of all members of the Labor Party to say they support one position or the other. I feel in awe of being in the presence of someone who can espouse a knowledge of how people within the Labor Party view this issue or any other. I certainly would test those figures as to the community support for abortion using RU486, knowing the full implications and the effect that it has on the baby, as opposed to generally saying that the good, safe abortion option of a surgical procedure should be available to Australian women on choice.

Ms Crozier—I think what is important in the Australian context is that currently abortion is legal and that in any health consideration each circumstance that a women might be faced with will be different. For the medical profession, women and the community of Australia to have the broader range of choices so that the most appropriate method for that circumstance is used is why we would encourage the Therapeutics Goods Administration to investigate the current literature to see if that choice is suitable for Australia. Regardless of what medical procedure one has to decide on, as a family, one sits down and looks at a whole range of things—whether it is for an abortion or any other purpose. Some women cannot have a surgical abortion and for those circumstances it might be the most medically appropriate thing to do. In those circumstances, I think it should be available.

Ms Kirkby—I am not a member of the ALP, Senator Polley; I am just a person who talks a lot to grassroots activists. I know that the conscience vote is not well liked by a lot of members of the Labor Party, just the same as in the Liberal Party. As I mentioned in the WAAC submission, that organisation has been around since 1972, and I have been involved in it since 1978. The thing that has struck me over those years is that the majority in support of abortion and it being available in the Australian population has just grown and grown. I

remember when I first got involved it was quoted at around 60 per cent. Obviously it always depends on the phrasing of the question and so on.

With regard to your specific issue about if people really know how RU486 works, it is going to be one of those issues where we just have to agree to disagree because you are framing it in highly emotive language, using words such as 'the baby'. Everybody knows that, in the window period in which RU486 is most efficacious, it is actually still called an embryo and perhaps moving on towards a foetus in medical terminology. Not everybody shares your language in thinking about this issue.

It is my understanding that it equates to a heavy menstrual bleed, which women are dealing with all the time. The foetal products or embryonic products are very miniscule in amongst the clots of endometrial tissue that women are going to be seeing. Women miscarry, without having known that they were pregnant, all the time. When you look at the statistics and if you have one of those wheels with four, eight, 12 and 16 weeks—the time when a miscarriage is most likely—you see that women miscarry all the time. It is only a heavy bleed.

Senator POLLEY—In relation to the fact that we started off today asking people to respect other people's views, likewise I respect the people that I represent and I also accept the fact that people have trouble with different terminology. But, when I found out I was pregnant, I was having a baby, and that is the language I use. I did not consider having a foetus; I had a baby.

Ms Kirkby—I agree with you having that view. I am fine about that. But another woman that I might talk to might prefer to call it an embryo and foetus all the way through her pregnancy. It is not for me to tell a woman how she should think about her pregnancy and it is also not for you to tell every woman how they should think about their pregnancy.

Senator POLLEY—And neither do I.

CHAIR—Thank you very much for your testimony today and for your appearance here today at this inquiry.

Proceedings suspended from 11.14 am to 11.32 am

JOSEPH, Mrs Rita, Private capacity

HOLZAPFEL, Miss Simone Maree, Executive Director, Australians Against RU486

GEORGE, Ms Katrina Mary, Director, Women's Forum Australia

TANKARD REIST, Ms Melinda, Director, Women's Forum Australia

SHERSTON, Mrs Anne, Private capacity

CHAIR—Welcome. Thank you all for appearing and thank you for the submissions which you have each lodged with the committee. You have all had information on parliamentary privilege and the protection of witnesses and evidence. I now invite each of you to make a short opening statement and then the committee will ask you some questions. Who would like to go first?

Ms Joseph—I am very privileged to be here today, and I am particularly keen to point out that this Senate is here as a continuum of the Australian government and the Australian parliament, right from 1901. It is important that you understand that you have obligations to fulfil that were made by senators before you on behalf of the government, on behalf of the Australian parliament and on behalf of the Australian people. This is particularly true for human rights issues.

As you know, human rights modern international law came out of the terrible tragedies and terrible deaths of World War II. The founders of modern international human rights law were particularly keen to proof humanity for the rest of time against new ideological winds that would once again enable governments and people to select categories of human beings like the unborn or the Jews and say, 'Human rights doesn't belong to them.' I think it is very important to bring up this issue in this discussion in this Senate inquiry, because human rights are there whether or not this government or the laws that we have here in Australia cover all human beings. The point is—and this was made in the Geneva conventions—that, even in cases not covered by law, the human being remains under the protection of the principles of humanity. This is so important. The founders of modern human rights, the ones who actually drafted the International Bill of Rights, were very clear about this. Renee Cassin said that equality was placed first in a series of rights because Nazi human rights violations began by asserting inequality.

Here we have an issue that involves the human rights of the unborn child, and this Senate and the Australian parliament should know what our predecessors promised about unborn children. The Nuremberg principles were the actual foundation of modern human rights law. Resolution 95 of the UN General Assembly was the one that said, 'Yes, we are going to set up Nuremberg, we're going to take the principles from Nuremberg and then we are going to codify them in an international bill of rights,' and that is what they did. What did the Nuremberg principles say about the unborn child? It is on record. They said that the unborn were denied the protection of the law. That is what they said—that is the very basis. Then we go on to the universal declaration, and what did that say? It was understood—and this was reaffirmed unanimously in 1959 by the UN General Assembly—that protective legislation was to be provided for the child before as well as after birth, and it is there in the foundation

document. Then it comes up again in article 6 of the International Covenant on Civil and Political Rights. The reason given in black and white for protecting mothers from capital punishment is to save the life of the unborn child. So there it is: it is embedded in international human rights. The Australian government is a party to these conventions. We have promised this on behalf of our people and for our people.

If Ben Chifley, Bob Menzies or Dame Enid Lyons came into this place today and sat in those chairs over there, they would say to you, 'What's this Senate inquiry about?' You would say, 'We're just trying to decide whether to give this new poison drug to get rid of unborn children to the TGA to decide whether we're going to put it into general use.' They would say to you, 'What? What happened to the Hippocratic oath? What happened to Blackstone? What happened to what we agreed, the universal human rights principles? What happened to the principles of humanity? When did the Australian parliament pass a law to say that it is okay to give this poison to unborn children?' And you would say, 'No, we didn't pass a law. It just happened in one of the minor courts that they reinterpreted the law. See?' And they would say, 'On what basis do you give this RU486 to mothers to get rid of their unborn children?' And you would say, 'It's on the basis of the life of the mother or the health of the mother.' And they would say, 'How many cases would you have?' And you would say, 'There are about 84,000 each year. Around 25 per cent of mothers that have babies are really not well enough. They are not healthy enough to carry these babies to full term.' And they would say to you, 'For heaven's sake, what happened to the health system? Twenty-five per cent of Australian women can't carry a baby to full term? What's wrong with us? What's happened here? How did this come about?'

That is what happens when an ideology takes over. That is what happened when Nazi ideology or the communist ideology came in. It is this idea of, 'No, this set of human beings is not equal with us.' Apartheid: 'That little black boy over there does not have the same human rights as I have.' Actually the ideology is failing now. We are almost in this post radical feminism era. People are beginning to think again, 'What is this about?'

Senators, I would say this: you really have to think about this. The real responsibility, when it comes to human rights, is not about conforming Australian laws to the will of the people, to opinion polls or to how many Australian women say: 'Yes, it's fine. We should have abortion on demand.' No. Right from the beginning of modern human rights Australia was right in there. I can show you some cablegrams from our people at the UN, at the meetings before the universal declaration, from Paris and New York. These cablegrams spell out clearly, 'Look, when these principles come into being we're going to have to change some of our domestic laws.' That was understood right at the time. When we signed these treaties we agreed to that. We understood that we would have to change domestic laws to conform to human rights. Now what is happening here? We are trying to turn it the other way around: we make human rights conform to ideological trends.

Miss Holzapfel—Thank you for the opportunity to appear. Australians Against RU486 is a coalition of concerned groups and individuals—including pro-choice individuals—campaigning on medical, ethical and moral grounds to retain the status quo approval process for RU486. Australians Against RU486 support positive outcomes for women but believe that advocates of RU486 are endangering the lives of Australian women in the name of choice.

Australians Against RU486 is a trust established specifically to campaign against the current bill. The coalition includes doctors, physicians, academics and community leaders from across Australia. Member organisations include the Australian Family Association, the National Alliance of Christian Leaders, Pregnancy Assistance, the Fatherhood Foundation, the Australian Catholic Lobby, the Australian Christian Students Association, Right to Life Australia and the Endeavour Forum. In addition, hundreds of individual doctors, scientists, academics and ordinary Australians make up the membership.

It is the view of Australians Against RU486 that RU486 should remain in the TGA restricted goods category, given its role as an abortifacient, and that the current restrictions surrounding its approval should remain. The current level of scrutiny and accountability associated with RU486 is right and appropriate, given the medical, social and ethical concerns surrounding the drug. The approval of RU486 must remain something the Australian parliament, through the Minister for Health and Ageing, takes responsibility for, given the higher criteria of ethical and social obligations related to this drug.

While we recognise the experience of the TGA and its good standing, the TGA is not designed to deal with morality with regard to any drug. The TGA is an organisation designed to look at a drug solely on the basis of its safety, efficacy and quality. Ethical and social criteria are not considered. This clearly indicates a role for the parliament, through the minister, in this process.

Contrary to what those who support the bill would state, we have found that Australian women do not support this drug or even want it. Recent research shows that the more people know about RU486, the less likely they are to support it. In fact, 60 per cent of Australian women were opposed to its introduction when given information about it. A poll, conducted by Quantum Market Research in late December, surveyed more than 500 Australian women of voting age, between 18 and 45, from all states and territories. Importantly, 60 per cent initially felt they did not have enough information about the drug to make a decision. In the study, they were provided with details including the complications, the time frame compared with surgical abortion, and the increased risk of death as compared with surgical abortion. Given this information, only one-third of Australian women supported the introduction of RU486.

Many of the supporters of this bill and this debate suggest that it is simply a matter of process. It is quite clear to Australians Against RU486 that nothing could be further from the truth. If a decision on the process was to be made, the Prime Minister would not have given a conscience vote on the issue. It would have been a vote along party lines and moved on. While a cleverly worded bill attempts to disguise the intent, this cannot be seen as anything other than a public policy issue. Public policy decisions condition the community, and this bill is most clearly about a public policy decision.

We must ask, as recent events unfold, as more deaths are recorded around the world, as countries around the world—including Canada, Italy and the US—move away from this controversial drug: why is Australia moving towards it? To an outside observer, the bill can be seen only as an unnecessary crusade on choice that achieves little other than a backwards step for women's health. Australians Against RU486 urge all senators to reject this bill.

CHAIR—Thank you. Would representatives of Women's Forum Australia like to make a statement?

Ms George—I will begin by highlighting some of the aspects of our written submission that you have before you. In that submission, Women's Forum Australia supported the process of accountability regulating the importation of prostaglandin antagonists, including RU486. It is worth highlighting, because it seems to have been overlooked, that if the bill is passed, it would remove from ministerial responsibility not only RU486 but at least eight other abortifacients plus fertility vaccines. Our written submission deals specifically with fertility vaccines as well as RU486.

Our written submission highlights the history of the importation and trialling of RU486 in the mid-nineties, when the then ministers knew nothing of its importation and the trials were exposed for their shoddy informed consent procedures. Our written submission examines the flawed approval process in the United States and France based on data from uncontrolled studies and thus susceptible to significant bias and of dubious scientific merit. We have documented the health risks of RU486 and questioned the adequacy of the TGA to assess drugs of this nature. We argue that women need policy initiatives and support which address their real needs and which enhance their freedom to continue their pregnancies rather than provide another method of ending their pregnancies.

I will focus now on two key areas: firstly, the risks that RU486 poses to women's health and, secondly, the social policy implications of this bill and the need for special accountability and scrutiny.

RU486 is demonstrably unsafe for women. There are well-documented risks of fatality. A study that I think Senator Barnett referred to this morning, published recently in the prestigious *New England Journal of Medicine*, estimates rates of maternal mortality related to the use of RU486 is about 10 times that of surgical abortions. It is remarkable that, of all the submissions by medical professionals to this committee advocating or supporting the bill, to the best of my knowledge, not one gives any acknowledgement of that paper or makes any reference to that paper and its implications for women's health and safety. The author of that *New England Journal of Medicine* paper, Dr Michael F. Greene, comments:

> These deaths have important implications … for public policy.

RU486 has other adverse effects on women's mental and physical health. There are documented adverse outcomes such as haemorrhage, infection, sepsis, ectopic rupture and emergency surgery. Significant numbers of women require surgical termination after the chemical method fails. Studies have also raised concerns about the lasting effect of the prostaglandin component of RU486 on cervical and uterine tissue, and our written submission details that. Prostaglandins have also been found in the egg follicles of women who have used them, and they can also suppress the immune system. Some researchers suggest that chemical abortion is more psychologically traumatic for a substantial number of women.

The US Food and Drug Administration is currently investigating a number of deaths associated with RU486. It has recently convened a meeting with the Centers for Disease Control and Prevention to investigate these deaths. Clearly, the FDA itself now has major concerns about the health and safety of women using RU486. In such a climate of uncertainty,

it would be premature to change the current system of accountability and scrutiny in Australia. Indeed, it calls into question the rush to push ahead with the Senate vote this Thursday.

RU486 raises additional health and safety issues. The fact is that RU486 is not like other drugs. It does not treat an illness or a disability or a defect or an injury. Pregnancy is not a pathological condition. RU486 is designed to cause an abortion that will end a developing human life.

The fact that there is a conscience vote on this bill demonstrates that we have before us a serious social policy and ethical issue. Policy decisions are the exclusive province of our elected representatives, of ministers, and those policy decisions should take into account community attitudes and concerns. Recent research demonstrates that 87 per cent of Australians support finding ways of reducing the number of abortions. Clearly, the Australian people do not think that abortion is just another medical procedure. So it is incongruous to say that the abortion drug is just another drug. But, if the Senate agrees to jettison the current system of accountability and scrutiny, that is precisely the message that you will be sending to the Australian people—that abortion is just another medical procedure, that the abortion drug is just another drug.

Given that the approval or non-approval of applications to import RU486 is so contentious and given that there is significant public concern, as reflected in the many submissions against the bill which you have received, we also have to ask this: which system would offer the greater accountability and transparency; which system would secure greater public confidence in the process? It is not enough that the approval process surrounding RU486 is independent and unbiased; it must be seen to be so. The health minister, whoever he or she might be, is accountable for any decision to approve or not approve RU486. If his or her decision is biased or lacks independence, he or she will answer to the electorate and to his or her parliamentary colleagues. Indeed, the current health minister has this morning written in the *Australian*:

> Any abuse of a ministerial discretion would be grounds for changing the minister, not for changing the law.

The TGA is an unelected body. As history demonstrates, faceless officials within it can make a major decision without a parliamentary office bearer knowing about it. Public confidence in the approval process demands that independence is manifest, and yet the TGA is funded by the pharmaceutical industry. Our written submission refers to the 2004 investigation by the Australian National Audit Office which found that the TGA lacked accountability and it criticised complaints-handling procedures, data management and documentation. The Deloitte review which followed called for improved transparency, governance and improved accountability. This was not the first time that the TGA had come in for criticism. Similar criticisms were made in a report in 1996.

There is already a doubt in the public mind about the ability of the TGA to properly assess dangerous drugs. The TGA issued only five so-called ‘black box’ warnings in 2005 even though more than 20 other drugs ordered to carry black box warnings in the United States are sold in Australia. The current system provides a much-needed safeguard for women’s health and wellbeing. RU486 also raises serious policy questions which the TGA was never designed

to address and assess. The ultimate responsibility for decisions to approve or not approve RU486 should rest with the health minister. Thank you.

Mrs Sherston—Thank you for giving me the opportunity to speak. I, along with the other ladies, in the submission that has been presented to you, feel that the decision for the use of RU486 in Australia for abortion should be left with the minister for health because it cuts across social, economic and mental health boundaries. From our understanding, and also from what is stated on the website, the TGA is a unit of the Australian government's Department of the Health and Ageing. It also carries out a range of assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access within a reasonable time to therapeutic advances.

I would like to share a little of my own personal experience. The abortion of my first conceived child took place when I was 16 years of age. I am now 46 years old. I had no choice as to what would happen to my baby; that decision was made for me. This profoundly affected my life and my relationships. Several times before and after the abortion I contemplated suicide. A lot of emotions were buried deep down inside of me because I had let them kill my baby when I did not have the courage to kill myself. It has only been in the last few years that I have reached out and got help from a psychologist. That makes it almost 30 years of living hell and not understanding why.

The women and men that come to the Rachel's Vineyard Retreats are in so much psychological pain that we wonder how they have even made it that far. One lady in sharing her story says how she was crying as she went under the anaesthetic and that once she recovered consciousness all she wanted was her baby back. How would that be if the method used were a medical abortion? If RU486 was introduced to this country, I can see the psychological issues for women being so much worse. As stated in our submission, if the abortion takes place in the woman's home the sanctuary of home would become the place of the abortion, a place which many women hold in fear and loathing for the rest of their lives, a place to be avoided at all costs. They have to wait days, if not longer, for their baby to die and to be expelled from their body. Can you imagine what would be going through that woman's mind during that time? What if she changed her mind after taking that pill? How would she react knowing what she has done and what is happening inside her? I know how I would react. I would want to tear myself to pieces.

On Friday, before leaving to come to Sydney, I received an email from a priest in the United States. He told me about a 28-year-old woman who took RU486. She came to one of these Rachel's Vineyard retreats over there in the States, only a couple of weeks ago. It actually took six weeks for her baby to be expelled from her body. In that time, she did not know whether her baby was dead or alive. By the time it was all over, she sat naked in her bathroom, on the bathroom floor, not wanting to live any longer. You cannot destroy the baby without destroying the mother. No-one is immune to this. It can happen to your spouse, daughter, girlfriend and to any woman on this committee or in this room.

Taking RU486 is not like taking aspirin for a headache; it is taking human life. Abortion is not just a simple procedure for women; it is a very traumatic time. It can also be very traumatic for family or friends around the woman who know what is going on. This is a

serious matter and should not be left to faceless public servants to approve. It should remain a ministerial responsibility. Surely there are other issues of lesser importance which still need to have ministerial approval. There have already been eight deaths reported across Britain and America. That might not sound like many, but one is too many. I urge you not to rush into a decision before you have the opportunity to speak to other women and men around Australia about this topic. Thank you.

CHAIR—Thank you very much to each of you who have made an opening statement today, and, of course, thank you for the submissions that you have placed before the committee. I will open by asking for your response to a particular argument that has been placed before the committee. The argument is that, effectively, surgical abortion in Australia has been legalised for a number of years, that therefore the option of the use of RU486 is merely an extension or a further manifestation of that option already available in Australia, and that therefore it is not really open to the federal parliament or a federal minister to block access to RU486, given the background of what is already available by way of surgical abortion in Australia. Could I have your reaction to that argument.

Mrs Joseph—Yes. I think we have to come back to the fundamental principle that, even where laws are not being effectively implemented, which is the case with laws protecting the child before birth here in Australia—even in these circumstances—this is an opportunity for the Australian parliament to pause and see what their underlying and fundamental human rights responsibilities require them to do regarding their legal obligations if RU486 is put out without restrictions in the Australian community.

If you look at paragraph 8 of my submission, you will see that I point out there that, under the human rights instruments that we have acceded to, our obligations require that the Commonwealth government has:

> ... a strict legal duty at all times to prevent, investigate, prosecute, punish and redress violations of the right to life wherever such violations occur, both in private and in public ...

Even in public emergencies threatening the life of the nation, you still do not have that authority—no government has that authority—to have unrestricted availability. You will say, 'Yes, but we do have restrictions'—but not the Commonwealth government. The Commonwealth government is not restricting this. It is saying, 'No, this belongs to the states,' because this is the policy of the Commonwealth government.

All these years that we have been losing tens of thousands of unborn children, the policy from all governments, from all political parties, appears to be that the Commonwealth government applies a presumption of innocence and assumes that, in the absence of a court decision to the contrary, every termination is performed by a medical practitioner in accordance with relevant state law. Remember what the relevant state law says. It says you can abort your baby if there is a serious risk of death or very serious injury. The Commonwealth government says: 'The states are looking after that. It's not our business.' Well, it is our business.

The medical benefits scheme says it tries to achieve a balance between the information necessary to establish entitlement benefit. So the Commonwealth government is paying for this but is not investigating whether it is really being done according to the law. It talks about

a patient's right to privacy. So that is another cop out. It says: 'No, on this issue we don't want to restrict or offend against the privacy,' yet we know that one of the fundamental things in human rights obligations is that we do not have that right not to investigate when there are human rights abuse. Privacy is not an excuse for human rights abuse.

So what I am saying to you is that the Senate and the House of Representatives have to really think about this. You have to think: 'If we put RU486 into the public community at this point in time then we've got to follow it up and check up exactly where it's being used, how it's being used and why.'

Ms Tankard Reist—It is Women's Forum Australia's view that it would be dangerous to expand a practice which has already resulted in demonstrable harm to women. We also have research that shows that there is reason to believe that chemical abortifacients such as RU486 increase the psychological risks for women. Our research comes in a number of forms, primarily a document that we included as an attachment to our submission, but I am happy to table it again here today. It is titled, *Women & Abortion: An Evidence Based Review*, which we published recently. It was launched in Parliament House. This document is a comprehensive evaluation of all of the current medical literature on the impacts of abortion on women. It is a pure research document. To summarise the evidence it contains, our submission says:

- Abortion results in short-term relief for most women, usually accompanied by negative emotions. Such relief tends to be transient.
- Ten to twenty percent of women suffer from severe negative psychological complications after abortion, despite the frequent presence of relief soon after the abortion.
- Many more women experience emotional distress immediately after the abortion and in months following. Women experience a range of negative emotions after abortion including sadness, loneliness, shame, guilt, grief, doubt and regret.
- Depression and anxiety are experienced by substantial numbers of women after abortion.

… … …

- After abortion women have an increased risk of psychiatric problems including bipolar disorder, neurotic depression, depressive psychosis and schizophrenia.
- Women who have experienced abortion also have an increased risk of substance abuse and self-harm. This is particularly true during a subsequent pregnancy.
- Abortion for foetal disability is particularly traumatic and can be psychologically damaging for women.

In terms of further research, my first book, *Giving Sorrow Words: Women's stories of grief after abortion* is a collection of 18 stories of Australian women who were not prepared for the trauma they suffered after termination. These stories need to be taken very seriously. I heard from hundreds of women for the research for that book and I continue to hear from them most days. The other lot of evidence we would like to present is that chemical abortion is even more stressful than surgical termination. Again, I refer you to this document that goes into these studies, but I will just to allude to them briefly now.

A 1998 study in England compared women having surgical abortions with women having chemical abortions. The researchers found that women having chemical abortions rated the

procedure as more stressful and painful and they experienced more post-termination physical problems and disruption to their lives. Women may not expect or are not told that they may see the foetus, and this was associated with more intrusive events, nightmares, flashbacks and unwanted thoughts related to the procedure. Fifty-three per cent of the chemical abortion group said they would choose the same procedure again compared with 77 per cent of the surgical group. Another study by the same authors found similar results. Chemical abortion was more stressful. This was related to the physical and emotional aspects of the process, seeing or feeling the foetus, waiting times during the procedure and the process itself.

Researchers also note that seeing the foetus is a particularly distressing experience for women. It can 'bring home the reality of the event and may influence later emotional adaptation'. Another researcher explains that the patient may expel the foetus at home and that some patients are curious about what this might look like. Hype around the drug can also raise expectations in women that they will have an easier time if they choose this method. A study reported in the journal *Contraception* found women who heard their own physician and media talking about the new method saw it as a magic one. Their abortion did not appear so easy and quick as they were expecting.

Ms George—Can I just add to that for Women's Forum Australia. Yes, abortion is legal but I have already referred to the research into community attitudes to abortion. When we dig down into what the community thinks about abortion, it is clear that Australians are concerned about the practice of abortion. I refer to the statistic that 87 per cent of Australians support ways to reduce the rate of abortion. Clearly, as we have said, RU486 is not just another drug, the sort of drug that should be assessed by the TGA. Senator, you also referred to whether it is right to block access to RU486. With respect, that is not the issue, as I am sure you are well aware. It is about who decides access to RU486.

Miss Holzapfel—Just briefly: we would suggest that, given the debate as it is—and the contention of the debate on both sides—it is an issue of social policy that should always be decided by the parliament of the day, irrespective of what the change is.

CHAIR—In light of the time—we are going to run out of time very quickly—I might ask senators to try to limit their questions to one and perhaps ask if we can have one or possibly two responses at most from the table in order to get through in the time available. I ask Senator Moore to begin.

Senator MOORE—Chair, I have always restricted my questions to one, but I am going to have a question and a request this time. My request, Ms Holzapfel, is about the research that you provided. As you would know—you have been following the debate very closely—we have been bombarded by statistics and research. I was wondering whether we could obtain the questions and the process that your research followed. I think that would be very useful, because it was looking particularly in the term of the debate. It would be good if we could have a copy of the questions you asked and, if there has been a study, find out how it went.

My question is much wider and it is in terms of the debate we have had. The bill before us looks specifically at the method of assessment of RU486 and other drugs that are part of the restricted group that was defined at the time when the clause was brought in. The information we have received from numerous groups seems to indicate that the concern that is being

raised is that the decision, whatever it is, on this particular bill will send a message to the Australian community and, depending on which side of the argument they are, people will claim some kind of success or defeat, based on that message.

I know that in your opening statements you did talk about the issues in Australia, but I would like to have an answer from each of you about how you see specifically the decision on what is a process amendment, a process bill, before the Senate—how you are able to determine what message that will be sending to the Australian community. I am picking up on comments that you made in your opening statements, where that was tending to be given. I throw that open to anyone who wishes to answer it.

Ms George—I will comment briefly. Advocates of the amendments constantly say—it is the mantra we hear: 'RU486 is just like any other drug; pass the responsibility to the TGA.' That is the message if the amendments are passed: that RU486 abortion is just another medical procedure. In our submission, that is contrary to public attitudes, which show concerns about the practice of abortion in Australia.

Miss Holzapfel—The wording of the bill may be the process, but the debate that has unfolded in the Australian community is about the drug, its safety and what people are comfortable with. To say that it is just about the process is not looking at the broader community and how they are viewing the bill and how they will view the message you send from this vote.

Senator MOORE—And what is the message, Miss Holzapfel?

Miss Holzapfel—It depends on what you think it is.

Senator MOORE—That was my question: how do you perceive the message?

Miss Holzapfel—They will take it as an indication of what the federal parliament believes is right and proper with this drug. They will take the view that the Senate either supports or rejects the drug.

Senator FIELDING—Ms Tankard Reist, you have recently published a book, *Giving Sorrow Words*. Could you go through some of the research and also how you think RU486 will affect women?

Ms Tankard Reist—*Giving Sorrow Words* was actually published in 2000 but it was reprinted last year. There were three main themes that came out of the book. The first was the unpreparedness of women for the emotional backlash—the psychological ordeal—they were to suffer after their termination. When I advertised seeking contributors to the book, many of the women who contacted me would say, 'I bet you I'm the only one that you have heard from. I bet you haven't heard from anyone else.' Abortion had been sold to them as safe, easy and quick and that you could get on with your life. They thought that the problem must be with them and not with abortion. They were not prepared for the suffering, and, believe me, the suffering of these women is terrible, which has been minimised in the debate around abortion.

The second theme to come out was the lack of counselling and the very poor pre-termination process. Unlike the witnesses who appeared before us, I do not hold the same blind faith in the medical profession in its care of women. Lack of care of women is really the

reality. These women felt that the whole process was designed to secure an abortion decision—that it was a tick-a-box type procedure, propelling them in one direction. Only yesterday I heard from a young woman who said to me that she went to her doctor unexpectedly pregnant. All she wanted was a blood test to confirm the pregnancy test. This doctor immediately told her all the reasons why she should abort this child. She had not gone seeking an abortion at all. So women are often propelled in the one direction and not given the time and space to make an informed decision.

The third theme that came out of the book was the myth around choice. The whole language and rhetoric around choice suggests that there are many options available for women. Most women were terminating because of lack of choice. There was only one option put to them. That is why Women's Forum Australia emphasises the need for structural change and positive life-affirming public policy initiatives which address the real felt needs of women. We do not believe that women need more abortion methods. They need more choices so that they are not compelled to have unwanted abortions in the first place.

Senator FIELDING—I want to ask a brief follow-up question. Back in 1996 both houses agreed that RU486 should remain the decision of elected members. Given the research you have done through your book, research that shows that the community is concerned about the high level of abortions and want to see that number reduced, and given that the RU486 allows abortions to occur at home, is there any other research that you know of that would point to why elected leaders of this country would want to shirk their responsibility and pass it to bureaucrats to make that decision?

Ms Tankard Reist—I believe strongly that we are witnessing a debate around ideology over proper process. This is all about ideology. It is all about the triumph of a particular set of beliefs around abortion rather than due process. I do not think that anyone on this committee should permit ideology to triumph over due process. This decision should remain with the relevant health minister of the day, whoever he or she is. This is not about one particular health minister at this particular time; it is about the proper office-bearer having that power. I think what has happened is that a lot of people have forgotten the history of the importation of this drug. Our submission went into that history. It really was a shambles. It was greatly contemptuous of the health of women, regardless of anyone's politics on abortion, with the way those trials proceeded, the fact that Carmen Lawrence had to intervene to shut one of them down and the fact that a journalist like Margo Kingston would write feature piece after feature piece about the fiasco that occurred with that importation. I think that history needs to be revisited so that the context for that original amendment can be fully understood.

Senator ADAMS—My question is to Women's Forum Australia. I live in a rural area and I am also a midwife. This is just a heading, where you have more abortion procedures and rural women at higher risk. The last paragraph of that particular section I will just read—it does not really quite make sense to me and I would like an explanation:

> However, those proposing RU486 for women in regional and remote areas are in fact suggesting that the Government facilitate an increase in numbers of women undergoing abortions.

I would like you to tell me about that. I will just go on—I think you probably have a typo in here because the next sentence certainly does not make sense:

Therefore, more rural women will be exposed to significantly higher risks than women in rural areas will.

I think that is probably metropolitan areas; is that what you mean?

Ms George—Yes.

Senator ADAMS—It continues:

If surgical abortion pathologies are not available close by, the availability of RU486 may reduce the impetus to improve not only medical facilities but also many supports and services for pregnant women in those areas.

I would like to you explain exactly what that is about.

Ms George—I did not have that open when you asked the question. It is the last paragraph in that section?

Senator ADAMS—Yes, it is the last paragraph.

Ms George—Just give me a moment to read that again. I think that has to be read together with the paragraph before that, which explains that, with our conservative estimates, if RU486 were made available, because of the failure rate of RU486 to complete the termination, about 3,600 women would also require a surgical abortion.

Senator ADAMS—No, it does not actually. What you have written there has a completely different meaning. You are referring exactly to the fact that the government will facilitate an increase in numbers of women undergoing abortions. I just wonder how the government can do that, because that is really quite tricky the way someone becomes pregnant and, if they are going to have an abortion, how does the government actually do that? It does not make sense.

Ms George—I am sure the government does not contribute to the pregnancy itself. I am sorry; perhaps I can come back after considering an answer to that. I cannot answer it now.

Senator ADAMS—Also the other part is that you are saying that medical facilities may be reduced because of this, and the supports. That whole paragraph just does not make sense. I would really like you to correct it and perhaps come back with exactly what you mean, because this is in *Hansard*.

Ms George—We can consider that and submit a revised version if need be.

Senator ADAMS—Thank you.

Senator BARNETT—Just quickly on that point as a follow-up: in five to eight per cent of the cases of medical abortion follow-up, surgical abortion is required. Is that correct?

Ms George—Yes, according to estimates.

Senator BARNETT—Is one of the points that you are trying to make that in rural and regional areas it is less safe for women if they cannot access adequate and appropriate medical care?

Ms George—Yes.

Miss Holzapfel—You only have to look at the numbers, because there needs to be a second procedure.

Senator BARNETT—Yes. In terms of the numbers, and I am not sure of the exact figures, but it is based on the five to eight per cent follow-up requirement of surgical abortion. Is that correct?

Ms George—That is correct.

Senator BARNETT—Ms George, I want to ask you about your opening statement and your submission. You are one of the very few witnesses who has actually addressed the fact that the restricted goods include eight abortifacient drugs and not just RU486. The media, the public and the entire community thinks this entire debate is about one drug called RU486. You have referred to vaccines as well that are covered under the restricted goods definition in the bill. So there is clearly a very big misunderstanding. Can you help clarify the record and give us your views of these drugs and your understanding of their impact, including the vaccine?

Ms George—My colleague Melinda has done particular research on the vaccine, so she might be in a better position to answer that.

Ms Tankard Reist—I am glad you have asked the question, because we actually think the drafters of the bill have not been perhaps as open as they might be because really the bill appears to be around only one drug, RU486, and yet the original amendment covered eight abortifacient drugs, a number of which are already being used off label to induce abortion—primarily misoprostol and methotrexate. Our document does go into detail about the use of misoprostol, which is an anti-ulcerant—and I understand you have already had evidence put before you as to why the manufacturer of that drug does not support its use in termination. Our submission also had an eyewitness account of a woman who administered that drug in a Melbourne clinic and described some of the terrible adverse events that she saw as a result of the use of that drug and actually resigned her job as a result.

The antifertility vaccine which has been trialled in India carries with it many risks for women's health. I will summarise them: potential adverse effects include autoimmune diseases, allergies, immune complex diseases and disease exacerbation. The drug can cause miscarriage, visible malformations and hormonal abnormalities where a pregnancy continues. A number of authorities on the drug have pointed out that the potential long-term effects such as harm to ovaries and pituitary glands may not be seen until years later. The reversibility of the vaccine cannot be guaranteed. There is an excellent book on this subject called *Vaccination Against Pregnancy: Miracle or Menace* by Judith Richter, and she goes into details about the potential health impacts.

The vaccine also poses serious health risks and potential for abuse in women in developing countries, and we have seen this in the trials to date where women in India, for example, were given consent forms written in English which they were asked to sign. Obviously, that is unlikely to happen here, but the drug does not have a very good history. So we appreciate you asking that question because the effect of the private member's bill if it succeeded would be to destroy any ministerial accountability and scrutiny over a range of hazardous drugs, and I have only really alluded to two or three of them today.

Senator BARNETT—And they all relate to abortifacient drugs?

Ms Tankard Reist—Correct, yes they do.

Senator BARNETT—Is that why they are separate to all other drugs and should not be seen as just another drug?

Ms Tankard Reist—That is correct, and they have always been separate; these drugs have always been restricted under the Customs legislation.

Senator BARNETT—If we get time, I will come back to an earlier statement that Ms Tankard Reist made.

Senator POLLEY—We have heard evidence given this morning that an abortion is an abortion is an abortion and that, because it is legal within the jurisdiction of all the states and territories, this is just another choice for women. Could you outline your concerns with that? I also want to see whether we could investigate further the trauma that would be caused to those women who may choose to have a medical abortion where the process is not completed and then they have to go on and have a secondary abortion through surgery. Has there has been any research done overseas that would highlight the psychological problems there? Furthermore, with the United States, where there is no necessity for any complications or deaths to be reported through the use of drugs like RU486 or any others, would you like to elaborate your concerns there? Some of us have been accused of being undemocratic because we are not taking notice of the supposed support in the community for abortion, whereas I see that the responsibility of all elected members is to represent not only the majority views but also the minority views—which in other circumstances we often get condemned for doing.

Ms Tankard Reist—Firstly, I do not think we have research on the psychological impacts of a combination of chemical followed by surgical, but we do have research on the impact of those individually. So we can extrapolate from what we already know that, combined, this double abortion would have to carry with it serious adverse health outcomes for women's psychological health. Your second question—I think this is a really important issue—concerns the voluntary nature of reporting of adverse events. How can we have any idea of how many women have been harmed by these drugs? With my own research, the cover-up is quite extraordinary and quite disturbing of what happens to women with any medical interventions. For example, I have been documenting the maiming and injury of women in front yard abortion clinics. I have documented the case of a 16-year-old Queensland girl who was left half dead after her abortion at a very prominent clinic in Bowen Hills in Brisbane.

I have also documented the cases of other women who have suffered terribly. That 16-year-old girl, for example, suffered a severed fallopian tube, a hole in her bowel and a torn bladder. She had a fist-sized hole in her uterus that needed 200 stitches. When she got to the hospital the doctor I interviewed had to remove the baby's head and other parts. I do not mention this just for shock value. I mention it to say that there is a lot going on and being done to women which is not exposed. Again I argue that, regardless of our politics on abortion, we should all agree that a woman should not go into an abortion clinic and come out half-dead.

There is a case in Sydney involving an abortionist who gave abortion drugs to a young woman who went home and expelled a live baby boy into a toilet. The baby was fished out by ambulance officers and died five hours later. This is the dark underside of this issue that does not get talked about. If the doctor in Brisbane who butchered that woman was a cosmetic surgeon, you would have *A Current Affair* and everyone else on his doorstep with a camera.

But the doctor I interviewed and the nurses at the hospital commented that this woman was one of eight in recent times who had been left in this particular condition. These stories do not see the light of day, or very rarely see the light of day.

In the US we know of five such Californian women but again, it is a voluntary reporting system. Even where there is a death, reporting is voluntary. So how do we have any grasp at all of the true rate of death and injury? With respect, I cannot see the People's Republic of China publishing anywhere details of the injury to women in that country. We already know the contempt in which women are held there, with forced abortions and coerced sterilisations, et cetera. We have no idea and, until we have a good idea, why are we prematurely going ahead, paving the way for the importation of this drug into Australia?

Ms Holzapfel—Certainly in the US at least one of the cases was initially not recorded as a death from the risk associated with RU486. It was only when the family actually requested an autopsy and they determined that it was sepsis that it was recorded as a death associated with RU486. So we do not know for how long how many of these deaths that are associated with what seems to be this bacteria have not been recorded. Certainly Professor Greene suggests that it is at least 10 per cent underreported. Again, in the UK they refuse to actually give the public any information about the deaths of three women there. They have just announced the death of a third woman there. They are refusing to release any information about the death. So there is not a lot you can gain from this from a scientific perspective if you cannot research it and understand it.

Senator WEBBER—I have a brief question for Australians Against RU486. The committee has heard a lot of evidence about the other uses that RU486 can be put to. I presume by the name of your organisation that you are opposed to the drug full stop.

Miss Holzapfel—No.

Senator WEBBER—But there is nothing in your literature that says that you support it for the use of cancer or anything else. The catch-all would be: you are against it.

Miss Holzapfel—We are opposed to the bill. Under the current approval process, which we agree should remain, the minister can at any time approve the use of RU486—and he has done in some circumstances. We are not opposed to the drug; we are opposed to you changing the approval process.

Senator WEBBER—I understand that.

Senator NASH—Ms Holzapfel, correct me if I am wrong, but in your opening statement I think you said that this is a 'cleverly worded bill to disguise its intent' but you did not go on to say what you thought that intent was.

Miss Holzapfel—Certainly the intent is the approval of RU486 for use as an abortifacient.

Senator NASH—I would not think that was disguised, though. I would think that would be very obvious.

Miss Holzapfel—Except for the fact that, throughout the debate, people have fallen back to the process, when raising issues about the safety of RU486, to suggest it is not about the drug, it is about the process.

Senator NASH—But if we are talking about raising the safety aspects, should we not then allow the drug to be assessed for its safety?

Miss Holzapfel—I think there is enough information before a range of people about the safety for us to suggest that there is more to be looked at before we even make a decision.

Senator NASH—That is exactly the point of the bill: there is more to be looked at before a decision is made.

Miss Holzapfel—But it is also an argument to suggest that the parliament should be the first to make the call as to what they do.

Senator NASH—But what we are suggesting is that it should be assessed for its safety, and the bill is there purposely to put forward that assessment should be allowed. Somebody in Melbourne raised the point that for those who say, 'it is not safe' it is illogical to then say that it should not be allowed to be assessed for its safety. I am just a little interested that you would open with that comment when I do not think there is any disguise at all. I think it is very clear.

Miss Holzapfel—Certainly people who have supported the bill in public have suggested that we cannot discuss RU486 because it is simply about the process—the bill before the parliament. That is why I mentioned it.

Senator FIELDING—We heard on Friday from Dr Cannold that politicians should stay out of medical issues like abortion. Obviously that includes matters like cloning, which politicians are about to debate. What is your response to her call for politicians to butt out of this major social, ethical and moral issue?

Miss Holzapfel—That would assume that abortion is only a medical issue, and I think it has been clearly illustrated that abortion is an ethical and social issue, hence the reason that the Parliament of Australia, the minister, and elected representatives should be involved in the process.

Ms Tankard Reist—Dr Cannold has basically always wanted business as usual for the abortion industry: no regulation, no restriction and abortion up to whenever. I would find it difficult to take her views very seriously.

Senator BARNETT—Ms Tankard Reist, you referred to the trials prior to 1996, when the amendments came in, and one of the motivating reasons for the amendments in 1996. Could you recap your views on those trials and the nature of them? Also, are you aware of any use of RU486 or abortifacient drugs in Australia today and the nature of that use?

Ms Tankard Reist—The background, as I said before, needed to be examined, because it sheds light on the events that led to this amendment. Those events were precipitated by the decision of an unidentified official within the TGA to authorise the importation of the drug in 1994. Prior to that, undertakings had been given by the then Labor government that the drug would not come in without the relevant minister being apprised of that. That action set in train a series of events culminating in the halting of a Victorian trial of the drug and four separate departmental investigations into the trials, ordered by the then minister for health, Carmen Lawrence.

Clinical trials of the drug were carried out in Australia by the Sydney Centre for Reproductive Health Research and by the Monash University Department of Obstetrics and Gynaecology, at Family Planning Victoria. What came out very strongly at the time was that the institutional ethics committees which approved those trials involved the same people who were running the trials—for example, Dr Edith Weisberg, who I understand will be appearing before you later, ticked off on the trial and then ran the trial—so there were a lot of questions being asked about the nature and the constitution of those committees and the whole process. Certain feminist health activists such as Dr Renate Klein and Dr Lynette Dumble exposed the informed consent procedures as being inadequate. For example, they did not even mention cardiovascular risks, so Family Planning was told to go back to the drawing board and rewrite those consent forms.

There is something I want to read to you from the review that was done of the Victorian trial. A special committee was appointed to review the trial process in Victoria, and that special committee described the constitution of the committee and the processes used by the IEC as 'suboptimal and insensitive given the nature of the trial'. It said that the absence of the religious member of the IEC left Family Planning Victoria 'vulnerable to the charge of opportunism'. Again, this led to the amendment and the strong bipartisan support for it, because the relevant ministers of the day were taken by surprise.

Senator BARNETT—Are you aware of the use of abortifacient drugs in Australia today?

Ms Tankard Reist—Certainly. Misoprostol has been used. It is very cheap—it is about 10c a dose. Misoprostol is the prostaglandin component of RU486—mifepristone plus this prostaglandin. Misoprostol has been used on its own, but it has all sorts of problems. One is the length of time between the administration of the drug and the expulsion of the foetus. I was attending a family planning conference here in Sydney a few years ago where Dr Geoff Brodie was relaying some of the problems with the trial of misoprostol in Sydney in the 1990s. He described a woman being in a McDonald's restaurant when she suddenly expelled the foetus. I regret to say this, but that got a big laugh from the audience. They thought that was highly amusing, but I was thinking of the trauma for that woman of this sudden, unexpected expulsion of the foetus. There were also problems with severe bleeding going on for a very long time. Methotrexate, which is an anti-cancer drug, has also been prescribed off-label in Australia to induce abortion.

Senator MOORE—I would just like to state something for the record before we finish on this section. There has been some inference that the proponents of the bill have been trying to mislead in terms of it just being RU486. There has never been any intent from any of the proponents of the bill to mislead on this issue. It very clearly states 'repeal the section' in the bill, which refers to all restricted goods. Very often, there is more detail within a bill than is actually given in a title, as Miss Holzapfel would well know. Given that the length of the bill is three very short pages, we certainly have not been trying to hide any detail in a lengthy bill.

CHAIR—I thank each of you very much for your appearance today, your submission in writing to the committee and your oral testimony today. It has been very useful.

Proceedings suspended from 12.43 pm to 1.22 pm

BUIST, Dr Robert Gerard, President, Women's Hospitals Australasia

FORAN, Dr Therese Margaret, Fellow, Chapter of Sexual Health Medicine, Royal Australasian College of Physicians

CHAIR—Welcome. Thank you both for appearing. I think you have both been provided with information on parliamentary privilege and the protection of witnesses and evidence. We have your submissions, or the submissions of the colleges and Women's Hospitals Australasia. I now invite you each to make an opening statement, and after that we will proceed to ask you some questions.

Dr Buist—Women's Hospitals Australasia is a not-for-profit organisation representing women's hospitals and women's health units in general hospitals throughout Australia and New Zealand. WHA currently has 32 member hospitals. WHA's major role is to support member hospitals in enhancing the health and wellbeing of women and newborn babies. Key activities conducted to fulfil this role are benchmarking of clinical outcomes, forums covering contentious or challenging clinical areas, guideline development and research.

WHA supports the role of the Therapeutic Goods Administration in examining the evidence available with respect to the therapeutic effects and risks of any pharmaceutical agent. WHA expects that the TGA monitors the activities of overseas regulatory bodies, such as the FDA. WHA supports the use of mifepristone in Australia with the caveat that it be used under strict medical supervision. This supervision should include exclusion of ectopic pregnancy and 24-hour availability of acute services that include the ability to conduct careful clinical assessments, appropriate laboratory investigations and safe surgical evacuation of the uterus.

Dr Foran—I was interested to read that the US commentator Steve Greenberg recently somewhat cynically described abortion as an intensely personal medical and emotional decision that can only be made between a legislator and his political party. I thought that was probably fairly apropos of what we are talking about today. I come here today as a representative of the College of Physicians and, in particular, its Chapter of Sexual Health Medicine. You have our statements, and I think they stand on their own in terms of very rightly and comprehensively drawing attention to the fact that the introduction RU486 into Australia is an option to be discussed by the TGA. It really comes to such issues as equity, choice and access, and I think they are the most important things we should be talking about. However, I would like to bring to the table here a much more personal perspective. I have now worked for over 25 years in reproductive and women's health, in particular, and I must have counselled thousands of women around unintended pregnancies. I have never yet, in all those thousands of women, met one that I would describe as having a frivolous abortion. I do not think such things exist. Most of the women I have spoken to have taken this decision with a fair degree of gravity, a fair degree of sobriety and a fair degree of really careful decision making. I really do not think the situation would be any different were the option of medical abortion available in Australia.

As you may have concluded, I have spent much of the last two weeks combing the web. It is a case of knowing thy enemy as well as thy friends, I suspect, in terms of what is out there. The thing that really struck me was just how conflicting is the evidence around this particular

medication; it is incredibly confusing. The one thing that really strikes me is how different the situation in America in the last five years of use there has been from the experience in Europe, where it has been used for 20 years. The number of clostridial post-abortion shocks that have occurred in the US has just not been seen in Europe, and, as a clinician, it made me wonder whether or not there might be something happening, particularly in the United States, to make this occur. What crops up is that the rate of pelvic infection, for example, in the United States is something like 10 times that in Australia, and this may well have something to do with it. The other thing is that ectopic pregnancies were claimed as a serious adverse effect of RU486. We know that they are not. RU486 does not cause ectopic pregnancies; pregnancy causes ectopic pregnancies, and to blame RU486 for that is somewhat unethical scientifically, I think.

The next thing I want to say, because, as I said, I think our statement really says it all, is that the TGA is in exactly the right sort of position to make this decision for us all. The committee structure, the consultative nature, the fact that the best of scientific minds and evidence can be brought to the decision making table at the TGA make it far less likely that ideological sway and political expediency will be the things that make the decision. It will be made on the basis of scientific and clinical evidence.

Lastly, I personally have some qualms, because the one thread that has been going through many of the things that I have been reading through is that of the protection of women. We know that, several years ago, Right to Life changed its philosophical tack so that, instead of claiming that women and the doctors who provided abortions to them were murderers, it was claimed that it was much more a situation of protection. For me, history has taught that whenever people talk about protecting women and children they should run very fast in the opposite direction, because it is much more likely to be a question of control. A number of surveys of Australians have shown that on the whole 80 per cent of us agree that any decision around abortion is between a woman and her clinician, and I do not think it should be any different with RU486. I think the TGA is the right body to make the decision for us.

CHAIR—I thank both of you for those opening remarks. I ask each of you to indicate what you think would be likely to be the result for the rate of abortion in Australia if RU486 were to become available.

Dr Foran—European experience has taught us that in fact the rate does not go up, that it remains relatively stable, but that around 40 per cent of women choose to terminate by means of medical abortion. Rob, are they your stats?

Dr Buist—Yes; I have some data here published by the New Zealand Department of Statistics from the Abortion Supervisory Committee which compares New Zealand's rate of terminations of pregnancy with international figures. The rate in New Zealand in 2004 was 20.5 per thousand. For Australia they quote a rate of 19.7 per thousand. What is interesting, to me at least, is that the rate in the United States, where mifepristone is available, was the same—20.9 per thousand. In England and Wales it was 16.6 per thousand. I cannot see from those international figures any data that suggests that availability of mifepristone alters the abortion rate.

CHAIR—I note those comments and they are certainly consistent with some other comments that have been made to the committee. But I have to say to you that in many

respects the suggestion that there would not be an increase in the abortion rate if RU486 were generally available seems to me to be counterintuitive. Perhaps that is to do with the factor, which might not be present in other countries with which these comparisons have been made, of great distances that some women need to travel at the moment to avail themselves of surgical abortion. We have been told that there are significant numbers of women in regional and rural Australia who have very limited access to surgical abortion. These are the ones for whom RU486 would be a 'boon'. It seems to me if that is the case and that suddenly there is a realistic option available to those women that is not there now that you would be likely to see an increase in the abortion rate. In any case, even if that was not a factor, it does not make sense to me—it seems, as I say, counterintuitive—to suggest that by adding another option that you do not in fact see an increase in the rate, because people are not attracted to that particular option and take it up when they would not have used the other form of abortion. Can you clear up that doubt in my mind?

Dr Foran—As I said, my experience, you are right, was from overseas situations where distances and lack of access is probably not so much of a problem as it may be in Australia. Certainly in those situations it has merely been an option. It has been a choice that women have made usually on the basis that for them the idea of terminating a pregnancy in a way that they see as more natural and less surgical is a more appealing option. So overseas experience has said no. You may be right that in Australia it may increase access to our sisters in rural and regional areas and it may be that some of those women will perhaps not continue an unintended, unplanned, unwanted pregnancy because that option is available to them. I do not see that as a problem.

Dr Buist—I have two comments with respect to that. The first is that I think we are making assumptions about the access of women to termination services in small-town Mississippi, Arkansas, the Dakotas and Alaska, where issues of access to abortion I do not doubt are similar to Australia. So while I accept that Australia perhaps has a geographical imperative, I think it is reasonable to assume that at least in some parts of the United States that exists as well.

My second comment, however, is to I think I agree with you in that it would be a grave error if we viewed RU486 or mifepristone as the solution to the problem of access to abortion services. As we have made very clear in our submission, this drug should be administered under circumstances that, in my view at least, are essentially equivalent to those under which a surgical termination of pregnancy might occur because of the need in up to 10 per cent of women to perform an emergency evacuation of the uterus. WHA would be very disappointed if this drug were widely available under those circumstances. I would put it to you that the issue of access to termination services is a separate issue, and indeed a serious issue, to the one of RU486.

CHAIR—A different issue is the circumstances of Commonwealth parliamentary overview of the circumstances where this drug might become available and how it impacts on the present practice of abortion in Australia. As doctors and as people who practice a particular form of health care in Australia at the moment, what would you see as the reasonable political or legislative limits on your capacity to roll out controversial new services

like RU486? In other words, what are the limits of political involvement in the decision-making process? Are there any limits as far as you are concerned?

Dr Foran—The reality in this country is that legal abortion is legal. There is a general acceptance of that fact: legal surgical abortion is legal. I think there is also a general acceptance of that by the public. My understanding is that parliamentarians are there to represent the public and public opinion. I agree that they have an overarching role to make sure that we in this country have access to the best possible scientific judgment around new technologies and new medications, but I think that merely allows them to garner the best possible information on that.

Where I have problems is that we are a very diverse country with many philosophical differences, viewpoint differences, and I think those need to be accommodated in any decision-making process. I think we are a secular state and I would hate to see philosophies that are largely religion based holding sway over this particular debate and others around other parts of legislation.

Dr Buist—I am not sure I am capable of answering your question, but I guess I would refer to the second page of my submission in which we have tried to point out, under the circumstances of termination of pregnancy being legal—and that is your job, not mine—the circumstances under which it should occur. From my point of view the critical things are access to services, provision of information, counselling, appropriate informed consent with respect to the procedures—whatever they are—that are undertaken, and then appropriate care following the termination, or the abortion. I am not sure how otherwise I can answer the question.

CHAIR—You made an interesting comment just then when you said that the decision about whether abortion was legal was our job. In a sense, state and territory governments decided on the legality, at least of surgical abortion, some time ago. As you point out, it is legal at the moment, more or less, across Australia. But the federal parliament has not, to my knowledge, determined questions of access to medical or chemical abortion, except for—this is only, in a sense, tangential—the 1996 decision that the minister for health would have to provide approval before RU486 could be used for abortion in Australia. So some would argue there has not been a decision by the law makers who should set the parameters for this kind of process in Australia, except for that decision in 1996, which has now been revisited.

I am still not quite sure what you would see as the rightful limit of political or legal intervention in that process. You have not given me a philosophical framework about when it is appropriate for us to make a decision for you to go off and use new drugs in the marketplace or whatever. No-one has quite been able to provide that, it seems to me, to date. You would not, I assume, subscribe to the view that, whatever science can do, it should be able to do, and politicians should not get in the way of that?

Dr Buist—Of course not. I work in New South Wales and if you look at the legislation in New South Wales and the framework that the New South Wales Department of Health have produced from that, it specifies fairly clear grounds under which a termination should be conducted and, further, that that is not, if you like, abortion on demand. It uses terms like 'a serious threat to the health and/or psychological wellbeing of the mother'. Obviously to do

otherwise, in my view, is unlawful. I think that perhaps with RU486 mifepristone we were making it a bit difficult for ourselves because, at the end of the day, if I were to envisage the circumstances under which it would be used, I would envisage that it would be used by a registered provider—however we might deem that—in a licensed facility, a facility that is licensed to conduct or supervise terminations of pregnancy, and that appropriate, albeit confidential, data would be collected about the methods, the outcomes, the adverse effects, if you like, from the abortion. So in that respect I am not certain that I see it as being particularly different from surgical termination, but I accept that that may be a minority view.

Dr Foran—I feel the same way. I would add that bringing this into a scientific and consultative forum allows all of us to garner the best possible evidence for protocols around its administration, for follow-up protocols that might be specific to Australia and for safeguards that can be put in place to protect women in this country. I think that could only be done though where you have got people actually using the medication in this country and developing the right scientific framework and medical framework for its use.

Dr Buist—In our submission we have referred to two guidelines, one by the Royal College of Obstetricians and Gynaecologists, London, and one from the International Planned Parenthood Federation. There are plenty of others out there but I have referred to both of those. If you looked at them you would see that while the authors, in the main, are doctors—certainly the RCOG ones—they have taken a very non biological approach. There is a lot of biological detail in there but they have also taken a very broad view about what they consider to be appropriate organisation and availability of termination services.

Senator MOORE—The two organisations that you represent have a long history of involvement in women's health and in particular gynaecological health. I am interested to know whether there has been wide discussion within your groups about the issue of RU486 over the last few years and now. It seems to me that since this bill has been on the record there has been a proliferation of experts, all quoting the same information often for different reasons. Both your submissions quote Dr Greene. In terms of what is happening people are churning through information and reflecting that information in giving it to us. I am interested to know from the professional groups that you represent—the women's health groups and the physicians—whether the whole issue of medical abortion has been on the agenda, what the knowledge level is and whether there has been any demand for it to come into Australia. Certainly from one lot of evidence we have heard people say that it is happening everywhere else so why not here. So it is within that context. I know that both of your submissions have been very useful in terms of straightforward reflection but in terms of the record I would like to get something about the expertise, the interest and what kind of discussion there has been within your professional groups.

Dr Buist—I have to confess, not a lot. WHA, to be truthful, probably spends more time and effort concentrating on obstetrics and care of the newborn. I would have to say that there has not been a lot of debate about RU486 and medical abortion and abortion services in our processes. Of course RU486 has not been on the menu until very recently so that might explain why we have only come to it very lately. But to be truthful, we have not discussed it in detail, if at all, over the last few years.

Dr Foran—I should declare my interest. My background is as medical director of family planning until about two years ago. That was for six years and prior to that I was with the organisation for about 20-odd years. So it is something that has been very high on the agenda for those I have worked with quite closely for most of the last 20 years. I have written several articles on the subject, that have been published and I was certainly there during the period which Ms Tankard Reist referred to earlier around ethics committee approval, which, by the way, was for morning after pills not abortion pills. I was there recently when we were doing a trial on using very low doses of RU486 to control bleeding in women using Implanon. I saw what hoops the organisation had to jump through and the rigour with which we were investigated on a number of levels so I know that this is an important issue. It has been an issue, I think, that has been off the agenda because of the political constraints around even bringing it up. But certainly women I know ask me about it and through the internet women know about it from overseas and ask when it is going to be available in this country. Those who are committed to providing women with choice are very much aware of the fact that it is simply another choice. It is not, as Dr Buist said, different from surgical abortion; it is simply another choice and it should be regarded in that way.

Senator MOORE—I know that you will be asked specific questions about Dr Greene by someone else, Dr Foran, but you mentioned your experience with the TGA. I asked this question of various people in Melbourne on Friday: from both of your perspectives, what are your experiences with the TGA? Have you worked with them? Do you know how they operate? Both of your submissions say that you have faith in the TGA taking this particular process forward, but it might be useful if you add to the record why you would have such faith.

Dr Foran—Only one thing: I was one of the people involved in the submissions to allow Postinor-2 to be available as a pharmacy prescribed substance. I made submissions to the TGA. I was aware of the huge number of submissions they received and the fact that, in my communications with them, I felt that they acted rigorously, scientifically, they looked at the body of evidence and, despite political pressure, they made a decision which I really, truly and honestly in my heart feel is in the interests of Australian women, and that is really where I am coming from. I do have faith in them. It must be very difficult to operate as an organisation with politics whirling around you, but in that particular instance I have nothing but regard and admiration for how they operated.

Dr Buist—I have had no experience in dealing with them myself.

Senator BARNETT—Dr Buist, earlier today we heard evidence from Women's Health New South Wales regarding their submission and their admission that their submission is based in part on a pro forma submission from Reproductive Choice Australia. In the last few hours I have been able to obtain a copy of that pro forma submission, and I would like to table that submission, Chair, and distribute that to the committee members. Are you aware of that pro forma submission that has been distributed by Reproductive Choice Australia?

Dr Buist—I am not.

Senator BARNETT—I want to ask about Dr Michael Greene and the research he did on the relative risk of surgical abortion compared to chemical abortion. What is your understanding of the Greene assessment?

Dr Buist—Dr Greene wrote an editorial commenting on a paper published by other people, so the first thing is that it is not his research. He was making an editorial comment on an article that had been submitted and agreed to be published in the *New England Journal of Medicine*. As we have all read, Dr Greene did what appeared to me to essentially be some back-of-the-envelope calculations based on the relative risks of medical abortion versus surgical abortion in the United States. He came out with the figures that I have quoted and that you are well aware of. He estimated the risk of such a death occurring as less than one per 100,000 terminations, and at similar gestations he calculated that the risk of maternal death was approximately 0.1 per 100,000—that is, one in a million.

It is very difficult to be specific about that. Clearly on that basis it does appear to be the case, but there are a few points that we need to consider. The first is that, as Dr Foran suggested, there is something a little odd about this in that these cases have, by and large, been reported not only in the United States but in California, but they have not been reported in Europe. I could not find a single case reported from Europe. I accept that I was not able to find them and that there were not none at all, which in itself is something unusual. For example, if Dr Greene did his calculation based on the number of terminations occurring in the Western world, he would have come up with a figure probably similar or lower than the risk of surgical termination, but I accept the point.

I also make the point though that this is new information. This type of infection has been demonstrated in less than 10 cases prior to these publications, and they were all following childbirth essentially occurring in a woman following either normal or caesarean childbirth. This is very new. It may well be the simple administration of a cheap antibiotic pessary at the same time as giving mifepristone may well completely eliminate this risk. On the other hand, if another six to 10 cases were published in the very near future, it may well be that the evidence then swings, if you like, against RU486.

Senator BARNETT—I would like to address your submission where you refer to the impact on women in rural and regional Australia and access to appropriate medical care in those areas, because this was a key motivating factor, at least in the public arena, when this debate first started last year. In your submission you stress the need for ready access to hospital facilities and include the ability to conduct an emergency surgical evacuation of the uterus. I would like to know how close to a fully equipped hospital would a woman need to be and for how long before being able to get to such a facility after she takes mifepristone or misoprostol?

Dr Buist—I do not think I used the word 'hospital', but I accept the point. I did not specifically say 'hospital' and I am not necessarily suggesting that. Nonetheless, I am talking about within four hours or less—and perhaps even a shorter time—of being able to get to such a facility. That is why I have been very clear, hopefully, that I do not see this as a solution for a woman who is a long way from at least a district general standard facility.

Senator BARNETT—If they are a long way from a facility then you would say this is not the preferred way to go and, if they did go this way with RU486, their health is more seriously at risk than if they had a surgical abortion?

Dr Buist—I believe so. Again, I am the New Zealander in the room, so perhaps I am not so familiar with the TGA. But I would envisage—if I can describe this in my head—a woman being administered, not prescribed, RU486 in a facility that is licensed for the purpose of doing what we are talking about, her going home—or to a motel or whatever—and then the process being monitored appropriately. I do not see this drug as being given to people who are a long way from these facilities, and I am not aware of people who are espousing that.

Senator BARNETT—Dr Foran, thank you for clearing the record early about your background with Family Planning Australia. In your submission you repeatedly refer to RU486 as a therapeutic agent. What is your definition of 'therapeutic'?

Dr Foran—To me, that simply means a medication or drug.

Senator BARNETT—Our committee has had advice from a range of witnesses who have gone to dictionaries and looked at 'therapeutic' and talked about medical assistance to address an illness. Witnesses have put to our committee that they are quite annoyed about some people referring to pregnancy—and a condition like that—as an illness and that this drug is treating what some people would describe as an illness. Certainly, I do not accept that at all. Firstly, I would like to get your response to that. Secondly, what is the impact of RU486 on the foetus? We have had it put to us that the effect of it is to starve to death the actual foetus. I would like you to describe that process for us.

Dr Foran—First of all, in answer to the first question, I obviously did not have access to the dictionary, but I am now starting to wonder whether we should be changing the name of the Therapeutic Goods Administration since it actually deals with other things than illnesses. It deals with devices and contraception which, as far as I am aware, do not treat an illness either, so perhaps that should be something we should all be considering. With regard to your second point, RU486 works by making the uterus contract, so the pregnancy is expelled from the uterus. Whether we use emotive words like 'starving', I do not know, but that is how it works. I think that different people with different philosophies will have different ways of viewing this.

Senator BARNETT—We were advised on Friday and again today that the restricted goods referred to in the bill do not refer to just RU486. There is a list of eight drugs, including some fertility vaccines. Can you outline in detail to us your understanding of those drugs, the nature of those drugs and the effect of those drugs?

Dr Foran—My apologies. I cannot do that without notice. I would have needed notice of that question to do that.

Senator BARNETT—Are you aware that 'restricted goods' also refers to drugs other than RU486?

Dr Foran—Are you talking about methotrexate and misoprostol?

Senator BARNETT—They are two of the eight.

Dr Foran—The wording of the bill obviously says 'drugs that can be used as abortifacients'. There are drugs presently available on our PBS which are used as abortifacients in this country.

Senator BARNETT—My point is that the bill specifically refers to restricted goods. 'Restricted goods' are defined as the eight drugs that I have before me; it is on the public record. That is what the inquiry is about. It is not just about RU486; it also refers to vaccines. I am asking you as a professional whether you can provide advice to our committee on the full gamut of the impact of the bill.

Dr Foran—No, I am sorry. I do not think I am the right person to do that.

Senator POLLEY—As medical experts who have come before us to give expert testimony—if you are confident about basing your views on evidence from America and Europe, where it is not compulsory to report any complications or, in fact, deaths associated with RU486, and if you have full confidence in the TGA being able to make recommendations based on scientific evidence—where does the role of elected members come in ensuring that policy is adhered to and that it is set by them? Why do we need to have elected representatives if we should leave everything to the scientific world?

Dr Foran—Elected members obviously have a role in responding to the best information that they can get from those who are best able to interpret that information. That is where I see the role of my elected members.

Senator POLLEY—Would you have full confidence then in whatever evidence has been brought forward, bearing in mind that in the United States it is not compulsory to actually report any side effects or, in fact, a death from this drug or others? Would you make a recommendation on the best interest of women's health based on that?

Dr Foran—I think postmarketing surveillance is always fraught with difficulty. It is in this country as well—it is not compulsory to report serious events in this country for a whole gamut of other drugs. I think that the information and the evidence that I was basing my opinion on were, in fact, clinical trials, which have been widely performed in Europe and in other parts of the world. Certainly under those clinical trial situations the side effect profile of RU486 seems relatively safe.

Senator POLLEY—We have had evidence given today and in other submissions that an abortion is an abortion is an abortion. Do you share the view that it really then does not matter what process takes place as long as the abortion happens, so therefore there should be no consideration by elected representatives about taking a pill where it reportedly takes up to three days for the baby to die? We should not have a view on that and we should not be there to make a decision based on what is in the interests of our community?

Dr Foran—No. It is important that politicians take a philosophical viewpoint. The other important thing is that others may not share that philosophical viewpoint. I think that there are situations in surgical abortions that are not complete where in fact that may be the same case. I always find it very difficult when somebody gets me into a discussion about when life begins and how precious is it, because my understanding is that that varies enormously depending on what your philosophy is and what your life experience is. I guess my position is always that we need to respect each other's viewpoint and to realise that we each bring

something to the table which can perhaps increase human understanding overall. That is where I see it. It is really very much a question of one's own personal philosophy.

Dr Buist—All a politician, a drug regulatory body or a doctor can do when they get out of bed in the morning is do their best with the information that is available to them. As I see it, it may well be that evidence will come, possibly in the very near future, that alters the view which a drug regulator or a doctor in particular may take over RU486, for example—and there are plenty of other medications where that may be the case as well. We can only base our decision making both as individual clinicians and as regulatory bodies on the information that is available. It is hard enough making decisions about those without overdoing the what ifs. I have quoted a lot of clinical evidence with respect to this agent, and there is a lot that does not apply directly just to termination of pregnancy. It has been studied in a lot of situations. So all we can ever do is make decisions based on the information that we have available to us, and there are a lot of unknowns about not only RU486 but other things. I would also like to reinforce Dr Foran's point. One of the reasons that RU486 has been used is that an incomplete or failed abortion is more likely with a surgical operation at very early gestations than using the medication. Given we are in a situation where the intent is to end the pregnancy, I cannot see that situation as being better or worse for the foetus or the embryo than the tablet being taken.

Senator ADAMS—Thank you both for your submissions. As both your organisations have close links with New Zealand health professionals, you would be aware of the memorandum of understanding between the TGA here in Australia and Medsafe in New Zealand. Medsafe has been given the right to evaluate mifepristone and to advise the minister accordingly. Do you think that the TGA could do the same here?

Dr Foran—Yes, absolutely. It is the right body to do it.

Senator ADAMS—Dr Buist, would you outline for us how the process works with a woman going to her GP to ask to have her pregnancy terminated? I have just been back to New Zealand—I am a New Zealander and I did my midwifery training in New Zealand, so you are not the only New Zealander here. Just give the practical side of how the process works.

Dr Buist—In New Zealand the system works whereby a practitioner, not necessarily a gynaecologist—it can be a general practitioner or a doctor with other qualifications—makes an application to the Ministry of Justice, under which the Abortion Supervisory Committee functions, to be designated or accredited as a registered provider. I think the term is 'certifying consultant'. If a woman attends her GP, requesting a termination—and in most circumstances that GP will not be a certifying consultant—even if the GP opposes abortion, the GP is ethically obliged to refer that woman to an appropriate provider or service to achieve that. The woman is then seen by a certifying consultant who may not be the person who actually surgically performs the abortion in that case, but that is the person by whom the woman is assessed.

The woman's reasons for seeking a termination, her mental health and her physical issues are all assessed, and then a decision is made as to whether she can proceed to a termination of pregnancy. That decision has to be countersigned by a second certifying consultant, but the

second certifying consultant may do so on the recommendation of the first consultant; they may not actually see the patient. If the first consultant is uncertain, they may ask the second consultant to see the patient before making the decision. Then there are forms to be filled in and sent off again to the Ministry of Justice. Once that has been done, the procedure can go ahead. So, as I have indicated, in this way very good data is kept. What it really means is that termination of pregnancy in New Zealand, as I think distinct from Australia, is conducted by practitioners who have set themselves out to do it and are registered and licensed accordingly, and it occurs in facilities that are registered and licensed specifically for that purpose. The Abortion Supervisory Committee reaccredits the consultants and the facilities.

Senator NASH—I want to follow on from something Senator Barnett said about the other abortifacients in the category of the restricted goods. I come back to this because there has been some comment on it. Certainly most of the focus has been on RU486, but, given that the intent of the bill is to ask for these goods to be assessed, can you see any reason why the TGA would not be able to assess any of those abortifacients, no matter which they are in the category, other than RU486?

Dr Foran—No.

Dr Buist—I would like to make a comment about misoprostol. Misoprostol, which I think is on the senators' list, is a very complex drug as well. Unlike mifepristone, it was never developed with any intention to be used in women's health at all. It was developed as an agent for managing stomach ulcers. But because it is a prostaglandin, and prostaglandins are the agents that in general act upon the uterus to make it contract, it has been used extensively in a number of situations, particularly in mid-trimester termination of pregnancy. I would use it if we have a woman with a serious, lethal, foetal anomaly and we have gone through the relevant processes. Misoprostol is used in many places around the world—less so in Australia—for the induction of labour at full term, and there are some issues around that. I have found it to be a life-saving drug in postpartum haemorrhage, where a woman is bleeding to death following birth. That has been a therapeutic agent that has saved the woman's life because of its ability to make the uterus contract.

The manufacturer of misoprostol has been very clear—perhaps wanting to stay clear of these types of issues, hearings and public opprobrium—that it wants no part of this. That is a very difficult issue which creates its own great difficulties for clinicians and women. Indeed, I would envisage that would create a problem for the TGA, because the TGA would be in a position where the drug company is proactively supporting misoprostol being used. If anything, I suspect the drug company would say: 'No, thanks. We don't really want this.'

Senator NASH—On the flip side of that, if the TGA did not believe that any of the drugs on that list were safe, you have no reason to believe that they would not approve them?

Dr Buist—I agree.

Senator BARNETT—This is a quick follow-up to that. Why would you answer 'No' to Nash's question if you do not even know the names of the drugs on the list?

Dr Foran—I meant the two that she quoted, which is methotrexate and misoprostol.

Senator BARNETT—I thought Senator Nash asked you about the drugs that are on the restricted goods list.

Senator NASH—With respect, I was asking whether the TGA would be able to assess any abortifacient drug. Knowing the name or not, I think, is irrelevant.

Senator BARNETT—Let me ask a supplementary question. With regard to the other drugs on that list—you have referred to two of them, but there are six others of which you are not aware of the names—do you have a view as to the appropriateness of the TGA reviewing their safety and efficacy? Or do you not have a view on that?

Dr Foran—I think the TGA is the appropriate body in Australia to review any drug's appropriateness and safety profile.

Senator ADAMS—I would like to say something for the record. I stated that I am a New Zealander, but I have had to renounce my New Zealand citizenship; I am now an Australian. I think that is important.

CHAIR—Senator Nash asked about misoprostol. Let us assume that RU486 and misoprostol were approved, pursuant to a repeal of the minister's power to not admit them to Australia, but you still had a situation where the manufacturer was refusing to warrant or authorise the use of that drug in connection with an abortion. It was put to us the other day that, if the drug were used in that way and there were some sort of complication, the doctor's insurance would potentially be voided by virtue of the drug being used for a purpose other than the one that the manufacturer had warranted or authorised. Do you have a comment on whether that is possible?

Dr Buist—I am certain it is. It is a very difficult area because, particularly in obstetrics, we tend to miss out. From a drug company's point of view, having an agent licensed for use in pregnancy is very difficult and expensive. At the end of the day, with the number of women who will need whatever the agent is—and I am not talking about abortifacients or anything else; I am talking about any drugs used in pregnancy—the drug companies almost invariably do not bother pursuing that.

So we actually use medicines off-licence on a reasonably regular basis. One is nifedipine, which is an antihypertensive. We use it to prevent contractions, to stop contractions, in premature labour. We use it to treat hypertension in pregnancy, and we do it when it is not licensed for that use. And, yes, we do it with our hearts in our mouths, but it is the best thing for the woman concerned. We should and we do seek specific consent, and part of that should include a discussion with the woman to the effect that this drug is not a licensed regimen, for these reasons, but we feel that it is the most appropriate medication for her situation.

I will also make a quick comment about misoprostol, in that there are two reasons that misoprostol has become used at all. One is that the normal licensed prostaglandin regimens cost in excess of $100 a time; whereas misoprostol costs a few cents a tablet. The other thing is that misoprostol is stable at room temperature and other prostaglandins are not, so its effectiveness is not lost if it has been out of the fridge et cetera. These issues—and, not least, pressure on budgets—have led a lot of organisations to prefer to use misoprostol.

Dr Foran—Can I echo Dr Buist's comments there. Off-licence use of many drugs is not uncommon in medicine. Regulation can only go so far. One obvious example is the use of minipills in breastfeeding mothers. It is not licensed for use in breastfeeding mothers, yet it is backed up by 40 years of medical experience and peer support for that particular practice. Dr Buist is absolutely right, too, that, in situations where we know that we are using drugs off-licence, the issues around informed consent become that much more important. We hope that under such circumstances and with peer support our medical insurers will in fact support us. We have no guarantee that that will happen. But we still have to practise the best medicine we possibly can with the evidence that is available to us.

CHAIR—I assume then, if this issue is a grey area, that there is no litigation that has resolved that question in terms of, for example, a doctor suing their insurer for failure to cover them in the event of a malpractice claim. Are you aware of any litigation in Australia that has covered that issue?

Dr Buist—No, I am not. And as far as I understand the principles of litigation, medicolegal litigation—of which I sure you are aware—surrounds the Bolam principle, which is that, by and large, your actions are defensible if a reasonable body of your colleagues deem them to be so. So I think that that would be the test that would be applied under those circumstances.

Senator WEBBER—First, I would like to go back to the evidence you were giving earlier about some of the adverse incidents that have taken place in America. We have received some evidence about what has happened in America, but no-one had actually taken me through what could well be those unique circumstances, comparing them to what has happened in Europe, so I was wondering if you could expand on that.

Dr Buist—I am not sure I can answer that. I think that Senator Polley's point may well be valid—that deaths may have occurred in Europe that have not been reported. I do not know. You would almost have to assume that that is the case; otherwise, why has this happened just in California? The report that was published in the *New England Journal of Medicine*—and I am not talking about Professor Greene's commentary; I am talking about the actual report—was from the Centers for Disease Control and Prevention. It is a piece of very assiduous clinical work, in that none of the women involved who died grew the bacterium *Clostridium* in the cultures that were taken from their blood or their vaginas when they were unwell. This organism was identified at post-mortem—again, as I said, by some very assiduous work—and it could easily have been missed. So I freely accept the possibility that there is underreporting. But on that point, if I can just digress for a moment, the United Kingdom, for example, has very good ascertainment of maternal mortality and publishes its confidential inquiries into maternal mortality very carefully, and I am not aware of any cases coming through that method. But, be that as it may—

Senator BARNETT—You are not aware of any cases coming through—

Dr Buist—Due to fatal toxic shock syndrome due to *Clostridium*, no.

Senator BARNETT—Are you aware of any deaths from RU486?

Dr Buist—I am aware of the four cases that were published from California, the one case that has been reported in Canada and, as I said, there are up to 10 more deaths that were reported previously following pregnancy at term.

Senator BARNETT—You are not aware of any cases reported from the UK of deaths from RU486?

Dr Buist—No, I am not aware of any deaths from clostridial infections following the use of RU486 in the United Kingdom. They may be there; I am just not aware of them.

Senator BARNETT—Are you aware of any deaths following the use of RU486 in the UK?

Dr Buist—I cannot answer that question.

Senator BARNETT—Is that a no or a not aware?

Dr Buist—No, it is an 'I cannot answer the question'. I do not have that information in front of me.

Senator BARNETT—So that means you are not aware of any deaths.

Dr Buist—I am not aware of any, but I am equally not saying that they have not occurred.

Senator BARNETT—I am not asking that.

Senator WEBBER—Can I continue with my questioning, Senator Barnett?

Senator BARNETT—Sure. It was a follow-up question, Senator Webber.

Dr Buist—I am sorry, I digressed. Having said what I have just said, there is a paper recently published which does suggest that there are some specific actions of mifepristone that indicate that it may contribute to this type of unusual toxic shock syndrome in that its actions lead it to block not only progesterone but other steroid hormones, including cortisol. So the combination of a very rare organism being in the vagina and the use of mifepristone may well have a specific effect where the mifepristone, in addition to its effects on the uterus, has a negative effect, if you like, on the response to infections—although again I would say the solution to this may well be a very simple antibiotic that removes the organism prior to the termination.

Senator WEBBER—Would it be your expectation that if this bill were to be passed and this group of drugs were sent to the TGA for assessment then that would be the kind of issue that the TGA would examine in terms of the guidelines under which the drug should be used, if it were to be used, in Australia?

Dr Buist—I would certainly hope so.

Dr Foran—That would be my understanding. My understanding also is that that is what is happening in the States. The way that these sorts of medical issues work is that somebody will notice something, write up on it and then try and answer the questions. In an incremental fashion our knowledge increases. So it may be that, as Rob says, it is simply a question of antibiotic cover, which we tend to do routinely with surgical termination. It may be that there is something happening in America that does not happen overseas. One of the things I think about is that American women have an awful tendency to douche whenever they have a discharge or bleeding, so perhaps that may well contribute to the risk of infection occurring in that particular culture and milieu, whereas it does not happen in places like Europe. I do not know. But I think what this does is raise questions; it does not give us answers.

Senator WEBBER—If I can go back to your earlier evidence about the framework under which you would envisage a drug like RU486 being used in Australia if it were permitted, the committee has received previous evidence that describes the use of RU486 as a do-it-yourself abortion or an at-home abortion and says that women go off and have abortions willy-nilly when they have got access to medications like this. That does not quite seem to fit in with the framework that you as professionals and representatives of professional organisations would deem to take place if we get access.

Dr Foran—The concept of a do-it-yourself abortion absolutely horrifies me. I think this sort of termination requires just the same amount of counselling, support and after care as a surgical abortion. As I said at the beginning, I have never met a woman who had a frivolous abortion. I think that woman will take it with just the same approach as they do to surgical abortion. I think exactly the right way to introduce this into our country is with a degree of safeguards and care. I want to safeguard Australian women; I do not want to put them at risk.

Dr Buist—As I understand it, if a doctor is going to administer intravenous pethidine, for example, he is not going to write somebody a prescription for intravenous pethidine and let them head on down to the pharmacy, pick that up and do whatever they will with it. Notwithstanding the fact that this is a tablet, I would envisage that a similar approach would be taken to this type of agent, which is that, as the Americans say, it will only be administered by a physician or something like that. I do not know quite how one puts that into operation, but that is my view of how this agent should be used. This should not be a situation where a woman walks out with a prescription in her hand to go and get this drug. I would envisage it as being something that is administered in an appropriate facility, wherever that may be.

Senator WEBBER—But that is something that would be determined by the TGA as part of their process of determining that it is safe and the conditions under which it would be safe to use it in Australia?

Dr Foran—I think there should be protocols. Yes, absolutely.

Senator WEBBER—Thank you.

Senator MOORE—That is the standard practice of the TGA in your experience?

Dr Foran—That is my experience of them.

Senator BARNETT—Dr Buist, the word 'efficacy' is one of the responsibilities of the TGA, which include safety and quality. What is your understanding of the word? What is your definition of efficacy?

Dr Buist—The first thing is that efficacy is like quality and safety in that it is a relative term, not an absolute one—and we rarely achieve 100 per cent in any of those areas, unfortunately. Such is human endeavour. From my point of view, my definition is 'doing what it says on the tin' or doing the stated intent of whatever it is.

Senator BARNETT—That is my understanding as well: that it does what it is designed to do or what it says on the tin. So do you feel in any way that we are compromising our processes when the manufacturer of the drug, as was noted last week by Pfizer, is saying not that it is designed as an abortive agent but that it is designed as something else? How does that make you feel?

Dr Buist—I feel very uncomfortable. As I said to you before, I do not use misoprostol—which I think is what we are referring to, because Pfizer make misoprostol—except under very exceptional circumstances. In the United States, misoprostol is widely used for the induction of labour at term, which I think is a very dangerous practice from the baby's point of view. I am aware of places in Australia where it has been used for induction of labour, and I regard it as being very dangerous from that point of view. So the answer to your question is that I would only do it under very exceptional circumstances.

Senator BARNETT—I have a question on the cost. I think you talked before about the importance of counselling and the importance of the consent form. I am not sure if you referred to having a cooling off period or what have you, but there are different things. In terms of the process, you need a rigorous protocol in place. Can you describe to us the protocol that you believe is appropriate for the use of RU486, and then I would like to follow that up.

Dr Buist—Would you like me to talk about the protocol as it is different from surgical termination, or do you want me to go through the RU486 protocol? The point I am trying to make is that there is a whole process that, in my opinion at least, needs to be undertaken whether the woman is having RU486 or whether she is having a surgical termination, and there is no difference in that process. There are issues of making sure that the woman is well aware of what options she has, what the alternatives are to an abortion and what services are available to her, and that she has appropriate counselling that involves assessing her situation. For example, in our hospital—and, as I understand, under New South Wales policy—we cannot do a termination of pregnancy unless the patient has seen a social worker, for example. That is the kind of general issue.

Then we get to the issue of surgical termination: surgical abortion, as we have discussed, has its own particular risks and, while the risks of fatality may differ for surgical or medical abortion, there are risks that may have implications for the woman's health that we need to go through. I would do the same with RU486, which is to discuss what the issue are. There is up to a 10 per cent chance that an operation will be required.

Senator BARNETT—That is surgical follow-up?

Dr Buist—Yes.

Senator BARNETT—Surgical abortion as a follow-up?

Dr Buist—Yes.

Senator BARNETT—I specifically wanted to know your views on RU486 and the protocols that should apply. Do you know those off the top of your head or would you need to do some research on exactly what protocols should be put in place?

Dr Buist—The protocols with respect to the administration of RU486 involve giving the RU486 and then, after a variable time period—and there are a lot of different protocols out there—a follow-up prostaglandin agent such as misoprostol is given. For example, the Royal College of Obstetricians and Gynaecologists—I am happy to leave this with you—has a very clear protocol from that point of view.

Senator MOORE—Is that the New Zealand college?

Dr Buist—No, the British college. In this, like anything, the issue really is information—making sure that the woman is well-informed about the process that she is going to go through, the adverse symptoms that may occur and the risks that are important to her.

Senator BARNETT—We have eight drugs on the restricted goods list. Earlier you referred to mifepristone and misoprostol as two of those eight. I assume you would agree that different protocols would apply to each of those eight drugs.

Dr Buist—Absolutely.

Senator BARNETT—So hypothetically, if the bill passed, we would be passing over entirely—in terms of our accountability and responsibility to the public—to the TGA responsibility for preparing and writing the protocols. We have to say today, if that passes, that we have entire confidence that they will do that as appropriate and as comprehensively as possible. Do you have some question marks or concerns about their ability to do it in the appropriate manner?

Dr Buist—We have been asked this a couple of times, and I have been very uncomfortable being asked by politicians what politicians should do. But I have been asked a couple of times about what the division of responsibilities are and, again, I am only working in New South Wales. New South Wales, for example, has legislation about termination. The New South Wales Department of Health has a very thorough framework for the provision of termination. For example, I do not necessarily expect the TGA to make decisions about counselling. They will certainly publish material on the adverse effects of any agent, but I would not expect them to enforce decisions about counselling prior to termination. That is your job, if you like, and I think that is the framework under which terminations occur. There is a legislative and regulatory body that sits above the TGA.

Senator BARNETT—Just to expand on that, what do you say we should be doing? Should we be fleshing out exactly how it should work?

Dr Buist—What I am trying to say is that in my mind—and maybe I am being naive—there are two entirely separate issues here. One is the framework under which termination of pregnancy occurs: the organisation of services; access to services; what we deem to be the appropriate processes a woman should go through prior to, during and after a termination; who should be doing it; where it should occur and all that sort of stuff. Those general issues—although they are very specific—are I believe the matters for the politicians, the state departments of health—for example—and the legislators. The issue of the methods to perform those terminations is separate. When a drug is put forward to the TGA I think the TGA has a responsibility to assess it.

Senator BARNETT—So in terms of our role and our responsibility—picking up on your point—should we for example attach to the funding, whether it be through Medicare or whatever, requirements and conditions for counselling, consent and 48 hours notice or whatever you deem to be appropriate? Should there be some conditions attached to the funding?

Dr Buist—I think we need to ask Dr Foran's view on it, but my view would be that those sound like very sensible suggestions. For example, if you are creating a Medicare item

number for this there is an expectation that that will occur. So from my perspective I would be 100 per cent supportive of that.

Senator BARNETT—Should we have a Medicare item number for it?

Dr Buist—Did I say that?

Senator BARNETT—Do you have a view on it?

Dr Buist—I have only worked in Australia for a couple of years, and I guess I have struggled with Medicare item numbers under the best of circumstances. So I am not sure I am willing to answer that. Although, as I think about it, that would be a start in terms of accurately collecting data.

Senator BARNETT—Doctor Foran, do you want to comment on that question?

Dr Foran—I do not know that I can improve on what I have said. I think that we understand that the issues around abortion legislation are very complex. It is difficult even for doctors, because the legislation varies from state to state and the rules vary from state to state. In South Australia it is only performed in hospitals. In New South Wales it is almost invariably performed in freestanding clinics. It is incredibly difficult, I think, to make wide-sweeping judgments. I go back to the beginning: I perhaps naively believe that the purpose of politicians is to reflect the mood of their electorate and to represent the mood of those people. One would hope that that is their primary reason for being there.

Senator BARNETT—Should we attach conditions to federal funding?

Dr Foran—I am not sure. I would very much like to have a look at those conditions before I actually answer that question.

CHAIR—I think we have run out of time, so I thank both Dr Foran and Dr Buist for their time this afternoon. It has been a very helpful session.

[2.32 pm]

GROCOTT, Dr Dianne Julie, Private capacity

JAMES, Dr John Edward, Private capacity

LENNON, Dr Catherine, Medical Spokesperson, Australians Against RU486

WILKS, Mr John Francis, Private capacity

CHAIR—Welcome to all four of you. Thank you very much for your appearance here today. Do you have any comments to make on the capacity in which you appear?

Mr Wilks—I am a community pharmacist and a registered consultant pharmacist.

Dr James—I am a family physician practising in the north-west of Sydney.

Dr Grocott—I am a psychiatrist. I am not representing any organisation.

Dr Lennon—I am a GP in Sydney who specialises in women's health and fertility problems.

CHAIR—I think you have been provided with information on parliamentary privilege and the protection of witnesses and evidence for your understanding today of the proceedings. We have your submissions before us. Thank you very much for the effort involved in producing those. What we will do now is invite you to make any short opening statement you would like to make, and then we will proceed to ask you questions.

Mr Wilks—I have been involved in literature research in the area of reproductive and sexual health for approximately 15 years. This research culminated in the publishing of my text *A Consumer's Guide to the Pill and Other Drugs*, now in its third edition. I have authored continuing education modules on the birth control pill for the Pharmaceutical Society and on the morning-after pill for the Australian Association of Consultant Pharmacy. As well, I have had articles published in international medical journals.

I commence my comments by notifying the committee of two typographical errors in my submission on page nine. I have a copy here of the minor correction which I will submit to you. The first important point I wish to make to the committee is this: the maternal death rate from a chemical abortion using RU486 is approximately 10 times greater than that seen from a surgical abortion when comparisons are made at the same point in the pregnancy. Put another way, women who undergo the RU486 abortion process are exposed to approximately a tenfold greater incidence of death than women who have had a surgical abortion. This evidence was uncovered by Dr Michael Greene and published in the *New England Journal of Medicine* on 1 December 2005. In preparing for today, I have read many of the key submissions from supporters seeking change to the regulations under consideration, including submissions from RANZCOG, the AMA, various family planning associations, and individual submissions. None of these submissions have acknowledged the findings of the Greene study.

Secondly, I wish to alert this committee to a matter rarely mentioned in the context of the safety of RU486. I refer to its capacity to interact with a broad array of prescription and non-prescription medications. Among this list are commonly prescribed antibiotics, calcium channel blockers used for cardiovascular disorders, lipid lowering drugs, prescription-only

antifungal agents, non-prescription over-the-counter pain medication, prescription-only pain medication, St John's wort—an over-the-counter herbal supplement—commonly used sleeping tablets, medications for migraine, as well as some HIV antiviral drugs. In my clinical experience as a consultant pharmacist performing home medication reviews, it is clear that patients frequently fail to inform their doctor of the full array of medications they are taking, particularly but not exclusively if it is a non-prescription item.

In view of these serious medical concerns, I come to my next point which relates to the apparent incapacity of the TGA to exercise authority over a drug once approval has been given. At the time of the Vioxx recall in October 2004, the then head of the TGA Dr McEwen said that his office 'is currently powerless to review a drug once it has been given marketing approval.' My own experiences with material I have supplied to the TGA support the view that it does not appear competent to act in the best health interests of Australians. Once approval is given for a drug, the authority of the TGA appears in practice to diminish. I am concerned that if full approval rights for RU486 are given to the TGA there will be no going back. We know now that this drug is many more times fatal than we thought six months ago. What happens if this danger proves in the future to be even greater and the TGA has already given its approval? Hence I think it is imprudent to act in a manner that would shift control over such a medically and socially divisive drug away from the minister and the Australian parliament.

Finally, a brief word about misoprostol, the second drug used in the RU486 abortion process. This drug is supplied by Pfizer and they have been reported in the media saying that they do not endorse nor will warrant its use in the RU486 process. Because there is a lack of safety data regarding misoprostol in chemical abortions, any use would constitute what is called off-licence use. Pfizer do not endorse off-licence use. Hence, in the event of pharmaceutical adverse drug reaction with misoprostol, a doctor would not be able to call on approved data as a defence in a law suit. The doctor and his or her insurance company would find themselves in a most precarious legal position.

CHAIR—Dr James, do you wish to make a statement?

Dr James—Yes, thank you. I would like to thank the Community Affairs Committee for this opportunity to present some further information for further consideration. I am speaking as a family physician with 25 years experience as a doctor. I am a fellow of the Royal Australian College of General Practitioners with postgraduate qualifications in paediatrics and obstetrics with some rural experience, including working in relatively remote Aboriginal communities. Currently I am conducting a busy family medical practice in the north-west of Sydney which is sometimes referred to affectionately—or maybe not so affectionately—as 'nappy valley' because of the large number of young families that are moving into the area. I have a large paediatric and obstetric component to my practice.

I think it is important, to begin with, to put abortion in its context. As a procedure abortion has no therapeutic value. Obviously, we are talking about a drug like no other when we are talking about mifepristone, which is specifically intended to kill and which measures its success in terms of the mortality it induces. Probably higher than 98 per cent of the terminations that are done across the Commonwealth, and certainly in New South Wales, are done on the premise that the pregnancy constitutes a threat to the psychological wellbeing of

the mother, and everyone involved in this debate knows that that is a charade. All the available evidence suggests that, when genuine maternal mental illness exists, abortion may exacerbate that illness.

We have heard reference to the recent prospective study in New Zealand which looked at a cohort of young women over several years and concluded that, in women undergoing abortion, there was a significant rise in post-traumatic stress and depression. The abortion industry—and it is an industry; we are talking about big money and big profits—dismissed this latest research, as it had ignored the growing body of evidence about the adverse outcomes for the use of mifepristone.

As far as I can see, not one submission from the proponents of this drug has addressed the issues raised by the recent reports, to which John Wilks has referred, in the *New England Journal of Medicine*. Abortion, therefore, is not a therapeutic procedure, as I said; it is done for social reasons and it has widespread social consequences, but it has medical consequences also for individuals and communities. Why, after all, have the Prime Minister and the Leader of the Opposition granted the parliament a conscience vote if it is not in recognition that we are dealing here with issues and concerns that even political parties have not really formulated firm policies about? Mifepristone is a drug which has enormous social and medical consequences. I do not believe that the TGA is capable of dealing with that. John has already referred to a quote where Dr McEwen said that his office was powerless to review a drug once it has been given market approval. He was obviously referring to a different drug, but that is relevant.

Regarding the adverse events that have been reported in North America, a paper published in the *Annals of Pharmacotherapy* in February this year by two obstetricians makes for very sobering reading. Two female obstetricians report that a total of 607 adverse events were filed with the FDA between September 2000 and September 2004. Remember that physicians in North America are not obliged to report adverse outcomes. The FDA itself estimates that the reports it receives probably constitute between one and 10 per cent of the actual adverse events that are occurring. As I said, it makes for sobering reading: 66 cases of infection and septic shock, of which 46 were life threatening, two were in girls between the ages of 13 and 17 and five were fatal. Remember that the American and French clinical trials excluded women under 18 years of age, but the abortion industry has no such compunction. These are young woman who are still developing and growing and are obviously under hormonal influences.

As John has said and as Professor Greene makes reference to in his paper, we see 10 times the deaths in abortions carried out medically in women under eight weeks gestation compared with surgical terminations. Of course, from a physician's point of view, what emerges is that recognition of this sepsis is very difficult because the organism involved is unusual and the normal clinical signs of sepsis are difficult to recognise. It goes on: 237 adverse events of life-threatening and severe haemorrhage, with one Swiss teenager dying, 68 transfusions required and 42 life threatening haemorrhages. Nineteen of those patients required three units of packed red blood cells or more, which gives you some idea of how much blood loss we are talking about. Eight per cent of these women bled for more than 30 days.

The FDA's protocol required doctors to supervise the patients over a 14-day period, with administration of the drug mifepristone on day 1, administration of prostaglandin on day 3 and follow-up on day 14. In terms of surgical procedures, there were 235 emergency surgical procedures, with 17 emergency laparotomies, mainly for ruptured ectopics. Two of the deaths that were recorded were on the operating table. Ninety-three per cent of those surgical procedures were emergency D and Cs to arrest haemorrhage.

The abortion industry often makes light of the fact that with Viagra there have been some deaths, but with Viagra it goes without saying that we are talking about a group of patients with significant comorbidities. These are fit, healthy young women—teenage women often. There were 17 cases, as I mentioned, of ectopics. Sentinel events—in other words, events of which there was at least one record—included a heart attack in a 21-year-old girl, abnormal ECGs, exacerbation of inflammatory bowel disease, pancreatitis—which the members of the Labor Party could identify with, as their former leader had it. With regard to the teratogenicity of the drug: there was a 23 per cent incidence of malformations. The abortion industry has been advertising that they can use this drug up to day 63 of the pregnancy. There are clearly numerous adverse psychological effects as well.

There are other concerns that I particularly want to mention. Dr Haikerwal, the President of the AMA, said in his submission late last year—it is recorded in *Hansard*—that mifepristone should be used if it was the most appropriate and safest option. We would contend that there is never such a situation. The only controlled study—and really these need to be done—in which there has been a comparison between abortions done medically and abortions done surgically was published in the journal called *Contraception* in 1999. There was a failure of what is called the primary procedure in the medical terminations of around 18 per cent, and significant numbers of those patients went on to require surgical intervention, as compared with a failure rate of the primary procedure in surgical abortions of around four to five per cent.

There are issues about cost. I happened to hear Dr Buist being asked about a Medicare item. I just wonder how the cost of these drugs is going to be borne. Is it going to be borne by the community and placed on the PBS? I would contend that any money spent would be better directed towards proper counselling support for women and their babies.

Last but not least there is the question about medical supervision. Three visits to the doctor is what the FDA protocol requires. I mentioned the fact that many women—a significant number—continue to bleed beyond day 14. In remote communities, and even in built-up metropolitan areas like the one in which I live, getting patients to attend for three visits can be very difficult. The Health Insurance Commission had an item number at one stage under which family doctors who were managing chronic illnesses like asthma could claim if they were able to get their asthma sufferers to attend for three visits. Most of that money went unused because family doctors could not get their patients to come back for the third visit.

One of my patients remarked to me a couple of weeks ago: 'Who'd be foolish enough to have their abortion at home?' All I can say, ladies and gentlemen, is: let's not be foolish enough to unleash this drug on the Australian community and future generations of Australians. Thanks very much.

Dr Lennon—RU486 has serious medical and ethical problems and I believe the TGA is not designed to deal adequately with these serious problems. RU486, as you have heard, has a death rate for women 10 times that of surgical abortion up to seven weeks, according to the *New England Journal of Medicine* in December, and a number of other publications. For every death there have been many more near misses from septic shock, severe haemorrhage and ruptured ectopic pregnancy. There is also a high risk of foetal malformation, of at least 23 per cent, in continuing pregnancies.

It is thought that RU486 impairs the body's natural resistance to infection, making it more susceptible to the rapid onset of septic shock. The evidence for this is in Professor Ralph Miech's journal article of September 2005 in the *Annals of Pharmacotherapy*. In discussing the cases of four women using RU486 who died from clostridial sepsis, Professor Michael Greene, an obstetrician from the Harvard School of Medicine, told the ABC *Health Report* on 5 December 2005 that all the women were young and healthy and all presented without fever. Professor Greene has previously described how the course of clostridial infection was:

> ... a terrifyingly rapid course. Some of these women were literally dead within 12 to 14 hours presenting to the local emergency room.

Clostridial infection causing deaths in women using RU486 is very different from infections after miscarriage or surgical portions. There have been no reported cases in Australia of women with clostridial sepsis following surgical abortions or miscarriages.

I had an international teleconference with Professor Miech recently and, having scoured the literature, there have been no international reports that we can find of clostridial sepsis following surgical abortions or miscarriage. In his testimony to the Senate, the Federal President of the AMA, Dr Mukesh Haikerwal, stated that RU486 should be made available where it has been medically ascertained that this is the safest and most appropriate option. But I would argue that, on the basis of the tenfold increase in mortality, it could not be said that RU486 is the safest and most appropriate option for pregnancy termination. The fact is that clostridial infections are extremely rapid and do not respond to antibiotics. Despite manufacturer Danco issuing warnings to doctors to suspect this type of infection in RU486 users, Australian doctors will find it almost impossible to adequately detect and treat this deadly infection and prevent deaths. The women with clostridial infection had bleeding, vomiting and abdominal pain, all symptoms common in users of RU486.

The FDA estimates in their system of voluntary reporting that only one to 10 per cent of actual cases are reported. In Australia, similarly, there is a voluntary system of reporting adverse drug reactions but there are problems with the TGA's ability to properly monitor drug safety once it is approved. I refer the committee to the Australian National Audit Office report of January 2005. That report mentioned problems, including that the TGA should improve the low level of reporting of adverse reactions to drugs in Australia. This ANAO audit was conducted following the Pan Pharmaceuticals crisis. Bureaucrats in the TGA are not accountable to the Australian people. RU486 is a pill designed to kill, unlike any medication that is currently approved by the TGA. Although the TGA may suggest guidelines or protocols, it does not have an effective system to enforce these for most medications. An example of that was the approval of Postinor over the counter. The TGA issued guidelines suggesting that all women should receive proper counselling in a confidential place. In

practice, it simply does not happen in busy pharmacies. The TGA may approve certain drugs for use and assess safety initially, based on studies provided by the drug companies, but many of these drugs are being used off label for other purposes and the TGA has not prevented this from occurring. Given the cultural and social impact of RU486 through the widening availability of abortion and its attendant medical risks, I believe that the approval of RU486 must remain a function of the Australian parliament.

Dr Grocott—My colleagues have already focused on the inability of the TGA to adequately monitor a drug such as RU486, so I will skip most of my statement and go on to the psychological long-term consequences. As a psychiatrist, I frequently deal with issues which are painful for people, and it may be that people in the audience find some of these issues difficult. For that I apologise, but I think they need to be spoken. Firstly, RU486 is a unique drug, because its aim is to take life; it is not therapeutic in pregnant women. There are no psychiatric indications of abortion. Some time ago the *Medical Journal of Australia* had an article that showed about 97 per cent of Australian abortions were done for socioeconomic reasons in healthy mothers with healthy babies who were conceived by consenting adults. There are no long-term studies showing the psychological benefit of abortion. There is a large body of literature showing the long-term adverse psychological effects, and you have heard about some of those this morning from previous speakers.

I want to speak briefly to the issue of post-traumatic stress disorder, because that is perhaps the easiest one to understand. But let me mention that unresolved bereavement is often found because of the taboo over feeling bereaved when one has chosen to have an abortion. Women and men mention guilt, grief and anxiety. Other problems include an increased suicide rate; increased depression; increased alcohol and drug use; eating disorders; sleep disorders; parenting difficulties, including child abuse and overprotectiveness, which have been found in different studies; and relationship breakdown—I think about 75 per cent of relationships are not intact five years after an abortion. Many women mention an anniversary reaction, and the concept of an atonement child is also well known to people in the post-abortion counselling areas.

Often psychological problems are delayed, and we do know the risk factors include previous psychiatric history—it has certainly been found that women who have psychiatric disabilities often get worse following an abortion. There are more likely to be some post-abortion psychological problems among women who have had children or women who are ambivalent about their decision or where there has been some coercion, an adverse experience during the abortion or physical consequences of abortion. This is an area that is very difficult to research, but the House of Lords in England had an inquiry—I think they published in 1994—and they found a 10 per cent incidence of negative psychological problems, and a large number of other women had wanted to have counselling and it was not given to them.

Often women do not disclose. Even when you ask them they do not tell you. I frequently ask, 'How many pregnancies have you had?' And ladies say to me, 'I've got three children.' I say: 'Great. How many pregnancies have you had?' And they go, 'Well, I had a termination some time ago,' and often they have not talked about that. They certainly have not explored the issues surrounding that. The other problem of doing research into this area is the nature of the woundedness and pain that some women feel. In order to protect themselves they deny or

suppress the issues and particularly deny their feelings. It can tend to be triggered by issues, and usually when there is a debate on abortion women will find that they are more hurt by this. Even with an article on the news, people often become irritable or turn the television off and cannot deal with the issues.

Let me go through the mental gymnastics that are required for a lady to have an abortion. For a start, if it were me I would get pregnant. After I find a positive pregnancy test, I would first work out when the expected date of delivery is. That is the baby's birthday. But if I do not think I can cope with the fact of having a baby—usually because I would not have enough support or financial support—and I seek help at an abortion clinic, the subtle pressure would be to pretend that this baby is not a baby. Usually, in order to get rid of the problem you have to say it is not a baby, so we have to go for the language of the foetus, embryo, the product of conception and things like that. After the abortion there is usually a sense of relief, but most studies, even by researchers who have a pro-abortion bias, tend to find that negative consequences increase over time.

What happens is the lady can for a while keep up the facade of, 'I had an abortion, it was nothing, and now I am getting on with my life.' Often that works for a number of years, and there are a lot of people who are able to maintain that. There are people who say, 'It was wonderful; it was great that I had an abortion.' But eventually the jack comes out of the box for a lot of people and the lady starts to consider herself as the mother of a dead child. That birthday comes around every year; the birthday is there even though the baby has gone; that day is the baby's birthday for the rest of the mother's life. So the crisis may be over, but motherhood is forever.

Like other unresolved traumatic incidents—and there are lots of studies on post-traumatic stress disorder—what usually happens is that content linked to the trauma may start to intrude via thoughts or feelings or dreams or even hallucinations. People talk about the baby calling them in the middle of the night, and they get up and find no baby. There is a sense of trying to put it down and pretend it did not happen. There is treatment available, although it is often not given because we do not recognise very well.

Often, if I say to a patient, 'I think you have a post-abortion issue,' because she has given me enough evidence—I do not necessarily say, 'Let's go looking for it,' but if it comes up I say, 'How are you feeling about that?'—they do not want to talk about it, and that is when they need to go in there and deal with some of the pain. In a very gentle way, the aim is to help give the lady a safe place where she can start talking about issues, start to face the truth and stop the lies. It is necessary to revisit the incident. People used to think that that was retraumatising the patient, but we have since found out that they are quite often traumatising themselves anyway and it is a relief when they can talk to somebody about how they are feeling.

The feelings are usually quite complicated. There is sadness, hope, guilt, anger and relief, and often women are not expecting this. I mentioned a number of web sites in my written submission. One of them is afterabortion.com, which is a pro-abortion web site for women who are having post-abortion grief. They basically say that they do not talk about religious or political issues but are there to support women who have had an abortion and who are suffering. They explain how best to help people with that. Basically, you have to say hello to

the baby before you can grieve and say goodbye. As a therapist, I need to deal with a lot of the other comorbid illnesses which usually come along—depression, alcohol abuse and things like that. I have seen men with post-abortion syndrome, and grandmothers with post-abortion syndrome.

There is also evidence in the literature that abortion providers also develop post-abortion syndrome, and there is a web site cited in my written submission which mentions that. There is a sense of avoiding the real issue, avoiding feelings, avoiding that it is a baby. Trying to cope and protect oneself is basically a normal thing that people do. I would contend that Australian society shows some aspects of post-abortion syndrome in that we do not deal with it in an open and normal manner. We pretend it is not a baby. The issue is very polarised, with one side trying to force the other side to take on their point of view. I would like to suggest that we need to look at society as well.

Just as an aside on the whole issue of chemical abortion, I certainly agree with the previous speakers, who said that it would be more traumatic, particularly for men. Often men send their ladies off to the clinic and feel better about it and do not think about it until maybe some years later when suddenly they think: 'Oh, my baby would be two years old. What have I done?' But it is different if a man is at home and he watches the foetus being delivered. A foetus looks like a little person—women do not necessarily just see 'a product of conception' and it is not just a little clot. When the baby is five weeks old, it is the size of the mother's little fingernail; at six weeks, it is the size of the mother's thumbnail; at seven weeks, it is two fingers in width; at eight weeks, it is four fingers in width; and at nine weeks, it is up to about nine centimetres, which is roughly about three to four fingers in width. If the mother is nine weeks pregnant and delivers the foetus and the people at home have a look, they are going to see something that is very hard to put away and pretend was not there. I certainly contend that chemical abortion would be far more traumatising to everybody involved.

In terms of our society, we need to look at how we can deal with this issue and find a safe place where we can do our own grief work as a society. In Germany after the Holocaust there were different things that were done for the whole society to try and get over what had happened there. In South Africa after apartheid there was the truth commission, where people could talk about what had happened without it being a polarised issue. In Poland after the fall of Communism there was that great long protest where they walked past Communist headquarters shouting out, 'We forgive you!' In Australia, we have tried to deal with the issue of what has been called the stolen generation in different ways to try and come to terms with what has happened to all of us.

We need to stop the lies and avoidance and face the truth that everybody is involved: the people who have had abortions; those who have not supported the women so that they could keep their children; the abortionists, who have certainly made a lot of money; the AMA, who has either done abortions or referred people for abortions; and the people who have done nothing. We have all driven past an abortion clinic. If you do not know where the abortion clinics are, you can look up the Yellow Pages and see the big ads in there. I asked myself when the last time was that I had been to an abortion clinic and said, 'Next time I get a teenage girl who is in a desperate situation and thinks she will be chucked out of home

because she has got pregnant, I will take her home and help her reunite with her parents so that they can support her.' We do not do that; we turn a blind eye.

As Australians we have benefited from the fact that there is a lost generation of kids. Where there might have been four kids in the family, there might be three, and those three kids have had a better house, holidays and education. A lot of us have blood on our hands because we have benefited from this. I think we need to say hello to the lost generation and to do some grieving both personally and collectively as a society for—I do not know the numbers—the half a million or more Australians who have been sacrificed so that we could have a better life. I certainly appreciate that we have had a better life because of it. There have been a lot of good things that have happened for women.

Groups of people on both sides of the so-called abortion wars have women's interests at heart. I realise that, but I would call for a 12-month moratorium on RU486 so that we can stop the blaming, the fighting and the condemning and we can say, 'We are all trying to help women.' At this stage, there has been lip-service: 'Oh, we ought to fix things.' The International Planned Parenthood Federation and the AMA have actually said, 'Yes, we should work together.' But I have not seen a blueprint from the leaders of our country saying, 'Let's have bipartisan support and a roadmap to help women who find themselves pregnant.' I would be very happy to do that. I would be happy to be involved.

Dr Caroline de Costa says that she has read 200 articles on RU486. I could show her almost 200 articles on post-abortion syndrome. I would be happy to go with her and Senator Allison to North Queensland and meet those ladies whom she would like to give a chemical abortion to and I would like to say to them: 'Congratulations, you're pregnant; you're a mum. Let's throw a party and let's ask you how the Australian community can support you to nurture our children.'

CHAIR—I thank all of you for your comments today. We will now proceed to ask questions. I invite Senator Moore to ask a question.

Senator MOORE—It is my area, too, Dr Grocott. I have been to North Queensland regularly, but we do not throw parties on those bases. I have two questions. One is for all of you. I would like to find out what experience you have had with the TGA. I ask this question each day to groups of people who are giving evidence. I am just trying to find out the views of the pharmacy, the family practitioner, the psychiatrist and your view, Dr Lennon, on your interaction and experience with the TGA and on your knowledge of what they do.

Mr Wilks—I can speak directly to that point. In mid to late 1998, I sent a 52-referenced submission to the TGA. My concern was that there was a clear and substantial gulf between the amount of information that was included in the package inserts for the birth control pill and also hormone replacement therapy.

Senator MOORE—Back in 1998?

Mr Wilks—Yes. There was a clear gulf between what was in the package insert, informing women about the risks, versus what was known in the medical literature in terms of research. I waited four or five months and then sent a supplementary letter inquiring as to what had happened. Another couple of months after that I received—to use the expression—a 'Dear John' letter and never heard another thing. Basically, it was: 'We'll pass your material over to

the relevant department.' I have a copy of the letter that I can give to you. The relevant department never contacted me. That was early 1999 and I have never heard any more from them.

My other experience with the TGA was when submissions were called for regarding the descheduling of the morning after pill from prescription only to over the counter and the moving of ibuprofen from a pharmacy product to a supermarket product. In my submission I put in a specific example of a woman who had come in to buy ibuprofen from the pharmacy. In questioning the purchaser, it actually turned out that she was buying it on behalf of her elderly mother who had seen an advertisement for ibuprofen on the television and had thought, 'This medication will help with my pain.' In further questioning it turned out that the elderly mother was taking warfarin. We know that there is a clear contraindication for warfarin users taking ibuprofen. I put this fact in my submission to the TGA and again heard nothing about it and, as we all know, ibuprofen went into supermarkets. That is my personal experience with the TGA.

Senator MOORE—You have not been involved with any kind of consultancy with them or anything?

Mr Wilks—Not at a bureaucratic level, no.

Dr James—My direct dealings with the TGA relate to concerns about another drug that was released—Postinor, the morning after pill. In my correspondence with the TGA were my concerns that this would be made available over the counter and whether pharmacists were going to provide proper counselling. I found the response very inadequate. My local member said: 'My hands are tied; what can I do? These people have made the decision—that's it.' It really brought home to me the frustrations of trying to deal with a bureaucratic body that really does not answer directly to the community.

Senator MOORE—And you said you went to your local member as well?

Dr James—Yes, I raised these concerns with my local member.

Senator MOORE—And their response?

Dr James—Just that the TGA had made its decisions and there was little that they or the government could really do. Indirectly I guess my concerns with the TGA were in looking with some dismay at the controversies that have surrounded some of the things that have been approved and subsequently withdrawn. There were controversies about hormone replacement therapy, controversies about the anti-inflammatories. Certainly I have done no consulting work for them.

Dr Grocott—My most recent understanding of how they work was from the witnesses who you have heard. I think the head of the TGA mentioned that safety, efficacy and quality is what they oversee, not ethics. As a medical practitioner, I am well aware that, with adverse reporting, there is a green card. It is entirely up to the doctor whether they feel like filling it in. There is no feedback from the TGA. The TGA does not at any stage contact any doctors to say: 'We are concerned about this drug. We are doing a study. Can you let us know?' The times that I have filled something in and sent it off to the TGA, the people have been very nice but it is a one-way street. I am also aware of off-label prescribing. One of the problems is

that, in order to make a bureaucratic decision about which patients are allowed to have a medication, you have to have a diagnosis. Most diagnostic boxes are based on research criteria, and a large number of our patients in the real world do not fit the box. So if a patient has one foot in this box and one foot in the box which would get them the drug which we know is better for them, and if we can ethically stand up in court a say, 'Yes, this patient would fit the vague criteria of that particular box,' it is common practice amongst my colleagues to prescribe that for the patient. I think that is what we have to do, because the boxes do not fit the patients. Certainly off-label prescribing is not uncommon. But there is no way of tracing that. The TGA do not phone me up and say, 'Prove to me that this patient for whom you have got an authority script actually has X, Y and Z,' because there are so many different boxes and vague things. So it is a difficult thing, and you have to leave it to medical judgment. But I do not think the TGA would be adequate to deal with this particular substance.

Dr Lennon—I certainly did put in a submission to the National Drugs and Poisons Schedule Committee with my concern about Postinor-2 being available over the counter. As an experienced GP in women's health, and having done a lot of counselling, it concerned me that the guidelines produced by the TGA were simply guidelines. There was no way of enforcing them. We have seen from feedback from the media that women are not getting counselling. In fact, men can go to a chemist and get Postinor-2. We have seen girls as young as 12 getting access to it and women can go as many times as they like and get access to Postinor-2, which contains the equivalent amount of chemicals as 50 tablets of Microlut—because the compound, levonorgestrel, is the same—which is a huge amount of hormones for young women to be taking quite often. So I was very concerned.

It was also in the medical media, in *Australian Doctor* particularly, in 2004. There was a general concern among doctors, because the 18 members of the National Drugs and Poisons Schedule Committee who allowed Postinor-2 over the counter, and a few other medications mentioned, were mainly bureaucrats. At that time there were no clinicians. When I checked the website in November 2004 I noticed that the 18 committee members seemed to be nearly the identical committee, with the exception of two—one of whom is the new principal medical adviser, Dr Rowan Hammet, so there is a clinician. When you think about how they vote—the vast majority are bureaucrats, and I was concerned that my submission, which contained a lot of medical material, may not have been interpreted correctly because of the lack of representation of clinicians on the committee.

I was also concerned that the National Drugs and Poisons Schedule Committee, which was at the time dealing with Postinor-2, ignored the vast majority of submissions. They wrote back to me and said that most of the submissions were opposed to Postinor-2 going over the counter. Ultimately they have the power and are not accountable. They are not elected and it is not a transparent process. I have had very poor feedback from them about adverse drug reactions generally in terms of communication with GPs, particularly on Vioxx.

Senator MOORE—So in terms of your own interaction, Dr Lennon and Dr James, you were in communication with the TGA over Postinor a couple of years ago?

Dr Lennon—That is correct.

Senator MOORE—But apart from that, not?

Dr Lennon—They are supposed to inform us of adverse drug reactions. As a GP, I am not satisfied that that mechanism is as efficient as it could be.

Senator MOORE—I will get advice, Dr Lennon, but I think the committee you are referring to was appointed by the health minister. I think the people in the specialist poisons group are appointed by the health minister, but the point about having clinicians is well taken. In the process we have before us we have been given very strong evidence as to why you are opposed to this bill. I am interested in your evidence Dr James and Dr Lennon. You have given evidence about why you are concerned about the medical abortion process, the particular drugs for which are the consideration of this committee. I am interested in your experience in surgical abortion. Do either of you refer your clients for surgical abortion?

Dr James—No.

Dr Lennon—I have been involved for the last 10 years in counselling, both on the 24-hour counselling line and in my practice. As you may be aware, for patients to access abortion services a referral is not necessary. I do not promote surgical abortion. I do my very best to provide information about a range of options and information about abortion and its side effects, both psychological and physical. But most importantly I give confidential and supportive counselling to the woman to help her work through some of the issues. Time is very important for that woman to work through some of the issues. I am concerned that, with RU486, the time period can be so brief from the time of the diagnosis of pregnancy until she has been given the abortion pill. It is a rapid process. Because it seems so quick and essentially very private and she does not have to tell anybody except the doctor, that can end up increasing the number of abortions. There is also a risk factor for post abortion grief syndrome when a woman is very rushed.

Senator MOORE—The other question I have been asking medical practitioners who have come before the committee is: are you aware of anything in the current system that would force you to refer a patient to take up an abortion option? In particular, is there anything currently before us that would actually force you to diagnose an RU486 process for anyone coming to you?

Dr James—Are there any circumstances that would compel me as a doctor to recommend—

Senator MOORE—Circumstances that would compel you as a doctor to recommend RU486, should it become legal. This is on the premise that it becomes legal.

Dr James—I am not aware of any circumstances that would compel me to do so.

Dr Lennon—There is a related dilemma, and I spoke to my medical defence provider on this. In the case where a woman has had an RU486 abortion pill or the two medications, there are eight per cent who continue the pregnancy. I assume I will be involved in caring for those women if it is approved. In that situation, the medical insurer did suggest that it is likely that there would be pressure for doctors to make a referral or arrange for a surgical abortion in that case. It is theoretical at the moment but I can say, as a doctor, having seen women change their minds from initially being upset about a pregnancy to a few weeks later being happy to

be pregnant and determined to keep that baby, that some women who have taken RU486 overseas change their minds: they do want to continue their pregnancy. That puts the woman in a terrible dilemma of either being pressured into a surgical abortion or continuing a pregnancy with a very high risk of birth defects.

Senator MOORE—That would be the linkage. We have had considerable discussion and evidence about the number of cases that may, after going through a process of RU486, still need surgical intervention down the track. That would be a case where other practitioners may be called in.

Dr James—I am concerned about being confronted by circumstances where, as a doctor, I am compelled—in a sense, willingly, but still nevertheless compelled—to rescue someone.

Senator MOORE—By someone coming to your surgery with post complications.

Dr James—Exactly.

Dr Lennon—That puts us, as a whole group of GPs, at the risk of being sued because they are quite complicated medical cases. Emergency doctors would not be the ones who prescribed RU486 but would be the ones responsible from a medical, legal and ethical point of view for the women who need immediate medical care, who present with severe haemorrhage, possible ruptured ectopic pregnancy, an infection. Then there is the dilemma they have with clostridial infection, which is so difficult to diagnose. Any complications become the responsibility of the emergency doctors. The medicolegal burden is put on them and the group of doctors as a whole. There is a big problem in the States with litigation regarding RU486, and I have received legal advice that that is quite likely to happen if it is approved here.

Senator ADAMS—Following on regarding this infection, I have just noticed that Dr Wilks, Dr James and you, Dr Lennon, have said that the deaths—Dr Wilks quoted four and Dr James, three—in the United States were definitely caused by the clostridium sordellii. I have looked at the evidence from the FDA, and they have not actually agreed that it was. It is likely but they have not come to any final decision on that. Could I just have some information on that?

Dr Wilks—It is true that the FDA has not formally recognised either the specific role of the bacteria in question or, most particularly, the role of RU486. That underscores, in my view, the inadequacy of the Food and Drug Administration, which candidly is paralleled by the TGA, in being able to promptly assess medical information. Because, as Dr Lennon has mentioned, Professor Miech put out a very detailed paper back in September last year which went into great detail to explain the intricate nature of how RU486 completely derails a woman's immune system, leading to this florid overgrowth of clostridium sordellii. So, essentially, it is the FDA not adequately, properly or promptly responding to what exists in the medical literature.

Dr James—My understanding is that the consensus is there were four deaths in the United States and one in Canada—a total of five. In three of those clostridium sordelli has been isolated. There is also a suggestion that that there was one in the UK, but certainly information from the United Kingdom is not as easy to obtain. There have been a couple of deaths in the United Kingdom attributed to mifepristone. So the FDA are examining these. As

I said earlier, these were fit and healthy young women who were dead one week after taking this drug.

Senator ADAMS—The reason I asked is we had evidence this morning to say this was found out post mortem and then there was the time elapsing between the actual death and when the post mortem was done, so I do not know. Another thing has occurred to me which relates to tampons being the cause of septic shock. Is this the same bacteria involved here? What is the story?

Dr Lennon—No, it is not. Clostridium sordelli is a very rare infection. Prior to the RU486 infections there were about 10 reported cases in the literature. As for the information that you were requesting about how it was confirmed, with most of them it was at autopsy that it was definitely confirmed. It is not a bacteria that is able to be cultured on a blood culture, which is normally how we would detect infections in an emergency. Could I draw your attention to Dr Donna Harrison's submission that she has made to the Senate committee. She would be a good person to confirm what we are stating: that of the cases in Canada and the US, if you include the death that the FDA revealed in November last year, there is a total of four deaths in the States from clostridium sordelli. One woman died from an ectopic pregnancy, which was separate, so that was five. Dr Harrison can provide you with further details because she accessed the information under freedom of information.

Senator ADAMS—You have all been rather scathing of the actions of the TGA. Because of their actions, do you believe there should be another body rather than the TGA to do their work? Where do we go with this?

Mr Wilks—If nothing else, I would be thinking that we need a rather more elite and representative body of professionals from right across the spectrum of pharmacology—experts in pharmacodynamics—and medical practitioners who perhaps could, for drugs of this nature which are socially and medically divisive, provide objective, apolitical advice to those people who are going to make the decision, be it the minister or the TGA, depending on how this Senate inquiry pans out. But it does seem that there is a lack of a capacity to digest, access and pronounce upon these important issues currently within the TGA.

Senator ADAMS—But you have talked about drugs other than this particular one, so it seems that you have got a consensus amongst you that you are really not happy with the TGA.

Mr Wilks—As it functions at the moment, no. That is correct.

Senator HEFFERNAN—Is that because this is not a therapeutic good?

Senator ADAMS—No, this on other drugs.

Senator HEFFERNAN—No, I am talking about this one. What is a therapeutic good?

Dr James—As I said, I do not believe that abortion is therapeutic at all.

Senator HEFFERNAN—So it is really not an issue at all for the TGA anyway?

Dr James—I do not believe it is.

Senator HEFFERNAN—What is the description—through you, Mr Chairman—of a therapeutic good? What does the English dictionary say it is?

CHAIR—It is not a question for me to answer though. Do you have any further questions, Senator Adams?

Senator ADAMS—I want to continue along these lines.

CHAIR—Please proceed.

Senator ADAMS—To my knowledge, there is an expert committee within the TGA to which they refer issues such as you have discussed. Leaving this particular drug out of it, there are other issues you have had with them.

Mr Wilks—One can only go by the track record, and we can cite both ibuprofen and the morning after pill as being decisions which I think were medically imprudent.

Dr Lennon—In theory, the TGA would have the power, if the bill goes ahead on Thursday, to even make RU486 available over the counter. They have enormous power to make that decision and they are not accountable to the Australian people. There is a serious problem with monitoring the drug's safety. I think there is an issue with the nature of abortion and particularly chemical abortions. Women overseas who have used it have a tendency not to tell their family or friends. Holly Patterson, who died from taking RU486, was extremely ill and she still had not told her family. It is the covert nature of the abortion. It means that if RU486 were approved there would be unique problems associated with monitoring the ongoing safety problems of RU486.

Senator ADAMS—The World Health Organisation holds the Australian TGA in great respect. I am concerned about these issues and about professionals thinking that it is not doing its job and I am really trying somehow to get to a consensus as to why.

Dr James—A recommendation from the World Health Organisation does not cut much with me. I think that the World Health Organisation would see mifepristone as something that Third World countries could benefit from and I have no confidence in the World Health Organisation itself. Someone once told me that it is easier to find an IUD in the Africa than it is a vial of penicillin.

Senator ADAMS—That is not really the point. Overall the TGA is a respected body.

CHAIR—I think that there is more a debate going on here than questions.

Senator WEBBER—I think that we have been very patient this afternoon. We were very patient with Senator Barnett before so we might like some reciprocal patience.

Senator POLLEY—As elected representatives we have been told through the course of these hearings that social policy in this circumstance should be left to bureaucrats. When there is a government policy in Australia to drill for oil I wonder whether we should hand over to bureaucrats the right or whether or not we ought to drill on the Great Barrier Reef. Today we have heard that an abortion is an abortion. The question to ask people from the medical fraternity is: shouldn't we give due consideration to the fact that with the chemical abortion it can take up to three days for the baby to die before it goes through the process of being expelled? I have been accused of being emotive because I refer to the baby rather than to an embryo, but that is the terminology that I personally use and I feel quite comfortable with that.

We have also heard evidence from the national students organisation that chemical abortion would be an advantage for young women because then they would not have to take so much time away from their study and it would be a cost-effective option for them. I wonder whether you could enlighten us on your views on some of those issues. To me, this is a health issue for women and that can be excluded from some parts of the debate that we have had regardless of whether you are a pro abortionist or not. I have had doctors say to me that they are pro-choice but they have grave concerns that there are extra complications with this psychologically as well.

Dr James—Firstly, your comment about using the word 'baby' is interesting. I have never heard a pregnant mother attending my practice refer to her pregnancy in any other term than 'my baby'. The only people who use the other terms are the abortion industry because they want to dehumanise this. For sure, there are important health issues for women and I think that all of us here have made a central point of that. But there are also broader issues in terms of monitoring, particularly from a medical perspective, how we learn to treat and deal with the complications, how we do so safely and what the cost is to the community. That is why I certainly think—and I think the others believe, though I will let them speak for themselves—that this is best left in the hands of elected representatives, who must then give an account of their decisions to the community.

Senator HEFFERNAN—Will RU486 bowl the baby over at 14, 18 or 20 weeks?

Dr James—No. As you advance in the pregnancy, the success rate of mifepristone decreases.

Dr Lennon—Regarding the experience overseas, usually RU486 involves a regimen which includes three visits to the doctor, and on that third visit a pregnancy test is done to check if the woman is still pregnant, because in eight per cent of cases she has a continuing pregnancy or needs a curette, for example. So certainly there is that long duration of bleeding where the woman literally has to live with her abortion for one to two weeks. Particularly in the first week there is evidence that the chemical abortion using RU486 is more painful, there is more bleeding and the woman is more likely to suffer this at home alone, wanting to keep it a secret from those around her, although obviously she could be in a workplace. But a lot of women are very unwell with this for at least a week, and that is a much longer period than with a surgical abortion.

Mr Wilks—From a pharmaceutical point of view, the other point is that in my profession we struggle continually with the concept of patient compliance—that is, the patient has to take the tablets twice or three times a day or whatever it might be or they have to finish the course of antibiotics and frequently do not. In a situation where, as Dr Lennon has described, a patient is required to revisit the doctor thrice, you are going to run into enormous follow-up compliance issues and that will play directly into the issue of the safety of women, particularly young women at university. We all grow up and are still growing up, but I remember that when I was at university I was perhaps not quite as mature and responsible as I am now. I would be concerned that, obviously, younger people at university are not going to have that holistic sense of the damage that this drug can do to them and perhaps are going to miss their follow-up visits, because I certainly know that in my pharmacy adults have that problem. It would be reasonable to say that younger people of 18, 19 or 20 would also have

that problem. Also, regarding the submission from the Australian Union of Students, I point out that there was never any vote. This has just been a hierarchical decision by the Australian Union of Students. I have two daughters at Sydney university in fourth and first year; they were never asked to vote on this matter.

Dr James—Getting back to Senator Heffernan's question, it is important to accurately date the pregnancy, and that is why ultrasound really needs to be available.

Senator HEFFERNAN—If I ever get the call, I am going to come to that!

CHAIR—Patience will get you there. Senator Polley, do you have any further questions?

Senator POLLEY—In relation to the lack of mandatory reporting requirements in America, the concern that has been raised during these hearings and also in a lot of the emails that we have received during the course of this inquiry is that the TGA relies too much on evidence from America and Europe that perhaps is already flawed and that it is not funded and does not have the resources available to do its own extensive research. There are alarm bells ringing within the medical fraternity that the TGA is not quite resourced sufficiently to be able to investigate the matter.

There have also been accusations made that people who have concerns about this legislation are not giving women credit for ensuring that they have follow-up medical visits. Coming from a regional and rural area, my concern is that we already have a shortage of doctors. In Tasmania, a large number of practices have already closed and, whether we like it or not, women are usually the ones who put themselves last in terms of medical assistance and therefore there are grave concerns that this is not the best option for those who make the choice to have an abortion. I would be interested in your views.

Dr James—You raise a very important point: the access to out-of-hours care in particular and the continuity of care. The abortion clinics close their doors at five o'clock. They will be sipping their martinis, watching the sun go down, while doctors like me, who are on call for their patients all the time, are having to confront the aftermath of the administration of these drugs. In the papers that have reviewed the data in North America, it has emerged that there would have been many more deaths had not those women been close to emergency facilities where they could be properly resuscitated and have access to surgical intervention as well. In fact, the FDA specified that in its trials. A doctor in that trial had to have admitting privileges to a facility where this sort of resuscitation and surgical intervention was available. The idea, as the proponents of this drug are suggesting, that this is a great boon for women in rural communities is just crazy.

Senator BARNETT—So are they worse off or better off in rural and regional communities?

Senator Polley interjecting—

CHAIR—Sorry. We have a real problem with keeping this in order.

Senator POLLEY—I wondered whether anyone else had a comment to make.

CHAIR—I am not sure that we are going to have time for the whole panel to answer the questions, unfortunately, because we are running very short of time.

Senator HEFFERNAN—Beef up the answers a bit.

CHAIR—That is up to the people answering the questions.

Senator BARNETT—To Dr James and other people: is RU486 going to make rural and regional women in Australia better off in terms of their health outcomes or worse off in comparison to women in city areas?

Dr James—Worse off—far worse. Dangerously worse.

Dr Lennon—There is a significantly increased risk for women in rural areas. If RU486 were made available they would be the ones most at risk because of the high death rate. For every death there are about 70 cases where they have potentially life-threatening complications and immediate medical care is required. Danko's website emphasised, when they put it out in November last year, the need for immediate medical care. We know that that is a problem in rural areas, and the doctors are already overloaded.

Mr Wilks—In Professor de Costa's submission she makes it very clear that all patients must live within eight kilometres of an emergency facility; otherwise, they do not get the medication.

Senator BARNETT—Do you have the same view, Mr Wilks?

Mr Wilks—Yes, I do. I agree with Dr Lennon, yes.

Senator BARNETT—We heard evidence earlier today from Women's Hospitals Australasia with regard to deaths in the UK. Dr Buist was not aware of any deaths in the UK. I have been advised, through the National Health Service in the UK, that there have been three, but I am seeking clarification or confirmation of that, if you can. If you cannot, that is fine. Does anybody have a view on that?

Mr Wilks—I have only read of two. Part of the problem is that the British Department of Health do not seem to be so forthcoming with the details. We simply do not have the access here in Australia, compared to the United Kingdom.

Dr Lennon—Last week a report revealed in Britain, through their health department, that there had been another death. That brings to 11 the total number of reported deaths of women from RU486. It is generally accepted that this is the minimum, that there are cases, particularly in other countries that do not have a proper reporting scheme, where there are likely to have been deaths that simply do not get reported publicly.

Senator BARNETT—Do those 11 deaths, and potentially other ones, give you reason for more concern about the legislation and RU486 coming into Australia?

Dr Lennon—The high death rate is a strong reason why I think that the Senate should keep the responsibility with the parliament for approval of RU486.

Senator BARNETT—Is that a yes, Dr Wilks?

Mr Wilks—I agree. We also perhaps need to keep in mind that, when we talk about deaths, it is not statistics that die; it is real people. That is whom we are talking about.

Senator BARNETT—There was reference to the need for counselling and the importance of that in the cooling-off period. I think Dr Lennon was talking about that. In the US, federal

funding of abortions has stopped in recent years. What is your view of funding of surgical abortions and abortions in Australia as to whether there should be conditions attached with respect to independent counselling, consent reasons, cooling-off periods and so on? Dr Lennon, do you, or anyone else, have a view that you would like to perhaps share with us?

Dr Lennon—I think everything possible should be done by both the community and the government to increase the availability of counselling for women with unplanned pregnancies and also those women who have been hurt by an abortion experience. There is a big cost burden that will be put on taxpayers if RU486 is approved. That cost burden would come through the possible subsidy funds through the PBS of an expensive drug like RU486. As I put in my submission, in the States it is far more expensive than a surgical abortion.

Senator BARNETT—Did you have the figures on that?

Dr Lennon—I did. In my submission, I have put a variety of figures. Certainly, there is a cost burden associated with having immediate medical care available and women with suspected sepsis having to be monitored and admitted very closely because it is such a complicated infection, as well as the cost of litigation. I remind the Senate that the current largest medical insurer is still having a premium support scheme because of the medical indemnity crisis that United Medical Protection Ltd suffered. The cost of the litigation that is likely to happen will then be put on insurers and passed on to doctors like me who, particularly through litigation related to pregnancy problems, experienced the medical indemnity crisis and eventually needed to be supported by the government—the taxpayers. So there are a lot of costs involved.

Senator BARNETT—On costs, in your submission you refer to a first trimester surgical abortion in the US costing $US300 to $US375 and you say that in press reports they charged $US600 for an RU486 abortion, so approximately double?

Dr Lennon—Yes.

Senator HEFFERNAN—At what age do you fail to knock the baby over with this drug?

Dr James—As the gestational age of the pregnancy advances, the success rate diminishes.

Senator HEFFERNAN—Can you give us an idea of when you get the higher failure rate? How do you work out within a week or two how pregnant the lady is who bowls up through your door?

Dr James—Probably the most accurate way is by using an ultrasound assessment.

Senator HEFFERNAN—Is it an intention to do that as part of this process?

Dr James—The FDA required or recommended that an ultrasound examination be conducted, but it is my understanding that that has not been adhered to. That is why some of the ectopic problems have arisen as well. The FDA recommended that this drug be used up to day 49, but it is being advertised for abortions up to day 63 of the pregnancy. As I said, the failure rate diminishes. The figure is something like eight per cent failure rate up to 49 days, then it jumps to 17 per cent from 50 to 56 days, then 23 per cent beyond that from 57 to 63 days. Given the malformation rate, it has dire sorts of implications.

Senator HEFFERNAN—So it would never want to become a drug that is obtained over the counter, that is for sure?

Dr James—Absolutely; not at all.

Dr Lennon—Abortion providers like Dr Grundman and others have discussed how it is used overseas for later term abortions. My concern is that FPA Health, Dr Weisberg, Dr Foran and a number of others who are very heavily involved in the education of doctors and setting protocols recommend off-label uses for drugs. So the fact that it may be approved for one purpose by the TGA does not necessarily mean that it is adhered to. If RU686 were approved for up to seven weeks, there is no guarantee that it would not be used by certain doctors later than that in Australia.

Senator HEFFERNAN—You can bet on that. Can I just move on, because we have not got much time. Given that abortion is legal in Australia and that people describe this pill, which is to knock over babies, as a therapeutic good, if euthanasia were ever to become legal—and there is a debate in Australia to make it a legal process—wouldn't the same term apply to a knock-yourself-over-at-home pill that someone comes up with? It will be a therapeutic good in the same way that this pill is described as a therapeutic good. The English dictionary does not relate what this pill does to any therapeutic good. Yet, for the convenience of this debate, this committee, the government and whoever else, it is being called 'therapeutic'. Wouldn't that term also describe a pill that could be used for euthanasia, if it were ever legalised? Would that be an issue for the TGA?

Dr James—Obviously not. Dr Nitschke would certainly define therapeutic in different terms to the rest of the community, I am sure.

Senator HEFFERNAN—These things happen by stages and by community standards moving.

CHAIR—I am not sure that the witnesses are really competent to answer that question.

Senator HEFFERNAN—As you know, Mr Chairman, I was trying to look at a 50-year snapshot of this. This morning I said that the danger with this debate is that it is going to move on the community in such a way that the world's greatest vocation, parenthood, will become a social convenience, which is what the Australian Union of Students are already talking about. That is how these things have to be viewed—over a 50-year snapshot. That is my only question.

Dr Lennon—I think RU486 is unique in that, if it were approved, it would be the first of a class of drugs designed to kill—the pill designed to kill—because the bill would also cover other abortifacients. To my knowledge, about 150 are currently being used overseas or are under trial. So it would be bringing in a new class of drugs and, for the first time in Australia, we would have drugs that are designed to be given to pregnant women and that are known to cause severe malformations to the foetus or death.

Senator HEFFERNAN—I wish you all well.

Senator WEBBER—I will try and be as brief as I possibly can, because I know we have gone over time already. Dr Grocott, in your evidence you talked about RU486 being used

solely to take life. Dr Lennon, you then said that this is a pill designed to kill. As medical practitioners, are you both aware that RU486 actually has other uses?

Dr Grocott—I said 'in the case of a pregnant woman, solely to take life'. I am aware of the other issues with Cushings disease and some cancers, but I do not think that is really what the debate is about.

Senator WEBBER—That may not be what the debate is about. If you look at the terms of reference, which I will come to, we do not get to that. Would you support RU486 being used in those other areas?

Dr Grocott—Of course.

Senator WEBBER—Do you think it would be appropriate for the TGA to make an assessment on the use of that drug in dealing with other medical concerns and to determine a safety regime for its use within Australia?

Dr Grocott—I believe that it is already able to be released by the minister for those sorts of purposes, but it is not my area of expertise.

Dr Lennon—There is already a system whereby they can apply to the minister for a dispensation. I think we need to have those checks and safeguards, because if it were simply classed as a S4 drug, or an authority drug, then doctors in Australia would very likely use it off label to induce terminations.

Senator WEBBER—We received a whole lot of evidence earlier on—I am not sure whether you were in the room or not—that, because of the medical indemnity issues and what have you, a lot of the medical treatments that pregnant women receive these days are actually off label when you are looking at treating them for hypertension and a whole range of other things. Off label is obviously an issue that the medical profession and insurance industry need to come to terms with, and you are right to highlight those indemnity issues.

I now want to return to the terms of reference for this inquiry. We all know the circumstances: this is about whether the TGA should make an assessment. You have given us some evidence about your lack of confidence in the TGA. We all know the views of the current minister for health. If we were to have a different minister for health, who had a different view and therefore was not going to exercise the right of veto, given that you say you have no confidence in the TGA, who should make the assessment about whether this drug is safe for use in Australian conditions on Australian women?

Dr James—No processes is infallible, but at least the process that we have in place at the moment means that the Australian community has some direct input. We do not believe that the TGA alone being left with the decision would allow that access for the Australian community.

Senator WEBBER—But should there be a role for the TGA?

Dr James—For sure. Absolutely.

Mr Wilks—I agree with Dr James.

Dr Lennon—I agree.

Senator HEFFERNAN—What is the maximum age to abort a baby surgically?

Dr James—There was an unborn child aborted in Melbourne at 32 weeks. Dr Grundman will do them at any time.

Senator HEFFERNAN—Just say that some smarty out there comes up with a pill, an RU486, that will knock them over at that age—isn't that the national extension of what we are on about here? We always move to a higher product—a better tractor or a bigger header. I spend too much time driving around on the tractor thinking about this, but won't that be where we will end up? We will have chemical abortion at 20 or 25 weeks. Would it be unreasonable to think that they will come up with that?

Dr James—I am sure that is the holy grail of the abortion industry: to get a pill that can end a pregnancy at any time in the privacy of a woman's home.

Senator HEFFERNAN—There you go. I am sure, given those comments, I can make a little prediction for everyone—you can put half a year's wage on it—that in due course you are going to turn Australia's greatest vocation into a social convenience.

CHAIR—We will draw this session to a close. I thank each of you at the table for your testimony today and for the submissions that you have delivered to the committee. Thank you very much.

Proceedings suspended from 3.58 pm to 4.12 pm

DODDS, Professor Susan Mary, Private capacity

McLEAN, Mr Cameron, Acting Chief Executive, Sexual Health and Family Planning Australia

WEISBERG, Dr Edith, Director of Research, Sydney Centre for Reproductive Health Research, Sexual Health and Family Planning Australia

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

Prof. Dodds—I am here as a private citizen but I have expertise in ethics and bioethics.

CHAIR—We have submissions from Sexual Health and Family Planning Australia and from Professor Dodds. Thank you for those. We have provided you with information on parliamentary privilege and the protection of witnesses and evidence. I invite you to make an opening statement, but I also indicate that this session is due to end at 5.15 so brevity on your part would be appreciated—and, equally, on the part of senators in asking questions—so that we are able to make as much of this session as we can.

Mr McLean—Thank you very much. I am not a medical practitioner, I am a senior health manager. My purpose for being here is to let senators know about the role of family planning organisations. Sexual Health and Family Planning Australia is a peak federated body for state and territory family planning organisations. Our members include family planning organisations in seven states and territories. We are a member of the International Planned Parenthood Federation. Our members' funding comes through the states via the PHOFAs—the public health outcome funding agreements. The federal body, which I am representing today and which our submission is on behalf of, is funded in part by the Commonwealth, who give us a small grant primarily to advise the government on national trends in reproductive and sexual health. We also get some of our funding from member contributions.

Family planning organisations have been around in this country for about 80 years. We are primarily service providers, and our mission is to improve the reproductive and sexual health of all Australians. We do this in several ways. Senators are probably very aware of our member network of family planning clinics across the country, and those clinics provide the services which we are most known for. Our core business in those clinics is contraception. Contrary to popular belief, we are not abortion providers. Perhaps senators may not be aware that we also have extensive health promotion programs. These programs aim to promote the best possible reproductive health in Australians, to equip people with knowledge and skills for healthier sexual behaviours and to provide early intervention.

Another very important role that Family Planning Australia has is in the training of doctors and other health professionals in reproductive and sexual health. In the last calendar year we trained approximately 19,000 professionals. These included GPs and other doctors but also nurses, social workers, disability workers and, indeed, teachers. We provide resources for teachers. We also provide resources for parents, in recognition that parents are the best people to talk to their kids about sex and sexuality. We provide a number of information seminars,

information lines and resources for parents and we build the capacity of health and welfare organisations to provide sexual and reproductive health information to their clients.

We also have a research program. This is in all member organisations, but in particular here in this state, at family planning New South Wales—of course, Dr Weisberg heads up the Sydney Centre for Reproductive Health Research. Family Planning Australia also runs a small international program, where we provide development aid, mainly to the South Pacific and Asia. That funding comes mostly through AusAID. There were about 100,000 Australians who attended our clinics. As I said, there were 19,000 professionals trained and probably many hundreds of thousands who accessed our information services and our help lines. Dr Weisberg is going to speak on behalf of our submission.

Dr Weisberg—Thank you very much for giving me the opportunity to speak to Family Planning Australia's submission. As you are aware from our submission, Family Planning Australia supports the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005. The issue really is that RU486 should be treated in the same way as all other drugs which are licensed for sale in Australia—namely, to be assessed by the specialist statutory body, the TGA. The removal of the clause requiring the health minister's signature does not automatically mean that the drug will be approved for use in Australia. It still requires a full evaluation by the TGA. The TGA, together with its expert advisory body, the Australian Drug Evaluation Committee, has the expertise to analyse research and other evidence to ensure that any drug marketed in Australia is safe, of high quality and effective. The TGA also stipulates conditions for use so that any approval of RU486 will contain strict guidelines on safety of use.

RU486, in any country where it is used, is used under strict protocols and medical supervision. It is not a do-it-yourself abortion method. Women are given full information on the pros and cons and risks of both medical and surgical abortion and then make a choice as to method, provided that they have been assessed as medically suitable to use the medical abortion drugs. Abortion is legally available in all states of Australia under a variety of conditions. Whether RU486 is assessed by the TGA alone or with the ministerial approval, the availability of abortion will not be affected, whatever the decision about RU486 is. I am happy to leave it at that point and to answer any questions that you may have.

Prof. Dodds—Thank you to the committee for allowing me the opportunity to participate in this public debate. I think that this is an opportunity for people like me, who are relatively unusual in policy debates—that is, philosophers—to come to the discussion. The submission which I am speaking to is one that was prepared by Professor Wendy Rogers, who has both medical and bioethics qualifications from Flinders University; Rachel Ankeny, who has qualifications in both science and philosophy; and myself. I have qualifications in both politics and philosophy. All three of us are members of the International Network on Feminist Approaches to Bioethics, which is a network of the International Association of Bioethics, of which I am a member of the board. But this is not a submission on behalf of either of those organisations, because we are not in a position to speak for all members.

The proposed legislation seeks to repeal the requirement of approval from the minister of health prior to importation of and access to RU486. That would end an anomaly and improve governance. The process for approval of RU486 would be brought into line with the approval

process for every other new drug in Australia—that is, that the Therapeutic Goods Administration follows an established and thorough process of assessing the quality, safety and efficacy of the drugs to be made available in Australia, based on the latest international scientific data, local drug trials and an evaluation of the appropriate indications for prescribing the drug. In addition, approved drugs are monitored by the TGA to assess whether new information means that a drug should no longer be prescribed or whether the circumstances for its use, indications and dosages should be changed.

The committees of the TGA that are involved in the evaluation and monitoring of drug safety, efficacy and quality are comprised of experts in a range of fields and specialisations, who have access to the latest international data through a number of sources, including the World Health Organisation. The TGA has overseen approval of over 50,000 drugs in Australia, and Australians have every reason to feel confident that the TGA approval process provides well-informed, safe, transparent and accountable means of assessment. It is well informed because of the range of expertise of the members of the committee, well informed because of their access to international data, and well informed because of their experience in evaluating drugs. It is safe because of the legislative responsibility of the TGA to follow an established process, which is also a transparent process, and because it has the responsibility for monitoring drugs that have been approved. And it is accountable through legislation and through international agreements with the World Health Organisation. The minister does not have the expertise or experience in drug evaluation required to make a judgment about the safety and efficacy of RU486.

RU486 is a drug that has been approved for use in 33 countries internationally, including the UK, France and Sweden. I know I am repeating things you have heard before, but some of them bear repeating. It is used to provide medical as opposed to surgical abortions. If the TGA had authority to approve access to RU486 in Australia, it would consider its safety, efficacy and use of the drug in Australia, drawing on the research and experience of the use of the drug around the world. There is no reason to fear that a drug that is unsafe would be approved for use here.

Abortion is legally available in Australia in accordance with state law. The proposed removal of the requirement for ministerial approval to access RU486 will not change the legal availability of abortion, but may provide some women seeking abortion with an alternative that is more appropriate to their circumstances. The repeal of the requirement of ministerial approval for access to RU486 will ensure that the decision regarding its access rests on evidence about its safety and efficacy. If it is approved for use in Australia, a physician's decision to prescribe it to a particular patient will be based on the particular circumstances of that patient and the relevant state legislation concerning termination and pregnancy, rather than on the political or religious perspectives of the sitting minister.

There is a real risk that the requirement for ministerial approval for access to RU486 could compromise the confidentiality of patients seeking access to the drug, because there is no arm's-length process for obtaining that approval, as is the case for most TGA approved drugs. A particular patient's reasons for seeking access to RU486 could become a political football to be used by politicians in trying to persuade voters of their commitment to a particular set of values or ethical viewpoint. The TGA process separates the question of the safety and efficacy

of drugs that may be approved for use in Australia from the particular patients who may wish to use that drug, given their specific circumstances. Where the TGA has responsibility for approval of a drug, physicians and patients are able to discuss in-confidence whether an approved drug is appropriate for their situation. Ministerial approval collapses these two issues and risks breaches of medical confidentiality.

The bill merits support because it will protect the interests and safety of Australians generally, and it promotes good governance through transparent processes. Australian women seeking access to a range of safe and legal means of abortion can have confidence in the TGA approval process, should it approve the drug. Others seeking access to RU486 to treat other conditions, including various cancers, should be able to access safe, effective drugs without having to establish that their need is genuine and acceptable to the minister. Australians should seek a process for drug regulation that ensures that all prescription drugs available in Australia have been rigorously assessed for safety and efficacy through an established process that meets the highest international standards. That is all I would like to say, and I am quite happy to answer any questions.

CHAIR—Thank you very much. Can I start by picking up those last few points you were making. My reading of the effect of the 1996 amendment is a little bit different to your own. You seem to take the view that the effect of the amendment is that the minister now has to make decisions about the safety and efficacy of a particular drug if it is to go on the market. My reading is that there is no intention in the amendment for the minister to try to make that decision either by himself or with the aid of a department or someone else. The intention is always that the TGA, and the TGA alone, would assess efficacy and safety issues but that the minister has the role of determining other issues, such as bioethical issues, in respect of the supply of that drug in Australia. Would you agree that the TGA, while well equipped to deal with the safety and efficacy of a particular drug, does not have a brief—or, for that matter, expertise—in bioethical issues? If so, is it not appropriate that some other body has that role? If that is the case, is it not appropriate that ethical issues, moral issues—if you like, political issues—be in the hands of a body like elected representatives: a minister, a government or a parliament?

Prof. Dodds—There are a couple of responses to that. One aspect is that neither the minister nor the TGA has expertise in bioethics. And even bioethicists disagree on the issue of whether or not we should have access to drugs that may be abortifacients. So it does not seem to me that this is a matter for expert opinion. However, I do think that, where we do have safe, legal abortion available in Australia for surgical means, the prohibition of access to a drug that can provide an alternative that may be more appropriate for some women is something which ought not to be treated as anomalous. It ought to be part of a general process for the efficacy and safety of drugs. We have other drugs in Australia that are equally ethically contentious, and it seems to me that we could ask questions about them. They seem to me to be equally ethically contentious; we might debate which ones are.

Senator BARNETT—Like Viagra?

Prof. Dodds—Sure. We might say Viagra is one. We might say that about some of the drugs that engage in hyperstimulation of ovaries as part of IVF treatment and we might say that about some drugs that have been proposed in the US, for example, where they are testing

drugs that can keep people awake so that soldiers can work for much longer and not feel pain. There is a wide range of possible drugs that could be used. I am not an expert in this area, but certainly there are drugs available in Australia for use in palliative care and for use in preserving someone's functions so that they could be used as a potential organ donor. There is a range of drugs that we do not treat in this very special way, and I think that the questions of whether or not a drug is safe and whether or not there is good evidence to establish that a drug ought to be able to be considered for use in Australia are matters for expert opinion based on science. The social policy issues are about the processes in a society in which we do not all share the same views about embryos, foetuses or children. We ought to not have the state decide to make it a political issue that imposes one set of values on everyone else.

CHAIR—Are you saying that there are or there are not bioethical issues associated with the supply in Australia of a drug like RU486?

Prof. Dodds—There are bioethical issues, but they are not unique to that drug.

CHAIR—Okay. If there are bioethical issues—and I grant you that there are other drugs for which the same comment could be made, for which there are bioethical dimensions—would you not agree that the TGA, as you have already said, in fact has no power, or no expertise or brief, to consider those bioethical issues. Are you saying that it is better not to consider them at all than to allow the minister to take those issues into account in making a decision? I accept he is not an expert—and I am not aware of any minister in recent years who has been an expert in bioethical issues—but, as the minister, he has the capacity to take advice on bioethical issues. Is it not better to have some input and some consideration of those issues through the agency of a person like the minister than to ignore them altogether?

Prof. Dodds—I do not think they should be ignored altogether. There is lots of room for much stronger, richer bioethical debate in Australia. We have actually fallen behind many other countries in this regard. This is not something which is completely separable from the political arena, but the question of whether or not a particular drug is safe is not a matter which is internal to that debate. It is rather the case that the ethical issues come out in the context. I think that we could sensibly have debate in Australia whether it is access to abortion, access to reproductive services, access to euthanasia and a whole range of things, about the use of health resources which would involve a political process. But this is about the tying up of the access for a particular patient to a particular drug with the minister rather than having a separate debate about the wider social policy. We are having that debate here. We are not asking whether or not a particular individual would like to have access to the drug. The collapsing of that debate with respect to a particular individual can be quite damaging and discriminatory to individuals and it may allow the particular ethical, political, religious views of an individual, who happens to be the minister at the time, to have an undue influence on the lives of citizens within Australia.

CHAIR—I cannot understand how assessment of individual requirements or applications needs to be part of this process. As I understand it, the minister has a power to approve in respect of individual's access to the drugs for things like cancer treatments and so forth but in respect of RU486, as an abortion drug, he would not have an individual assessment capacity in the case of an individual woman seeking an abortion. How do you consider the bioethical

issues if you accept, as I assume you do or as you argue, that the parliament should pass the bill in front of it and remove any opportunity to consider those bioethical issues?

Prof. Dodds—No, I think that the bioethical issues need to be taken into a much broader sphere not—

CHAIR—How?

Prof. Dodds—These sorts of issues do not fit neatly into the current parliamentary process. It seems to me that there needs to be a more general public debate about these issues, not something driven by concern about one particular drug for one particular purpose. I think that the debate is a much wider one. There is the argument that people put forward that politicians are accountable for their decision making. Often a person who becomes the minister is not elected to be the minister and we may not know their views on a particular area at the time at which they are elected and hence later appointed. Whether or not a party wants to divide on party lines about bioethical issues ought to be part of the public debate prior to elections. If the issue about accountability is that we elect politicians who represent a particular set of views then we ought to know what those views are. They ought to be articulated and debated rather than having, as we currently do, a debate where, very largely, politicians are trying to maintain maximum control over the centre of politics. That does not give us an opportunity to have sensible debate about bioethical issues. But to do that would require a very different view about the way in which policy is developed.

CHAIR—I do not want to go into the debate now. I will just point out that there have been three ministers for health since the 1996 amendments and none of them have taken a different view on the subject so it is not a question of an individual. The individual does not make the decision in isolation; effectively they make the decision in the context of what their colleagues are likely to wear. I would suggest to you that no minister for health in the last 10 years has made that decision without being acutely aware of the sentiments of their colleagues, if only in their own party, before that decision has been made.

Prof. Dodds—I do not doubt that but we have not had a wider Australian debate.

CHAIR—No, and with respect you will not if this bill is passed because this bill allows you to proceed to have a TGA assessment and nothing else. There is no capacity for a bioethical debate at all on RU486 if the bill is passed.

Prof. Dodds—Not on this specific drug, but it does allow it in the context of a much wider debate about bioethical issues in Australia generally. I think that in a pluralist society we have to acknowledge that there will be differences on the range of values associated with these issues.

Senator MOORE—That was fascinating. We have not had a bioethical debate before. I have asked previous witnesses about their own knowledge and interaction with the TGA. I think that it is important for the record. This morning, evidence was given by people from the Women's Forum about your previous interaction with the TGA in a previous time of trials. In terms of process, we should actually get that on record.

Dr Weisberg—May I say that I have been associated with the TGA for at least 10 years, because I have been on their Medical Device Evaluation Committee.

Senator MOORE—What was the process for getting on that committee?

Dr Weisberg—I was approached by the TGA. I was originally the representative for reproductive and sexual health and then I was asked by the then head of the TGA to continue in that position.

Senator MOORE—So it is an appointment?

Dr Weisberg—Yes.

Senator MOORE—I just think it is important to have it all on record.

Dr Weisberg—Right. It is an appointment because of my expertise in the area. Certainly my experience with the TGA is that they are extremely thorough and extremely conservative, and if there is any doubt at all they will consult experts. They are not prepared to take any risks at all with the health of the community or with having any drug or device available in Australia of which there is any question at all. As far as my research role has been concerned, at the moment we are doing research with RU486. We are using a lower dose than is used in abortion to treat bleeding problems. In the pilot study we found that in combination with oestrogen it is actually very effective in stopping an episode of bleeding in women using long-acting progesterone-only contraceptive. In fact, if we can do that we will reduce the abortion rate in Australia because it will make long-acting contraception, which has a much lower failure rate than any other method, much more attractive to women. That is really an ironical point.

Regarding our attempts to obtain approval for importing RU486 for this trial, normally when we put in a clinical trial notification we get approval from the TGA within three weeks because the ethics committee of our organisation is responsible for the research and assessing it. In this case it took four months because the TGA came back with numerous questions, so they were very concerned about the conditions under which we were using it. In fact, we had the first ever audit that the TGA has ever done. When we started the pilot study, they actually came out and had a look at how we dispensed the drug, how we accounted for it, what the results were and how we informed women, so they were extremely careful. So I have every confidence that the TGA has the ability to assess this drug from a safety, quality and efficacy point of view and that they will very carefully look at the conditions for use in Australia if they should approve it.

Senator MOORE—One of the concerns that has been raised by some witnesses is about the ongoing monitoring role of the TGA once approval is given for any drug and, in particular, if guidelines are developed for its usage. There have been statements saying that, once that is done, there is no ongoing monitoring of how that occurs in the community. That was seen as quite a serious allegation.

Dr Weisberg—That is actually not true any more because, in fact, the TGA is looking towards implementing post-marketing surveyance because it now has harmonisation with the EU. Part of that harmonisation is to look at post-marketing surveyance. It is difficult and expensive to do but it will be a requirement for drugs. Certainly there is a reporting system whereby adverse events are reported to the TGA. I certainly know, as far as the devices are concerned, that a whole department looks at complaints and adverse events that are reported both by users and by sponsors, which are followed up very carefully and investigated. If there

is any problem at all, they send out alerts, put out hazard warnings and also withdraw products for which there is any possibility of an adverse event that is serious and will affect the health of Australians.

Senator MOORE—Do you have any further comment on that, Mr McLean?

Mr McLean—I have no experience with the TGA.

Senator MOORE—Professor Dodds?

Prof. Dodds—Just on that point, I was for 10 years a member of the University of Wollongong Illawarra Area Health Service Human Research Ethics Committee, and for five years its chair, so I had responsibility for approving the kind of research that Dr Weisberg refers to, which would then be subject to CTN or CTX approval. So there is a relationship with the TGA through the HRECs.

Senator BARNETT—Professor Dodds, are you aware of the federal parliament's legislation and regulations regarding human embryo research and cloning?

Prof. Dodds—Yes.

Senator BARNETT—Do you believe it is appropriate that the parliament made laws and set guidelines and parameters on behalf of the community as to what is appropriate with respect to the experimentation on and use of human embryos?

Prof. Dodds—Yes, I do. It is appropriate for the parliament to make judgments about that. That is a question about an area of debate in which there was no regulation previously. There was a development of a set of guidelines through the National Health and Medical Research Council. There was different legislation in each state. The kind of research that was being conducted was international research, and there was research across state borders. That is a question about the kind of people we want to be. That is appropriate. However, I might have quibbles about the content of that legislation.

In the case of the TGA, we are asking questions about access to drugs. We have a mechanism for approving access to drugs. If we want to have a debate about the question of abortion, then we ought to have that debate. I do not think it is appropriate to conflate that discussion with one about a drug which allows for a process which is legally permitted in states under particular conditions under state legislation. It is not appropriate to treat it as anomalous in the circumstance where we have an effective regulatory mechanism.

Senator BARNETT—I asked the question to follow up the chairman's earlier question, because we are talking about a human embryo which develops into a human being and we have set laws with respect to stem cell research and cloning. In this regard, we are talking about the parliament having jurisdiction and discretion, rather than a bureaucratic, unelected entity. I am puzzled by the assertion you made in the second last sentence in the last paragraph of your submission, where you say:

Seeking Ministerial approval for each use of the drug potentially breaches the confidentiality of the patient for whom its use is sought.

The chairman touched on this a little bit. I want to clarify with you as to how on earth it is possible for the minister to breach patient confidentiality by approval or otherwise of the drug RU486 for abortion purposes.

Prof. Dodds—In the current situation, people who are seeking access to the drug for non-abortion purposes have to apply on the basis of a patient-by-patient, case-by-case mechanism in order to get access to the drug for their conditions. At the moment, their confidentiality is at risk because of the need to defend their use of the drug to the minister.

Senator BARNETT—But that is through the special access scheme, which does not require ministerial discretion.

Prof. Dodds—My understanding had been that for those who are seeking special access to a drug which could be used as an abortifacient there was a requirement for ministerial approval, and that their request would not be dealt with by the usual special access scheme. I may have been incorrect about that, but that was my understanding.

Senator BARNETT—For the special access scheme, ministerial approval is not required. If you want to take it any further, feel free. Dr Weisberg, have you as a doctor or has your organisation recommended off label use of any drugs previously—for example, for the over-the-counter morning after pill?

Dr Weisberg—Yes. We did in fact provide emergency contraception for women using the combined pill when it had not yet been approved, mainly because the company had not developed a specific pack in Australia. The specific packs for emergency contraception were available in Europe and were available in New Zealand, but not in Australia. Therefore, we made up our own packs.

Senator BARNETT—You believed and deemed that that was appropriate at the time?

Dr Weisberg—Yes, there was enough evidence to show that it was a safe and effective method for averting or preventing a pregnancy in women who for a variety of reasons had unprotected intercourse. Therefore, it had peer support. I think off-label prescribing is very common because the companies often do not believe that it is worthwhile changing the indication for a drug through the TGA if a new indication becomes apparent through research. It is very expensive for a company to do that and they often do not think the commercial gain from it would be adequate to make that worthwhile.

Senator BARNETT—Any other drugs?

Dr Weisberg—There are lots of drugs that are used off label, but I have worked in the area of reproductive and sexual health for the last 30-odd years, so I am really out of touch with general medicine.

Senator BARNETT—What about mifepristone? If that was approved for use to treat irregular bleeding—and you referred to that earlier in your statements—would you ever consider recommending mifepristone off label for inducing an abortion?

Dr Weisberg—The only time that mifepristone would be used off label under those circumstances would be if the woman was deemed medically unsuitable to have a surgical termination—for instance, if she was an anaesthetic risk, she had a previous Asherman's syndrome or there were contraindications to surgical abortion and it was important for her to have an abortion. But I do not anticipate that would be the case. I also do not anticipate that the firms that manufacture mifepristone or RU486 would actually be prepared to put in a

marketing application for the indication for bleeding with progesterone only methods because, again, I do not think that it would be a commercially viable enterprise for them.

Senator BARNETT—So have you or your organisation ever recommended it for off-label purposes?

Dr Weisberg—No, never. We have only ever used it within the indications that we were given a CTN approval for.

Senator BARNETT—You mentioned the pilot program earlier in your statements—the trial of mifepristone. I understand that you have received a grant from the US National Institutes of Health for your trial of mifepristone for irregular bleeding.

Dr Weisberg—Yes, that is correct.

Senator BARNETT—Can you describe the nature of that grant and how much it is?

Dr Weisberg—Yes. We still have it at the moment. It is still valid. We received $US1.3 million over five years to research management protocols for unacceptable bleeding patterns in women using Implanon, the long-acting subcutaneous implant. That grant will expire towards the end of next year. The pilot project has been completed. We have published the results. We are now in the process of enrolling for the main study. The grant is through the American government.

Senator BARNETT—I understand that one of the treatments that you are studying or have under review involves a course of RU486 in an attempt to stabilise the endometrium. Were you the doctor who applied through the special access scheme to import the drug?

Dr Weisberg—Yes, I did, but it was not through the special access scheme; it was through the CTN. What we did was put in a CTN—a clinical trial notification—having had it passed by our ethics committee. We received approval for our CTN. It was not through the special access scheme.

Senator BARNETT—How many batches of the drug have been imported? Can you describe to the committee the nature and quantity of the import?

Dr Weisberg—I cannot remember offhand exactly how many tablets we imported, but we imported enough for the 200 women in the trial program to be given 25-milligram tablets daily for five days. Actually, I am wrong, because it is a randomised trial. They were randomised in the pilot study to mifepristone alone, mifepristone with oestrogen, and doxycycline, and placebos. So it was actually only for 50 women.

For the main trial we have imported enough for 100 women, because we have 500 women in the study and we are randomising them to mifepristone plus ethinyl estradiol, to mifepristone plus doxycycline, to doxycycline alone, to doxycycline plus ethinyl estradiol and to placebos. So there will be 500 women in the study, of which 100 women will get mifepristone plus EE. I have no idea who they are because we do not break the randomisation code until we have actually analysed the data.

Senator BARNETT—So you have no idea who they are?

Dr Weisberg—No idea.

Senator BARNETT—But 100 of the 500 will be receiving mifepristone.

Dr Weisberg—Yes, and they will be taking 25 milligrams daily for five days in combination with ethinyl estradiol or doxycycline and they will be repeating that after 28 days for three cycles. We will compare their bleeding pattern for the three months or 90 days before, for the 90 days of treatment and for the 90 days following treatment.

Senator BARNETT—Has this occurred or will it occur in the future?

Dr Weisberg—It is actually under way at the moment.

Senator BARNETT—Do you have any records of their adverse events and those from use of RU486?

Dr Weisberg—We keep very strict records of any adverse events, whether they are related to drug treatment and trial treatments or whether they are totally irrelevant to the trial. For instance, in one study a woman fell off a horse and we had to record that, but it had absolutely nothing to do with the treatment she was receiving from us.

Senator BARNETT—Can you advise the committee as to the nature and extent of the adverse events as a result of the use of mifepristone?

Dr Weisberg—I can only tell you from the pilot study, because we of course have not analysed the data for the main study because it is still under way. From the pilot study the percentage of adverse events and the type of adverse events were equally the same for all four arms of the study, so they were the same for the placebos, they were the same for mife plus EE, they were the same for doxycycline and for mifepristone alone. So there were no adverse events that were not common to the other groups.

Senator BARNETT—How many people were in the pilot program and when was it undertaken?

Dr Weisberg—There were 200 women in the study. There were 50 in each group.

Senator BARNETT—When was that undertaken?

Dr Weisberg—It was completed last year, so it must have been started in 2004.

Senator BARNETT—Would you be willing to make the outcome of that public, or is it public?

Dr Weisberg—It is published in *Human Reproduction*. That was published in January this year and it was put on the web for *Human Reproduction* in November.

Senator BARNETT—So we will not know the answers to the full study until next year, you are saying, in terms of the adverse events.

Dr Weisberg—Probably later than that, because it is going to take some time for us to analyse the data and I am not prepared to jeopardise the study by breaking the randomisation code before we have analysed the data, because that would bias the results of the study.

Senator BARNETT—All right. Are you aware or can you categorically state that your organisation has not been involved in using mifepristone for abortion purposes?

Dr Weisberg—Yes, I can. We have never done abortions at Family Planning. We do not do abortions and we have never used mifepristone for abortion.

Senator BARNETT—Do you think it is possible that doctors outside your organisation could have accessed mifepristone, perhaps through other means?

Dr Weisberg—No. It is extremely difficult—we had difficulty in getting it. We had to get it from China. We actually got it through a hospital in China.

Senator BARNETT—My question is: once it became available in Australia through your organisation for your research purposes, do you think it may have become available to doctors outside of Sydney, perhaps in Canberra, for abortion purposes?

Dr Weisberg—No. We actually keep very careful account. Part of good clinical research practice is keeping very strict account of all drugs that go in and out. We ask patients to return their empty pill packages and to return any capsules that they have not used. We have no way of identifying which are the ones which contain mifepristone anyway, because they have been made into identical capsules for all arms of the study. So I cannot tell which ones have mifepristone in them.

Senator POLLEY—We have heard a lot of evidence in relation to it now being legal to have an abortion. I was wondering whether, from your perspective, there are in fact limitations that ought to be based on the process whereby the baby dies and limitations as to the length of time when using medication as opposed to surgical abortion. Is there any limitation? Or should it just be that, as other people have given in evidence, an abortion is legal and therefore there should be no bounds?

Dr Weisberg—In fact mifepristone, or RU486, is only recommended at the moment for medical abortions up to eight weeks or nine weeks of pregnancy; it is not recommended for late terminations. So, yes, there will be the same requirement in Australia and the same protocols, I assume, will be used as are being used overseas.

Senator POLLEY—But the actual time it takes for the baby to die, from the time you take the medication to the time the baby dies to when it is expelled, is considerably longer than a surgical procedure—

Dr Weisberg—We do not know that.

Senator POLLEY—Should there not be any consideration given to that?

Dr Weisberg—We do not know how long it takes for the embryo to become unviable. What happens with the way that RU486 works is that it is an antiprogesterone. It binds to the progesterone receptors in the endometrium, the lining of the womb. Once you get a lowered progesterone level, the viability of the embryo is prejudiced because you need progesterone to maintain a pregnancy. The misoprostol that is used two days after the mifepristone is only to help uterine contractions to expel the products of conception. It is not to kill the embryo.

Senator POLLEY—So should there be limitations on the medication that is used, depending on the time that it takes for the baby to die? Yes or no?

Dr Weisberg—I cannot understand that question, I am sorry. Can you explain to me what you mean?

Senator POLLEY—I do not see any need to go on. I withdraw. I think you have answered it already.

Senator ADAMS—Thank you for your submissions. I would just like to ask a question on the Australian Drug Evaluation Committee within the TGA. Are they set up to look at specific drugs, or is it one evaluation committee that calls on expertise from different areas?

Dr Weisberg—It is one committee, and they call on expertise in different areas. I have had no experience with ADEC itself, but I know how MDEC, the devices panel, works. They have expert panels which then report to MDEC on a particular subject on which they are expert. For instance, if they have a problem with an intrauterine device or something, they would ask me and several other people who have expertise in the area to give an opinion, and then the devices evaluation committee would discuss that, make a decision it and give some advice to the TGA. They have a group of experts, and then they have expert committees and expert groups who report in and assess the data that is being given to them by the TGA.

Senator ADAMS—How is the first group of experts, the top tier of experts, appointed? By the minister?

Dr Weisberg—I think they need ministerial approval. I certainly had to be appointed by the minister.

Senator ADAMS—As far as RU486 and needing ministerial approval rather than the TGA having not evaluated it because it has not been approved, where would the minister go to obtain information?

Dr Weisberg—I presume he would have to go to the TGA. I do not know where else he would go, unless he goes to the research data, and there is an enormous amount of research data on RU486. It has been used for medical abortion for at least 10 years, and over 2.5 million medical abortions have been carried out with it. There have been quite detailed reports about RU486 which have shown the level of side effects, the level of problems that arise with it and also women's attitudes towards having medical or surgical abortion.

Senator FIELDING—We heard evidence on Friday from Dr Seman, whose submission quotes the *New England Journal of Medicine* as saying that there is a higher maternal death rate for chemical abortion versus surgical abortion in early abortions. Are you concerned that that 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?

Dr Weisberg—I think your statistics are somewhat wrong, because in fact there have been more than one death from surgical abortion in the last 11 years. I cannot tell you the exact figure, but there certainly have been more. If you look at the American statistics, the mortality rate from abortion is 1.1 per 100,000 women for medical abortion and one per million women for surgical abortion. I agree that the earlier the surgical abortion is done, the lower the mortality rate. I know the article that you are referring to. It is the one by Greene. Can I read to you what his conclusion was at the end of that article:

As tragic as the deaths of these young healthy women are, they remain a small number of rare events without a clear pathophysiological link to the method of termination. Patients should be informed of this risk before they consent to the procedure and should be vigilant for symptoms after the procedure. Providers must be aware of this potential complication and not be reassured by the absence of fever.

They are talking about sepsis, which was the cause of the four deaths in the United States over four years. It continues:

Regulators should keep this rare complication in perspective and not over-react to exact data by prematurely foreclosing the only approved medical option for pregnancy termination.

That is the conclusion that Greene came to in that article.

Senator FIELDING—Just following on, the figures I was quoting there were expected, not actual. If, for medical abortions, the figure is higher, then you would expect it to be even higher for the other way around. Those are expected figures based on the professor's ability to predict those numbers. So, even though the numbers you are quoting are actual, I was quoting theoretical values. So it is a comparison between the two. You would expect more coming from RU486.

Dr Weisberg—No, I would not expect that, because those four deaths in the United States were due to *Clostridium sordellii* infections. *Clostridium sordellii* is a fairly rare organism. It is found in soil and in water and in human guts, and five to 10 per cent of women carry it in their vagina. There have been four deaths from that—sorry, there was a fifth one in Canada during the trial. There have been seven post-partum deaths from *Clostridium sordellii*. So, no, I would not expect that the rate of mortality amongst women having medical abortions would be higher. The interesting thing about all those deaths was that they all occurred in California. I have no idea why it should just happen in California and nowhere else. They certainly have not been reported from elsewhere in the world. There have been another, I think, seven cases of death or infection by this particular organism in men undergoing prostate biopsy, in a child with an ear infection. So these infections can occur in anyone. Nobody has as yet said that they were due to the RU486. We do not know why these women developed this infection.

Senator FIELDING—Some of those are based on voluntary reporting, but I can say that from what I have seen in looking at the submissions we have had in the three days of hearings, there seems to be a consistent view that there is a higher number of potential deaths from RU486 compared to surgical. I am sure you do not agree with that, because you have a different view. I am saying it is from what I have heard.

Dr Weisberg—Let me say that the data does not support that. There were four deaths reported in France very early in the use of medical abortion and that was because the cardiovascular risks of misoprostol, not RU486, were not recognised at the time, and those women were really not suitable to be given misoprostol. Now there are very strict exclusion criteria for medical abortion.

Senator POLLEY—Following on from that, isn't part of the difficulty that we all have, in making a true assessment of whether or not RU486 is indeed a healthy alternative form of abortion, the fact that in the United States it is not mandatory to report any deaths or any complications from the use of the drug, therefore all the research that is being done in Australia now is based on flawed evidence from the United States? And we have just seen as well that Italy have now banned RU486.

Dr Weisberg—But I would think that that is probably much more for political reasons than for safety reasons. All the evidence has been assessed by 35 different countries throughout Europe and including the United States and Israel. They have all looked at the data and found

it to be a safe alternative to surgical abortion. I think the issue really is that women in Australia should have the same choice as women overseas as to whether they opt for medical or surgical abortion. I am sure that most of them will still opt for surgical abortion. It is a much quicker and simpler procedure than going through medical abortion.

Senator BARNETT—Safer?

Dr Weisberg—No, I do not believe it is safer. I think they are equally as safe. If you look at the incidence of adverse events, they are exactly the same. The incidence of haemorrhage and of transfusion is exactly the same for medical abortion. The incidence of infection is exactly the same for medical as for surgical abortion.

Senator POLLEY—But we really do not know that because it is not mandatory to report any complications.

Dr Weisberg—There is a very big study that was done by Planned Parenthood in the United States and I actually have the figures here. They had a very strict protocol for the reporting of all adverse events that occurred in planned parenthood clinics over a period from 2001 to 2004. There were 95,163 medical abortions carried out, which was a very small proportion. It was about five per cent of the abortions that were carried out at the time. The failed abortion rate was 3.5 per 1,000. Heavy bleeding was 2.2 per 1,000. Heavy bleeding requiring transfusion was 0.5 per 1,000. The uterine infection rate was two per 10,000. The sepsis rate was 2.1 per 100,000. Amongst those women, the septic shock death rate was 1.1 per 100,000. That is very strict evidence, because they had to report every single adverse event.

Senator WEBBER—Before I actually ask my question, I refer, Dr Weisberg, to the other information you were giving us before about deaths not being just connected with the use of RU486. I was wondering if you could actually provide the committee with that data, because you are the first person that has actually talked about the other deaths.

Dr Weisberg—I have not got it here, I am sorry.

Senator WEBBER—No, not right this minute but at some time.

Dr Weisberg—Yes, certainly I can give it to you. That was very early; that was about 10 years ago.

Senator WEBBER—It would be useful for us if you would put that in context. In terms of the clinical trial that you have been conducting, is it fair to say that all clinical trials, particularly when they revolve around the import of a fairly contentious drug, have very strict ethical and scientific guidelines with which you must comply in order to be able to conduct those trials?

Dr Weisberg—Yes, there is actually a code of conduct for good clinical trial practice and we have to comply with that—and we do comply with that.

Senator WEBBER—Otherwise there are fairly severe consequences if you do not?

Dr Weisberg—Yes. There are extremely severe consequences. We also have to report annually to our ethics committee so that they will continue their approval of the research. Any amendment to the protocol or any adverse events have to be reported to the ethics committee.

Senator WEBBER—The terms of reference of this inquiry are about who should evaluate and who should decide whether a particular pharmaceutical is safe for use in Australia within our circumstances and context. There has been some criticism of the Therapeutic Goods Administration by previous witnesses about whether they have the capacity to make that decision. You have expressed some confidence in their ability to do that. It would be fair to say, as Senator Moore has alluded to, that not only would there be ongoing monitoring but, if they were to make that assessment—and we do not yet know that they are going to say that it would be safe; this legislation just talks about initiating that process, not determining the outcome of that process—they would then devise a regime for the administration and ongoing monitoring of that drug. It would not be a free-for-all where you can do what you want once it is able to come into Australia. It is being referred to as though, if this is allowed to go ahead, it is do-it-yourself abortion, do-it-at-home abortion.

Dr Weisberg—That is a complete misconception which has been propagated in the media. Basically what happens in its use in other countries is that the woman who has decided that she wants to terminate her pregnancy—and in Australia she would have to be within the law of the particular state—goes to the clinic. She is then assessed as to whether medically she is suitable to take the drugs involved. She is then given all the information about both surgical and medical abortion—the benefits, the risks et cetera—and it is then her decision which method she decides on. If she decides on medical abortion, she is given the mifepristone, the RU486, and she then goes away. In some countries—certainly in the UK—she has to go back to the clinic to get the misoprostol. They usually abort within four hours of taking the misoprostol. The bleeding can go on for some time after that, but it is always done under supervision, and all the protocols insist that the woman has to be within easy access of medical assistance, should there be an adverse event. So it is done under very carefully controlled conditions.

Senator WEBBER—I am aware we only have about three minutes to go, so I will try to wrap this up now. It would be fair to say that we do not know and cannot predict what the TGA are going to say, but we therefore also do not yet know what that administration regime would be in Australia. If they were to say that it was safe, we do not know what guidelines or what have you they are going to give us. How the drug would be used is subject to media conjecture.

Dr Weisberg—No, I do not think that is true, because I would imagine that anybody who is putting in an application to the TGA for marketing would in fact put in recommendations for how it should be used, and the TGA would either approve that or go back to the sponsor and say: 'We don't agree with that. What about doing it this way?' And the sponsor has the right to reply to that.

Senator BARNETT—I wanted to draw the committee's attention to a letter from the Australian Christian Lobby. They believe they have been misrepresented by the Public Health Association. So that is on the public record. Dr Weisberg and any others, are you familiar with the list of drugs on the restricted goods list, to which the legislation refers?

Dr Weisberg—I have looked at the legislation, and it says 'restricted drugs such as mifepristone or drugs that can be used as abortifacients'. I have not looked at the restricted drugs list, but I still think that if a drug is going to be safe, irrespective of what its use is, it

should be the statutory body which has been set up to assess its availability and safety who should make the decision.

Senator BARNETT—My point is that we are referring to eight drugs—they are on the public record on the restricted goods list—as well as a vaccine. It is of great concern to me that none of the witnesses who have been before us have outlined the nature, impact and effect of those eight drugs. We have all been talking about mifepristone, but it seems that there is a huge gap with respect to the other seven and the vaccine.

Dr Weisberg—Could you list them for me? I would be interested to know what they are.

Senator BARNETT—I am happy to pass this to you if you like, though it is on the public record.

Dr Weisberg—The hCG vaccine has stopped being developed. That is what it says in the legislation—'such as vaccines'. The human chorionic gonadotrophin vaccine could be used as a contraceptive but it has not proved to be effective and is no longer being developed, so that is not relevant anymore. Gemeprost is on the market. If you look at MIMS, Gemeprost is actually approved for use to induce labour, but it is also approved in MIMS for use for induction of second trimester abortion. Misoprostal is also on the market as Cytotec for the treatment of gastric ulcers. So these drugs are not really restricted as such, and prostaglandins are available for the induction of labour. They are not totally restricted.

CHAIR—I thank you all for your appearance today and your submissions. I also wish to thank all those who have been present or have contributed to the work of the committee. The committee will adjourn until its meeting tomorrow to deliberate on the report.

Committee adjourned at 5.16 pm