
COMMONWEALTH OF AUSTRALIA

# Official Committee Hansard

# SENATE

## COMMUNITY AFFAIRS LEGISLATION COMMITTEE

**Reference: Research Involving Embryos and Prohibition of Human Cloning Bill 2002**

THURSDAY, 26 SEPTEMBER 2002

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## WITNESSES

**SENATE**

**COMMUNITY AFFAIRS LEGISLATION COMMITTEE**

**Thursday, 26 September 2002**

**Members:** Senator Knowles *(Chair)*, Senator Stott Despoja *(Deputy Chair)*, Senators Barnett, Denman, Heffernan and Hutchins

**Substitute members:** Senator McLucas for Senator Denman and Senator Eggleston for Senator Heffernan

**Participating members:** Senators Abetz, Bishop, Boswell, Buckland, Brown, Carr, Chapman, Collins, Coonan, Crossin, Eggleston, Evans, Faulkner, Ferguson, Ferris, Forshaw, Harradine, Harris, Hogg, Lees, Lightfoot, McGauran, McLucas, Moore, Murphy, Nettle, Payne, Tierney, Watson and Webber

**Senators in attendance:** Senator Barnett, Bishop, Boswell, Collins, Eggleston, Harradine, Harris, Hutchins, Knowles, McLucas, Stott Despoja and Webber

**Terms of reference for the inquiry:**

On 21 August 2002 the Senate, on the recommendation of the Selection of Bills Committee, referred the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 to the committee for inquiry and report by 24 October 2002.

**Committee met at 3.38 p.m.**

**DILL, Ms Sandra Kaye, Executive Director, ACCESS, Australia's National Infertility Network Ltd; and Chair, International Consumer Support for Infertility Network**

**ILLINGWORTH, Associate Professor, Peter, (Private capacity)**

**JANSEN, Professor Robert, Medical and Managing Director, Sydney IVF**

**POPE, Dr Adrianne Kristina, Director of Laboratory Services, Monash IVF**

**CHAIR**—I call the meeting to order. This is a continuation of the Senate Community Affairs Legislation Committee inquiry into the Research Involving Embryos and Prohibition of Human Cloning Bill 2002. As I have stated previously, the committee has been asked to inquire into the bill to inform the Senate in its deliberations on the bill. I remind honourable senators that their questioning should remain focused on the issues that are relevant to the bill. I welcome Professor Peter Illingworth, Professor Robert Jansen and Ms Sandra Dill. I believe that Dr Adrianne Pope is on her way, so we will welcome her when she arrives.

Witnesses are reminded that the giving of evidence is protected by parliamentary privilege. However, the giving of any false or misleading evidence may constitute a contempt of the Senate. The committee has approached these hearings as a panel style committee hearing whereby we have your submissions in front of us and we invite you to make any brief additional comments that you might like to add, at the conclusion of which honourable senators will be invited to ask you questions. Professor Illingworth, would you like to be first cab off the rank?

**Prof. Illingworth**—Thank you for inviting me here this afternoon. I did not put a submission in to the committee but I am very pleased to be able to assist with this important and serious inquiry. I wear a number of different hats in relation to this process. I am a

gynaecologist who has spent the last 14 years in reproductive medicine and infertility. I am director of a medium-sized research clinic in the western suburbs of Sydney. I am Vice President of the Fertility Society of Australia—although I need to emphasise that my comments today are entirely my own and should not be taken as official Fertility Society policy. I chair the Fertility Society committee revising the national IVF data collection process with the twin objectives of improving the efficiency of the system and enhancing the transparency of infertility data reporting. I am a member of the NHMRC working party advising the Australian Health Ethics Committee in its current revision of the ethical guidelines for ART. I lead a research group with NHMRC funding for a study of egg development, maturation and release. We do not currently carry out human embryo research.

You have already heard discussion about some of the potential applications of embryo research. I would like to describe the other side of things by taking you through an IVF cycle, and I have provided some diagrams which I will talk to. I am aware that some you are already extremely well versed in this area. The account may be a little basic for you, but I think it is important to lay out the clinical background to this debate. During a normal menstrual cycle, a number of eggs will start growing but only one will go on to be released. One of the principles of IVF is that injections of follicle stimulating hormone mean that all or most of the available eggs will grow and can be collected. The main determinant of the number of eggs collected is therefore the number already growing at the start of that particular cycle, and it is simply not possible to predict the number of eggs that will be collected in an individual woman in response to a given dose of drug. The eggs are collected and fertilised in the laboratory by either coating the egg with sperm, IVF, or injecting a single sperm into the egg—a technique called ICSI. Either way, the number successfully fertilised is going to vary and it is not possible to know in advance how many embryos will result. My figure illustrates a typical number of six out of nine, but sometimes all of the eggs will fertilise and sometimes it will be one or even none.

From the day of fertilisation onwards, the appearances can be quite distinct between high-quality embryos with a good chance of implantation and clearly abnormal embryos with no chance either of implantation or of surviving a freeze-thaw process. Again, it is just not possible to know in advance how many embryos are going to be of good quality. Normally one to two embryos are replaced, with the remainder being considered for freezing. In our unit, decisions about the subsequent storage, use, disposal or donation of these embryos, or research on them, are made through tight procedures involving the informed consent of the parents at each stage. These procedures have been developed under the guidance of the bioethics consultative committee of the Western Sydney Area Health Service and take into account the wide ranging moral and cultural beliefs of the diverse population that we serve.

I, too, am aware of the figure of 70,000 apparently excess embryos in Australia, but I would like to describe our experience in this area. As of five o'clock yesterday afternoon, we had 3,695 embryos in storage in our clinic. However, the vast majority of these embryos are in active clinical use. In 2001 we stored 1,708 embryos and thawed 1,210 embryos. In other words, the turnover every year is over 60 per cent of the total number of embryos in storage at any one time. Only six per cent of the embryos stored in our unit have ever been actively disposed of. Another six per cent have been in storage longer than five years. Why would any parents leave their embryos in storage for so long without making a decision? The main reason, in our experience, is that they find themselves torn by the ethical dilemmas involved. On the one hand, they cannot bring themselves to dispose of the precious embryos while, on the other hand, they cannot bring themselves to donate and thus effectively put their embryos

up for offspring. The end result, in practical terms, is that they do not return our letters and we lose contact with them.

We actively promote embryo donation but, once the couples have been through the processes of counselling and reflection, in practice fewer than one per cent finally opt to donate. It is therefore simply not realistic to suggest that embryo donation could be an alternative to the ultimate disposal of some of these embryos. I would like to point out that embryo freezing is clinically very important as it contributes to over a quarter of all the IVF births—in other words, creating 1,400 Australian families in 2000 alone—without the need for repeated courses of drugs and procedures. Patients will sometimes choose to dispose of their embryos. They should also be able to opt that, prior to this disposal, those tissues can be used for the improvement of human health through worthwhile scientific research and other activities.

**Ms Dill**—Thank you for inviting me to be here today. I represent infertile people as the executive director of ACCESS, Australia's National Infertility Network and chair of the International Consumer Support for Infertility, the iCSi network, which is a coalition of patient leaders from around 35 countries. In addition to serving as a consumer representative on national and state government working parties, I have been invited to bring consumer perspectives on infertility to scientific, governmental and patient organisations including the World Health Organisation, where I have just completed two years as a temporary adviser; the US Centers for Disease Control and Prevention; the European Society of Human Reproduction and Embryology; the Japan Society of Fertilisation and Implantation; the Australian Medical Association; the Victorian Infertility Treatment Authority; and the South Australian Council on Reproductive Technology. My experience over 12 years of medical treatment included eight IVF attempts, an IVF miscarriage in the second trimester and facing a decision to cease treatment and live with involuntary childlessness.

Our primary concern with the Research Involving Embryos Bill 2002 lies in the way it impacts on IVF clinical practice, which is already governed by several layers of regulation. I have detailed a few examples in our submission. I would like to comment briefly here on three recurring themes raised by other witnesses. Firstly, several witnesses have mistakenly referred to 71,000 surplus frozen embryos. In fact, these are stored embryos, most of which will be transferred back in treatment, as Professor Illingworth has indicated. Secondly, concern has been expressed about creating excess embryos, as though doctors could somehow control this. With the greatest respect and appreciation for the expertise they bring to our endeavours to have a child, doctors do not create life—they provide a safe place for the gametes, the egg and the sperm, to meet; they cannot control how many eggs will fertilise. Thirdly, as infertile people, we have heard judgments being made by other witnesses about our attitudes to our embryos. Some have suggested that we have stored them like frozen vegetables, that we treat them without respect, that they are our sons and daughters, that they are fodder for scientists, that they are not surplus but unwanted.

These assumptions are inaccurate and misguided. We care about the fate of the embryos that once had the potential to be our children and want to see that their existence has had some meaning. We are responsible for their future. The opportunity for our embryos to have some added meaning would be given if we were permitted in law to donate them to embryonic stem cell research. This would be consistent with families who give consent for organ donation following the death or impending tragic death of a loved one. The wishes of the families are rightly respected, as no-one loves the person more or has a greater interest in their welfare. It is important to note that no research may be conducted without our express consent.

We do not believe that to use surplus embryos for research would be disrespectful—quite the contrary. For many couples, allowing them to expire on a laboratory bench without ever having had any added value would be less respectful. An IVF embryo is not a human person who would suffer in the process; it is a cluster of cells with extraordinary potential, even though more than 90 per cent will not result in a live birth, given the chance. Infertile people reject the suggestion that anyone else values or respects our embryos more. We value life and we value children, which is why we have been prepared to undergo extensive investigation and treatment in order to create a family.

The Sydney Diocese of the Anglican Church accuses us harshly of possibly treating our surplus embryos as a commodity, and argues that our guardianship should be transferred. I am a Christian and a parishioner of an Anglican church in the Sydney Diocese, and I have a different view, one that is more aligned with that one of the Anglican Primate, Dr Peter Carnley. The contentious nature of this debate is clear evidence of sincerely held but different moral views, whether faith based or otherwise. ACCESS believes that this diversity of views should be respected. If this bill is passed with the amendments proposed by Ms Teresa Gambaro, you will ensure that consumers of ART services continue to have access to the highest quality health care and the best chance of having a healthy baby. You will acknowledge infertile couples—who have sought from the beginning to act in their embryos' best interests—by allowing them to make decisions according to their conscience. Fertile people in our community enjoy the right to act in their children's best interests; importantly, you will treat infertile people with the same respect by ensuring us corresponding rights to make decisions about embryos that once had the potential to be our children.

**Prof. Jansen**—The amendments which I will be asking senators to consider could appear to be relatively minor, but I believe them to be important. Let me open by saying that I believe there is much to be commended in the bills. The Research Involving Embryos Bill is predominantly enabling. Amongst other purposes, it would encourage states in which embryo research is presently illegal to correct that unfortunate situation. The Prohibition of Human Cloning Bill is proscriptive, but I think we all agree that its central thrust, to ban human reproductive cloning, is a proper subject of prohibitory legislation.

I draw senators' attention to the Human Embryo Experimentation Bill 1985. It was considered by a Senate select committee, which reported in September 1986. The main report was not endorsed by the parliament of the time, perhaps at least in part because of an articulate and well argued dissenting report by Senator Rosemary Crowley and Senator Olive Zakharov. They drew attention to that bill's lack of meaningful respect for the rights, wishes and interests of women.

I would like to take the opportunity to elaborate on this perspective. Advertently or inadvertently, the present bills risk the same difficulties for women, and I respectfully suggest that senators who are interested read Senator Crowley and Senator Zacharov's dissenting report of 1986. I suggest they consider in that light the amendments to the Research Involving Embryos Bill which Ms Gambaro has moved and the amendments to the Prohibition of Human Cloning Bill which I have suggested. Rosemary Crowley and Olive Zakharov focused on identifying the woman who would live with the consequences of her decision, rather than the status of the embryo—which is at least as ill-defined and ill-definable today as it was in 1985—as the crucial decision maker on the fate of individual embryos. The senators wished to see precluded, prohibited, the creation of embryos for other than IVF purposes. They wished to see the creation of embryos prohibited other than in the context of infertility treatment, because it could lead to the existence of embryos with the potential for life with no responsible decision makers—a result I believe all of us today, too, wish to see avoided.

Senators Crowley and Zakharov felt that firstly, by properly attributing to prospective parents the right to make choices concerning their embryos, there is an in-built break on areas of medical and scientific research. I believe the Research Involving Embryos Bill 2002 as it stands, unamended, is capable of advancing this central principle, but it will depend on the manner of implementation of the foreshadowed regulations under section 25(2)(f). Secondly, Senators Crowley and Zakharov felt that in any medical treatment program every step possible should be taken to reduce risk, to minimise pain and suffering and to achieve a successful outcome and that this should apply to IVF as it does to other areas of medical treatment. Sections 14(1), 15, 18 and 22(4)(c) of the Prohibition of Human Cloning Bill 2002, if left unamended, risk violating this imperative.

I am asking senators, in debating these two bills, to be cognisant of the possibility of unintended consequences of this legislation. These unintended consequences comprise, firstly, the risk of pushing IVF treatment protocols involving fertilisation of eggs and the culture of embryos directly into clinical practice without adequate evaluation in the laboratory under approved and, if necessary, licensed protocols; and, secondly, the risk of pushing women into accepting other women's eggs as treatment instead of their own. In this respect, I draw attention to the point I made in my submission on the Prohibition of Human Cloning Bill. Of the sections that I mentioned before: section 14(1) bans experimental fertilisation of eggs, and sections 15 and 18 ban studies on cytoplasmic transfer. These prohibitions will comprehensively prevent research into what normally, but unexpectedly and dismayingly, causes sterility in women from their mid-30s, years before the menopause. I am grateful for the opportunity of making those points before answering questions.

**Senator BARNETT**—Thank you for the submissions today. Ms Dill, thank you for the comments you made in regard to the ethical issues. I agree with your views that it is a dilemma we all have as members of the committee to try to determine what the right framework is. I respect your opinion and respect others who have a different view, and I appreciate your comments in that regard. Can I clarify that the Gambaro amendments that Professor Jansen referred to in his submission and introductory comments were considered in the House of Representatives, but I understand that they were withdrawn. Is that your understanding?

**Ms Dill**—Yes. They were withdrawn and the person who spoke to the amendments said Ms Gambaro was hoping that the Senate inquiry would allow particular scrutiny of the issues that she raised.

**Senator BARNETT**—Sure, but they were withdrawn from debate in the House of Representatives?

**Ms Dill**—Yes.

**Senator BARNETT**—Can I clarify your understanding of the number of stored human embryos in Australia?

**Ms Dill**—There are over 71,000.

**Senator BARNETT**—I will ask some questions on the consent provisions, to whomever would like to respond. What are your thoughts or views on the consent provisions in the Research Involving Embryos Bill? Some witnesses have put the view that you simply require a one-line consent from the donors of the human embryo. I was wondering if you believed that that was an appropriate measure of consent or whether something more comprehensive would be required.

**Prof. Jansen**—I am sure you would appreciate that formal protocols for human embryo research are illegal in some states in Australia, but in New South Wales they are permitted under the guidelines of the National Health and Medical Research Council. Sydney IVF is the principal organisation in Australia conducting such embryo research under formal protocols. Those protocols are, of course, known in detail to the Australian Health Ethics Committee and have also been described in detail in submissions that Sydney IVF has made to the review presently taking place on future guidelines on the conduct of assisted reproductive technology in Australia.

Therefore, I can describe with confidence the nature of what I would call 'adequate consent' for embryo research, and that is how it is conducted at Sydney IVF. In addition to the provisions for consent to immediate clinical use of embryos, I believe the provisions in relation to the storage and ultimate disposition of those embryos is fairly uniform amongst clinics and is not a point of contention. It is more to do with the conduct of experimentation along the lines of the protocols that I have referred to. We see that consent occurring in stages. We obtain detailed consent, which includes description of those protocols, quite early in the consent and treatment process.

**Senator BARNETT**—Did you say that it does include the description of the protocols?

**Prof. Jansen**—Yes, it does; in lay detail.

**Senator BARNETT**—Have you got a copy of those consent forms or can they be provided to the committee?

**Prof. Jansen**—Most certainly.

**Senator BARNETT**—How extensive are they? Can you describe the types of provisions in such consent papers?

**Prof. Jansen**—Maybe the best paradigm would be embryonic stem cell research. Would that constitute a satisfactory example?

**Senator BARNETT**—Yes.

**Prof. Jansen**—The existence of the protocols is shown to the patients, and they elect at that point to either agree or not agree for spare, unused embryos to be used according to those protocols generally. It is not practical to identify several weeks in advance which precise protocol the embryos might be used in, but we have no indications from our patients that they make meaningful distinctions between them, except that lately some have specifically asked for their unused embryos to be used for the production of embryonic stem cells or research related to that. If there are such embryos, those studies will at that point be done. Advance consent is obtained for stored embryos to be used for some time in the future.

Embryonic stem cell research is only in very preliminary stages at Sydney IVF, but it has been subject to proper protocol evaluation by the independent ethics committee at Sydney IVF and the details of it are known to the Australian Health Ethics Committee. I should also add that that program is not actively being pursued at the moment, pending knowledge of the outcome of the present legislation. In relation to the protocols that were approved about 18 months ago when we were asked by Professor Bernie Tuch if we could help with the research of the diabetes transplant unit at the Prince of Wales Hospital, if embryos were deemed to be no longer of use—under the terms of the legislation, I believe, they are declared surplus embryos—specific consent would be obtained if the research were to involve the promulgation of any kind of cell line. We would then envisage—and we have not taken the research past this point—that further consent would be required for the maintenance of cells in any kind of useable form.

**Senator BARNETT**—What does that mean? Are we talking about two levels of consent?

**Prof. Jansen**—Three. There is the initial consent for research—

**Senator BARNETT**—Is that type of research defined—or can it be defined?

**Prof. Jansen**—Yes, it is—and I am happy to provide that to you. I cannot remember the exact wording but it is sufficient to give patients a comprehension of the fact that embryos will be, say, subjected to different culture media observations.

**Senator BARNETT**—Can the patients in that case define the type of research or say, 'I want it going this way' or 'I want it going that way' in terms of the research?

**Prof. Jansen**—I have not heard them express a wish for any of our particular protocols, which is essentially the testing of culture media, improvements in embryo culture techniques—the development of genetic testing methods on embryos and now the possible production of embryonic stem cells. I just cannot recollect anyone making a distinction, except that lately, as I say, some people have specifically said, 'If my embryos can be used for stem cell research, that is my wish.'

**Senator BARNETT**—What was your second level of consent?

**Prof. Jansen**—That is the first level. The second is that if, at the time of commitment of surplus embryos to research, a cell line is to be established, if cells are to be propagated—in other words, any component of that embryo is to exist in culture for more than several days—separate consent is obtained. We have not taken the work to that point.

**Senator BARNETT**—And that is necessarily done.

**Prof. Jansen**—That is necessary under our approved protocols.

**Senator JACINTA COLLINS**—You are suggesting that, if that is not to be the case, there is only that one level of consent. Is that correct?

**Prof. Jansen**—Yes. There is the consent at the time the embryos are stored. When we are notified by the patients that the embryos are surplus to their needs, if my memory serves me correctly—and I am pretty sure it is correct, but I cannot say how far back in time the necessary paperwork for it may reflect that—the patients are asked if they wish to have the embryos allowed to succumb, or be destroyed, or to have a research project done which will involve manipulations or observations for no longer than several days and which will not maintain the embryos or components of those embryos in indefinite culture. We do not say that at that point but we do not do it either. If we intend to maintain any of those cells in culture beyond the several days that they expect, we must obtain another level of consent.

**Senator JACINTA COLLINS**—A third level.

**Prof. Jansen**—That is correct. A fourth level of consent would be required before those cells were put to any clinical purpose.

**Senator BARNETT**—How does that work?

**Prof. Jansen**—At the moment we can only try to guess the future. Those purposes would be in the hands of people like Professor Bernie Tuch and others who are working on the therapeutic applications of embryonic stem cells.

**Senator BARNETT**—So it is a bit open at the moment—it has not been clearly regulated or defined as to how it would work?

**Prof. Jansen**—No. We would need to be able to put to the people involved just what clinical purpose was being investigated.

**Senator BARNETT**—So, if it is being used for a clinical application, those regulations and the framework for how that consent would be provided has not been formulated as yet?

**Prof. Jansen**—No, I think that is still several years off.

**Senator BARNETT**—I guess that is one of the points I am trying to bring out. Under the bill at the moment you require only that initial consent. It says it is then subject to regulation, which is the point you have been making. So it is not up to the legislators; it is up to whoever is defining the guidelines or the regulations. Is that correct?

**Prof. Jansen**—That is correct the way the bill stands. Much will depend on how those regulations are implemented. I do not think that that would remove from me or my organisation the need for those additional levels of consent.

**Senator BARNETT**—If I am a donor and those levels of consent have been provided, at a later time after that research has been undertaken, can I find out what type of research has been done?

**Prof. Jansen**—Yes, absolutely, and that is true of everyone who donates embryos.

**Senator BARNETT**—Is that legally allowed at any time? What about if, in one year's time, I want to find out exactly what sort of research took place?

**Prof. Jansen**—Every embryo that passes through our laboratory can be traced—its location is accounted for.

**Senator BARNETT**—Do you think there is a commitment that that would be required under this law—or is that still open-ended and to be determined by the framework and regulations that will be potentially set up under this bill?

**Prof. Jansen**—I would need to refer to the wording of the bill. Sandra, do you have anything to add? You are also familiar with the bills.

**Ms Dill**—No.

**Senator BARNETT**—The reason I asked that question is that we have had a witness here who has put the view that, once the consent form is signed, at a later date they have no idea what type of clinical application or research happens to their human embryo. That is a fair question. We are sitting here as a committee trying to work through these issues.

**Prof. Jansen**—I may not, for example, be able to tell a patient whether the medium was designed to test magnesium concentrations compared with calcium concentrations. I would be able to inform them that the embryos were used in the development of culture medium. Likewise, I would be able to tell them to what extent their cells were developed along ES cell development lines.

**Senator BARNETT**—Can I clarify, with respect to some of the sperm donors, that they are anonymous?

**Prof. Jansen**—No, definitely not. Sydney IVF does not deal with anonymous donors at all.

**Senator BARNETT**—Does that happen anywhere in Australia?

**Prof. Illingworth**—Some clinics do still use anonymous donors, but the use of anonymous sperm donors is dying out. In a research context, I do not think that one would ever use embryos that had been conceived as a result of sperm donation. The ethics are just too complex for that and the numbers involved are exceptionally small in any case.

**Ms Dill**—The majority of the embryos stored belong to the couples who contributed them. I am sure there are lots of issues there, but it would go to consent. The sperm was donated to

assist an infertile couple, in those instances where that donation occurred, to have a family. So to then use it for another purpose is outside the terms of the consent. I want to comment that you have been speaking about embryo stem cell research here, but in fact AHEC guidelines require that couples who have frozen embryos stored must give advance directives about what will be done with them. That issue arose initially before stem cell research occurred, where clinics were having difficulty contacting people five or 10 years later and then were loath to destroy embryos without the consent of the couple but were left in some sort of limbo.

In fact, some consumers have come to us saying, 'Clinics are wanting us to give consent up front for our surplus embryos.' They either donate them to research—I am talking about ART research here, not embryo stem cell research, because this bill will capture that and that is the point of our concerns—or say that they want to donate them to another couple or that they wish to allow them to succumb. People will have different views about that, but that has to be given up-front so that there is some certainty. Some consumers do not like having to grapple with that decision up-front. Our view is that if we are going to use these technologies, we need to accept responsibility for the consequences and part of that is to consider what we want done with them in the event of our death, for example.

**Senator BARNETT**—I think the point has been made, because the bill simply requires the consent and it does not talk about an anonymous donor, as Professor Illingworth said, or where you cannot locate and identify the particular donor. If they are not available then you cannot get their consent.

**Ms Dill**—You would not use them.

**Prof. Illingworth**—I think the bill is adequate in that respect in that it specifies that, where it uses donated gametes, consent has to be obtained from the gamete provider. The instances where you would have an embryo with gametes donated by an unknown donor are so small that to prohibit research in that context would have no impact whatsoever on research activity and would be a perfectly reasonable limitation.

**Senator BARNETT**—Nevertheless, there is a gap there. There is a small number where you say consent cannot be obtained.

**Prof. Illingworth**—In that case research cannot proceed on those embryos.

**Senator HUTCHINS**—Are all the people involved in the IVF program infertile?

**Prof. Jansen**—No. There are some couples who have genetic disease. The answer is no, they are not all infertile.

**Senator HUTCHINS**—What about same sex couples? Are there same sex couples involved in the IVF program?

**Prof. Jansen**—There are, but not very many. It is really genetic—

**Senator HUTCHINS**—So if there is genetic—

**Prof. Jansen**—Yes.

**Senator HUTCHINS**—So if they are infertile or there is a genetic disease; there could be another category of fertile but—

**Prof. Jansen**—Socially childless couples.

**Senator HUTCHINS**—And they would want to go through another process.

**Prof. Jansen**—Socially childless is not a common indication for IVF.

**Senator HUTCHINS**—I am sorry, I didn't hear that.

**Prof. Jansen**—I think you are referring to what has been described as social childlessness, as opposed to medical infertility. I know that it does occur in various programs. It is not prevalent at Sydney IVF.

**Senator JACINTA COLLINS**—Is sex selection a component of what Senator Hutchins is referring to?

**Prof. Jansen**—Yes. We do carry out IVF for families with a strong wish to have a child of a particular sex. It involves a great deal of counselling and not all couples are accepted for it. We are painstaking and scrupulous about making sure that no Health Insurance Commission benefits are paid and the full cost of IVF is borne by those couples and families, including the payment of the GST, and the availability of that in our program of genetic diagnosis in embryos for the prevention of genetic disease is the first priority. In other words, we need to be satisfied that no families who are having IVF for prevention of genetic disease are jeopardised or put to a disadvantage by that.

**Senator MARK BISHOP**—How many couples have come to you seeking assistance within the category of sex selection?

**Prof. Jansen**—Over the past four years, perhaps 100 or so.

**Senator MARK BISHOP**—Has there been a preferred gender outcome?

**Prof. Jansen**—We will be presenting this data, as we believe that is the responsible thing to do in such a socially innovative area, at the Fertility Society meeting in Brisbane next month, but I am happy to make that information available to senators. Yes, 60 per cent are after a daughter and 40 per cent are after a boy, which compares with evidence from other Western countries where IVF might not necessarily be used for sex selection, but sex selection clinics exist which are based on the supposed separation of X bearing sperm from Y bearing sperm. The efficacy of those methods is in substantial doubt and many would say that it is no more effective than a full moon and a rooster on the end of the bed for instance. Many folk methods are employed to fulfil a family's desire for a child of a particular sex, including prayer as I am sure you would be aware. Polls, such as they exist, consistently show that in Western countries there is a predominance of people wishing for a daughter.

**CHAIR**—Professor Illingworth wanted to add something to that.

**Prof. Illingworth**—Most clinics will treat a very small number of same sex couples, but the practice of sex selection is not widespread in Australia and I think that it is probably safe to say that your clinic may be the only one in Australia using that technique.

**Senator JACINTA COLLINS**—Do the NHMRC guidelines authorise that process?

**Prof. Jansen**—They do not mention sex selection.

**Senator JACINTA COLLINS**—They are silent.

**Prof. Jansen**—Yes, they are silent on the matter.

**Senator HARRADINE**—Weren't you on the NHMRC when those guidelines were prepared on the first occasion?

**Prof. Jansen**—No. From 1982 until 1988, I was a member of the Medical Research Ethics Committee which, in some ways, was the predecessor of the Australian Health Ethics Committee. The guidelines on IVF, which were the subject of supplementary note 4, which I am sure the senator is familiar with, were produced in 1983, which was two years before I became clinically involved in IVF.

**Senator HARRADINE**—Did you have a substantial amount to do with the 1982 guidelines?

**Prof. Jansen**—With the 1982-83 guidelines?

**Senator HARRADINE**—Yes.

**Prof. Jansen**—I was very much a junior member of the Medical Research Ethics Committee. I am sure that Senator Harradine recalls the distinguished membership of that particular committee, and I would not suggest that I had any major influence over the course of that committee's deliberations.

**Senator HUTCHINS**—On page 3 of your submission, you state:

... 'playing God' is what ... people have to do in a modern society.

Some may consider that IVF itself is 'playing God', particularly with sex selection. On what grounds do you believe, as you also say on page 3, that your responsibility for stored embryos permits people to make a decision to use them for destructive purposes? Would you like to expand on that?

**Ms Dill**—I think that I have the gist of your question. What I said was:

... 'playing God' is what careful, responsible, ordinary people ... do ...

Parents make decisions every day about the kind of medical treatment that their children will seek. We intervene in nature, and we do that in the best way that we can. We do that answering to our conscience and considering everything in a very thoughtful way. People on IVF programs have had to grapple with many of the issues. When my husband and I were first referred for treatment, I had 29 questions to ask, much to my husband's embarrassment, because I wanted to be sure that we would be comfortable in undergoing treatment and that it did not conflict with our particular values. Had we not been comfortable with that, we would not have proceeded. A baby at any price? No. What we did was to try to make choices with the information we had.

The very nature of the discussions surrounding when life begins, the diversity of the theological views and Christian opinion and otherwise about this issue shows that it is one where there is no consensus. Certainly within a group like ACCESS we have people that have very different views. We have learnt not to impose a view that we may have on any individual, and we believe that those views that they have should be respected. That is really what that comes down to. The question of whether or not you are going to allow destructive research on an embryo encompasses how you view an embryo. Yes, it is life and, yes, it is human; so is human sperm, but I do not hear us passing legislation about how that should be used. That is not meant to be flippant. If you have seen sperm under a microscope, you will know that it is very much living. There is no question about that.

**Senator HUTCHINS**—I have never seen it like that.

**Ms Dill**—It is alive; it is quite dramatic. It highlights the fact that, in dealing with science, sometimes we have to separate things that may be a theological judgment or a scientific one—

**Senator HUTCHINS**—Did any of those 29 questions that you asked, which you said were uncomfortable, involve any of the situations such as destroying embryos?

**Ms Dill**—We had to think about that.

**Senator HUTCHINS**—Were they part of the 29 questions?

**Ms Dill**—Yes, we had to ask what would happen. We were told that we may have some excess embryos. They were some of the things that we had to grapple with. We had some time to think about that. We did not have to make those decisions on day one, but they were certainly things that we grappled with ourselves; absolutely. They are not easy decisions. I am not suggesting that they are. But I have seen my embryos under a microscope. I was very connected to them. But we came to a view that they were not a human person. They were a very different thing from that. These perhaps just sound like arguments, but an embryo begins to grow when it is returned to the uterus of a woman. There is no way that that embryo can develop into a child unless it is given the opportunity to embed into a uterus.

My understanding is—and the professors will perhaps clarify this if I get it slightly wrong—that human fertility is very inefficient. For example, around 80 per cent of embryos that are produced by fertile women or couples are going to abort, many before the women even realise they are pregnant. More than 90 per cent of embryos produced in IVF, given the fact that people have barriers to fertility there anyway, even given the opportunity, are not going to develop into children. So it is not accurate to say that embryos that are stored are all going to become children. We can argue utilitarian versus autonomy versus something that is inherently right. They are things that as individuals we have had to do and we have honestly before our consciences tried to come to terms with those things.

**Senator HUTCHINS**—So in the questions you made a decision—not you personally—to donate the embryos for research, did you?

**Ms Dill**—Yes. I just wanted to elaborate on what Senator Barnett asked and whether that ties in with the bill—the description about proper consent. It is covered because it says that consent must be obtained in accordance with the AHEC guidelines, and 3.2.5 of the AHEC guidelines requires that the gamete provider and any spouse or partner of that person must give consent to the keeping or use of any gametes. It goes on to articulate that and the purposes for which they may be used to provide treatment for the provider and a named partner or to provide treatment for others or for specified research. That is an advance directive that must be given. That is only part of the consent that is required.

Once again, as I said before, we believe that if we are wanting to enter into this it can be difficult and there are some difficult questions that we must answer. But surely we have a responsibility to deal with those before we take that step and enter into that medical process, which is trying to correct a medical dysfunction that unfortunately we have. So they are things that are very serious and that we take seriously. Infertile people often feel very isolated. Infertility is not a visible disability and it is something that is very difficult to deal with in society. Publicly and privately everyone has a judgment about the decisions that we make. We are trying to make decisions about our relationship, our partner, ourselves, and any future family we may have. They are decisions that impact on us for the rest of our lives in ways that really only infertile people understand.

**Prof. Illingworth**—In practice, the reality of the situation is that there is not one decision to be made but two really quite distinct decisions. The first decision is: are these embryos going to be allowed to succumb or to be disposed of? Secondly, if so, should they then be used for research prior to being allowed to succumb? I have never met a patient yet who would opt to use their embryos for research rather than donating them for clinical use or using them for their own use. In practice, the decision about research comes as an afterthought, after the issue of inevitable death has been covered. There is nothing particularly unique about that context.

The same situation, for example, would apply to parents of, say, a young child who had been taken into an emergency department and was on a ventilator and was ruled, for example, brain dead. It is an accepted ethical practice that the parents be approached for use of the organs for organ donation and that the parents in that context, where death is inevitable, be in a position where they can choose, or not choose as the case may be, that those organs be donated to save another life somewhere else. The ethical principle is not particularly new.

The second point I would like to make is that we are caught in a situation where the AHEC guidelines for assisted reproduction are loose in places. As you are aware, AHEC is currently in the process of revising those, and that process has been interrupted; it is awaiting the outcome of this legislation before it continues any further. AHEC does also have quite clear guidelines for medical research in general, which specify some quite clear requirements for research for anyone taking part in a research project. It seems likely that those same guidelines would apply to the process of human embryo research.

**Senator HUTCHINS**—I would like to ask Professor Jansen and Professor Illingworth a question. In Dr Bowman's submission—and I gather he is one of your colleagues—he refers to minor projects with regard to IVF research as projects which would require licences under the proposed legislation. What type of minor projects do you believe Dr Bowman is referring to? How would you define 'minor'? What sort of minor tests would Sydney IVF consider minor enough not to require a licence?

**Prof. Jansen**—I believe that would relate to such endeavours as teaching young embryologists new techniques such as embryo biopsy and manipulations in the laboratory.

**Senator HUTCHINS**—Surgery?

**Prof. Jansen**—Do you mean surgery?

**Senator HUTCHINS**—Some minor surgery or microsurgery or whatever.

**Prof. Jansen**—Such as using a laser to make an opening in the membrane around the embryo without overdosing the embryo—in other words, the types of procedures which are very delicate in clinical practice and which, for the first number of times that a young embryologist carries them out, it is better that those procedures be with embryos that are to be destroyed in any case rather than embryos that are destined to be transferred later that day to a woman.

**Senator HUTCHINS**—By destroyed, does that mean that the donors have made the decision to destroy them—

**Prof. Jansen**—Correct.

**Senator HUTCHINS**—or they are having difficulty with—

**Prof. Jansen**—There are also embryos that will not be used because their appearance, we know from experience, is not associated with clinical pregnancy. They have ceased dividing, for instance, or they have degenerated into fragments and for these reasons they will not be transferred and will therefore be discarded without being stored.

**Senator HUTCHINS**—That is the decision the couples are making when they fill out those 27—

**Prof. Jansen**—Correct. At the beginning of their treatment program.

**Senator HUTCHINS**—So they make the decision whether these minor projects are going to be—

**Prof. Jansen**—That is correct.

**Senator HUTCHINS**—For these embryos that are going to be destroyed, what is a major project, and do you need additional permission from the couples?

**Prof. Jansen**—The major projects that we have approvals for, which I referred to earlier, are the development of culture medium improvements, particularly what might be regarded as big step alterations in culture medium rather than slight variations. The other is the development of genetic diagnostic techniques which can involve encouraging cells to divide, because that is what is required to study the chromosomes of an embryo. It is those specific projects that I regard as the major projects of embryo research that perhaps distinguish Sydney IVF from other programs. They need to be essentially healthy embryos and so they come from embryos that are excess to the couple's reproductive ambitions. These are the embryos that would be defined as having been produced prior to the certain date envisaged by the legislation and would be declared surplus embryos.

**Senator JACINTA COLLINS**—And this is destructive research that we are referring to?

**Prof. Jansen**—Yes.

**Senator JACINTA COLLINS**—I will take Senator Hutchins's question just one step further. You have indicated—for want of a better phrase—major projects that have been through the approval process.

**Prof. Jansen**—Correct.

**Senator JACINTA COLLINS**—Can you describe for us what that involved?

**Prof. Jansen**—Yes. They were approved in the late 1990s by the Ethics Review Committee of the Central Sydney Area Health Service.

**Senator JACINTA COLLINS**—Who are they?

**Prof. Jansen**—Royal Prince Alfred Hospital is where it is based.

**Senator HUTCHINS**—Professor Tuch is on that, isn't he?

**Prof. Jansen**—Professor Tuch is at the Prince of Wales Hospital but I do not understand that he is on the ethics committee.

**Senator JACINTA COLLINS**—Was this prior to your establishing what we referred to earlier as an independent ethics committee for Sydney IVF?

**Prof. Jansen**—That is correct.

**Senator JACINTA COLLINS**—And what were the extraordinary circumstances, as I understand the guidelines under review, and how were they determined to be extraordinary in relation to these projects?

**Prof. Jansen**—I cannot say what arguments the committee regarded amongst themselves as compelling in that regard. What we articulated was our proposal and our belief that they were important, and the committee agreed. In particular, I draw attention to the development of particular culture medium additives, which from the mid-1990s doubled the pregnancy rate at Sydney IVF. Those methods have now been made more widely available. As other programs adopt those methods, they see the same quite dramatic improvement in pregnancy rates. Time has informed us that they were important, worthwhile projects.

**Senator JACINTA COLLINS**—Following Senator Hutchins's comments, the issue which I have been trying to get to the bottom of—and Professor Illingworth referred to this earlier, too, when he indicated the review process that has been under way for these guidelines—is where is the public scrutiny in these guidelines? I have been told, at least informally so far—

and in one sense you have confirmed that from your comments just now—that there is no central record of how these guidelines have been applied by institutional ethics committees. How AHEC or the NHMRC can now say, 'This is how the guidelines have operated in a review process,' is beyond me, because there has been no public scrutiny of it.

**Prof. Jansen**—I cannot answer for AHEC on that. I can say that these processes and procedures at Sydney IVF are open to anyone responsible who wishes to look at them. They have been given in some detail in my submissions to AHEC, which I understand are public documents.

**Prof. Illingworth**—I think you raise a very valid point, Senator. The proceedings of all human research ethics committees are meant, in principle, to be public knowledge. The difficulty, though, is that because such ethics committees are essentially local—and they guard their local independence really quite fiercely—it is difficult for the public to see what is happening across the whole of Australia in one particular field. I think that is an issue that AHEC, or whoever is responsible, should take on board. I think that is a very reasonable point.

**Senator JACINTA COLLINS**—I will be asking this of AHEC later, but you may wish to comment from your experience. You have said that they have put this process of review on hold. My difficulty is that we have some fairly grey terms in this bill, such as 'significant gain in knowledge'—and to some extent the proper consent issue falls into this as well. We are told that the revised guidelines will underpin the meaning that is attached to those terms. Then we are told that these guidelines are being reviewed, but even the review is being held up. Essentially, we are being asked to legislate in faith of future determinants of what these terms might mean. The process, with all due respect, seems to put the cart before the horse.

**Prof. Jansen**—I do believe that it is possible to review what has happened in the last 10 years in this area, and to use that as a guide.

**Senator JACINTA COLLINS**—As I said, I have been told—informally only at this stage—that this would be a very difficult process for the NHMRC and AHEC. I have put questions on notice to this effect to be able to provide that detail. I have asked you, in relation to two of the projects that you mentioned, what the extraordinary circumstances were that the ethics committee would have hung their cap on in terms of those guidelines, and you were not able to point me in a direction to understand that.

**Prof. Illingworth**—Could you repeat that point?

**Senator JACINTA COLLINS**—The current guidelines indicate that decisions should be made only in extraordinary circumstances. My question is: in these two cases for Sydney IVF, what were regarded to be those extraordinary circumstances? Professor Jansen said to me a moment ago, 'I can't really tell you what that might have been. I can tell you what our case was, but I can't really tell you what the ethics committee regarded as the extraordinary circumstances.'

**Prof. Jansen**—It clearly is a value judgment, in which you rely on a group of well-meaning people to form a view. That is the current process.

**Senator JACINTA COLLINS**—But shouldn't they record that in a way so that the public can scrutinise it?

**Prof. Jansen**—I have no objection to them doing that, but I cannot speak for the internal note keeping of the ethics committees.

**Senator JACINTA COLLINS**—That is part of my question: has that been done to date and, if not, how do you review what has been done?

**Prof. Illingworth**—It has never been done in any aspect of ethics practice, because historically each individual human research ethics committee is an independent entity in its own right. Although ethics committees follow the guidelines laid down by AHEC, they act independently. I think you are making a very valid point, that there are some areas of particular public sensitivity, such as embryo research, where it would be extremely helpful for you and others in your position to find out quickly what is the situation in terms of embryo research in Australia. I do not think you would find anybody on the clinical or scientific side who would be at all opposed to that principle.

**Senator JACINTA COLLINS**—Yes. What I am trying to understand is how the guidelines relate to that. That has been the problem area.

**Prof. Illingworth**—Yes.

**Senator HARRIS**—Professor Illingworth, thank you very much for your helpful diagrams. At step 5 you state that sometimes spare embryos can be frozen and that abnormal embryos cannot be frozen. Are abnormal embryos used for research at all, with consent?

**Prof. Illingworth**—Yes, they can be. The patient, at the time of the initial IVF procedure, may give consent that in the circumstance where embryos are not suitable for freezing and are not of sufficient quality to be transferred and that they would not survive, those embryos can be used for research prior to their succumbing.

**Senator HARRIS**—So they would not be accountable in the 70,000-odd that are frozen?

**Prof. Illingworth**—No.

**Senator HARRIS**—Could you indicate any research that could not be carried out on those embryos? In other words, is there research for which you need viable embryos?

**Prof. Illingworth**—There is. I am not an expert in stem cell research.

**Senator HARRIS**—No; we will stay with IVF.

**Prof. Illingworth**—But the opinion that I hear from stem cell biologists is that these embryos which clearly have abnormal particles and shapes in them would not be suitable for that type of research.

**Senator HARRIS**—Discretely for IVF purposes would there be a percentage of viable embryos that would be needed for research—in other words, research that could not be carried out on the non-viable?

**Prof. Illingworth**—That is exactly correct, yes, because these embryos are inherently abnormal. If one is testing, for example, a new culture medium one would not test it first of all on an inherently abnormal embryo.

**Senator HARRIS**—Professor Jansen, you may want to comment on this: you mentioned earlier that the bill would place restrictions on some of the research that you can currently carry out. Would that be one situation? You have mentioned clauses 14(1), 15 and 18.

**Prof. Jansen**—Clause 14(1) prevents the fertilisation of eggs in the investigation of a scientific question unless the embryo is for the particular woman whose egg it is, more or less.

**Senator HARRIS**—So that would restrict you from carrying out research for anyone other than the donors. Is that the point you are making?

**Prof. Jansen**—Yes. It will not necessarily be in the interests of that person but it will be in the interests of infertile women generally. There are several areas where these questions are very important for improving IVF. I should preface this by saying that the area where IVF fails to make an impact on socially important infertility is the infertility that occurs in women as they get older, well before the menopause, and which is from the mid-30s and on.

**Senator HARRIS**—Yes. I was going to come to that.

**Prof. Jansen**—That is widely thought to be a shortcoming in the fleshy part—the cytoplasm—of the egg. Ways in which that might be sampled are available. Unless we can see whether the egg is capable of fertilising and then dividing for a couple of rounds, we have absolutely no idea whether or not what we are finding in those eggs is important. We are not in a position where we can make an addition of some crucial molecule that may enable that to be overcome.

The other area is that stimulation—for instance, of the follicles of the ovaries—is necessary to increase the number of eggs available. It would be very useful—and it is felt to be imperative by some—to try to work out what governs the final stages of maturation of the egg, which today occur in the woman's body and lead to considerable enlargement of the ovaries before the eggs are retrieved, so that stimulation might not be necessary. It would not use more eggs but it would enable eggs to be matured in the laboratory instead of in the ovaries of women, which has some consequences. Again, whether our ability to mature the egg is successful or not can only be tested by then fertilising the egg.

**Senator HARRIS**—It would not stop you in the initial stage of doing your research on the egg—singular—but it could impede your ability to then fertilise that egg?

**Prof. Jansen**—Yes.

**Senator HARRIS**—In clause 15—

**Prof. Jansen**—I am sorry, I wonder whether it might be useful to give an example of how such eggs might come about.

**Senator HARRIS**—Could you take that on notice and provide it for us, as I am mindful of the time?

**Prof. Jansen**—Sure.

**Senator HARRIS**—The second clause that you referred to is clause 15, which says specifically that it is an offence to create or develop a human embryo containing genetic material provided by more than two persons. Could you give us an example of where that particular clause would restrict your present ability in the IVF program?

**Prof. Jansen**—It is the specific subject of one of my submissions so it is on record. Briefly, the genetic complement that we all see as our genes of which we get half from one parent and half from the other—they are complementary so there are two versions of each gene—all reside in the nucleus of the cells. The exception to that is that there are 13 genes—13 proteins—involved in metabolism which are not inherited that way. They occur in small battery-like or bacteria-like objects in the fleshy part of the egg, outside the nucleus in the cytoplasm, which are called mitochondria. They contain a small amount of DNA. That DNA has a circular form reminiscent of that which occurs in bacteria. It is almost entirely packed with genes, and those genes are normally the same in all individuals. Hundreds, even thousands, of them occur in each cell. An egg contains perhaps 400,000 of those DNA circles. Whereas the nucleus of, say, a one-cell or two-cell embryo contains just two copies of each gene, these genes for metabolism are there in the hundreds of thousands at that point.

Occasional mutations occur there which have drastic consequences. Those genes are all inherited from the egg—they do not receive a contribution from the sperm—so they only come down the maternal line. If there is a mutation in high concentration—remember that one or two mutations in the nucleus may determine genetic disease, but out in the cytoplasm it is much more concentration dependent—if 40 per cent are mutated, there may not be any clinical consequence. But if 60 per cent are, there will be. All the cells of the forming baby will have this defect in metabolism.

**Senator HARRIS**—I am sorry for breaking in, but the point I am asking is: do you then need to implant something extracted from a third entity?

**Prof. Jansen**—Yes. In effect, the woman who has the misfortune of having every baby affected by this debilitating genetic disease must receive the whole egg of another person under the legislation, which means that baby will not be her own. If she were to receive a cytoplasmic transfer, donated from the fleshy part of someone else's egg, to replace a good proportion of that mitochondrial DNA, the prospect is that she would have a normal child, who would still be her own in every important genetic way. But it would have involved genetic material from a third person.

**Senator HARRIS**—Thank you, Chair.

**Senator McLUCAS**—I want to go to the issue of the licensing of the ART centres that I think all of us have raised. Ms Dill, in your submission you say that essentially it goes beyond the COAG statement. Would you like to expand on that?

**Ms Dill**—It just seems interesting that all the speeches we have heard in the House and all witnesses who have been heard here have spoken about embryonic stem cell research. We understand that this is what has generated particular interest in this bill. Our point is that IVF clinics in Australia have been regulated with various layers of regulation for 24 years. You would be aware of those. In three States there is additional state based legislation. What we are seeing here, because the bill captures some aspects of IVF which are and should be properly accountable, is adding another layer and it does not seem to give any added value. Then there will be the cost that will be passed on to consumers. The way that IVF clinics are currently regulated is in fact supported by clause 11 of the COAG agreement which references the Reproductive Technology Accreditation Committee. Laboratories in addition to that have to undergo NATA accreditation. Some people have suggested, particularly in those States where there is not state based legislation, that the clinics are somehow operating in a vacuum. That is just not true. IVF is arguably the most highly scrutinised area of medicine in Australia.

One aspect of RTAC that is important to note is that although it is a self-regulatory model it is one that has earned the respect of government which was quite sceptical when it was first introduced in 1987. RTAC have withdrawn accreditation from clinics and given reduced accreditation. They are quite serious about what they do. They see the need to do that. But importantly RTAC provide for an independently appointed consumer representative. There are also independently appointed representatives from the national bodies of counsellors, nurses and scientists. Doctors do not approve or appoint these representatives. That is unique in ART practice worldwide and as far as we understand—we have tried to identify other areas—it is unique in the accreditation of medical centres in Australia.

We have four representatives who are specifically trained and give up their time to be part of this process. They go into clinics and see the records. As consumers, in conjunction with the other committee members, we are able to identify whether or not clinics are adhering to guidelines. We are encouraged by that openness to scrutiny. We find that sometimes in dealing with government, consumers of ART are welcomed into processes where things are discussed

and at other times in particular situations they work very hard to keep us out of it, which does nothing but raise our anxiety because you wonder what it is that is so confronting—we would always just be one person on a committee. Our involvement in public policy issues, legislative issues or changes is spasmodic when dealing with other entities. What we do have here is an opportunity to go in there and be welcomed as equal partners. That is not to say it is an easy process. It is one that works but it is one where candid discussions are held. Clinicians take it seriously. All you have to do is to give reduced accreditation, which has happened in a couple of instances, and some clinics have threatened to sue. They very much want to have that stamp of RTAC accreditation. ACCESS makes it quite plain that we will only include on our clinic list clinics that are accredited by RTAC. It is something that is valued.

**Senator McLUCAS**—Can I ask any of the witnesses here to address the issue of extra cost and give us an understanding of what an extra layer of licensing could mean in terms of costs?

**Prof. Jansen**—Perhaps the best example is to look at the situation in Victoria where the state legislation involves an extra cost to couples. Sandra may know what that is.

**Ms Dill**—I do not know what the specific is.

**Prof. Jansen**—It is about $70 or something per cycle. I am just recollecting that that is the case and the same has occurred in the United Kingdom.

**Ms Dill**—From a consumer perspective, we are careful not to be seduced by the assumption that legislation will necessarily protect us from harm. We have the situation in the HFEA in the United Kingdom of the widely reported transfer back of the wrong embryos to a woman. You have a situation in a model that is widely touted as being very useful where consumers in that instance were not protected. We have a situation in Australia, for example, where RTAC goes around to accredit clinics and do site inspections. In the states where there is state based legislation, representatives from the various treatment authorities accompany RTAC people on a site visit so there is clear confidence in that process. They then make their own inquiries. Our concern is that it is an added layer.

The other side of that is that we do not know what the composition of this licensing committee will be. We are always a little paranoid about political processes—you will have to forgive us for that—because we understand that people have very strong views about IVF. Our concern is that, if practices are in place which are going to delay normal clinical research that will improve success rates, that will mean that women will have to undergo treatment that is invasive for longer than would otherwise be necessary. That is of real concern to us too.

**CHAIR**—I now welcome Dr Pope. Would you care to elaborate on the capacity in which you appear?

**Dr Pope**—I am a scientist in clinical IVF. I also represent the Fertility Society of Australia, as a director on their board. I also represent Scientists in Reproductive Technology, of which I am the chairman, which is a subgroup of the Fertility Society of Australia representing scientists in IVF, and I represent the scientific representative of the Reproductive Technology Accreditation Committee.

**CHAIR**—Are you happy for your submission to stand as is and allow senators to continue questioning?

**Dr Pope**—Certainly. I have some comments and a statement that I wanted to make, if possible. I must apologise: it has been an absolute nightmare today; being an engineer would have been useful this afternoon.

**CHAIR**—Are you happy to provide that statement in writing?

**Dr Pope**—Yes; I have a copy in writing.

**CHAIR**—Would that be satisfactory?

**Dr Pope**—Yes, certainly in view of the time.

**CHAIR**—We can have that distributed immediately and allow questioning to continue.

**Senator McLUCAS**—Pursuing that issue of the added layer of licensing, do you want to make any comments on that matter from the point of view of Monash IVF?

**Dr Pope**—Yes, I do. It is becoming quite significant now to patients, particularly because many IVF units in Australia, in attempting to follow quality systems, are now adhering to the NATA ISO 17025 accreditation as well. This is not a requirement for NATA but it is again recognised as another way of an external auditor coming in to assess our systems and for transparency to exist. Again, all of these situations of auditing require additional costs which unfortunately are getting passed on to the consumers.

**CHAIR**—Do you have any indication of costs?

**Dr Pope**—I have been racking my brain trying to think at the moment. I do not know an exact figure for you at this time, but I have a feeling—and I would have to pursue this for you further—that it could be as much as $200 a cycle with many of these ISO accreditation quality systems being added to the quality assurance systems.

**Senator McLUCAS**—Professor Jansen, did you want to make any comments about licensing?

**Prof. Jansen**—No.

**Senator STOTT DESPOJA**—I am going to pursue a couple of the issues that Senator Harris began: one is cytoplasmic transfer; the other one is abnormal-normal distinction. Senator Barnett will have a couple of questions on those issues as well. I would like to start with cytoplasmic transfer because I would like to get my head around that one. Professor Jansen, I understand that the consequence of the clause to which you have referred means that that process would be banned.

**Prof. Jansen**—Correct.

**Senator STOTT DESPOJA**—How much of a part does mitochondrial DNA play in being transferred to an individual's DNA? As per the definition in the bill of a cloned embryo, is there some possibility that cytoplasmic transfer would actually fit that definition—that it would not necessarily be banned as a consequence of the provision that deals with more than two people's genetic involvement?

**Prof. Jansen**—As far as I read the legislation, it does not have anything to do with cloning and it is an extraneous feature of the legislation. I cannot really envisage in what other circumstances the genetic material from three people might be operative. But when reactions of lay people or non-biologically trained parliamentarians include, for instance, the reaction that to have more than three genetic parents would be monstrous, as anyone could tell, one envisages that they are nuclear genes that we are talking about. Mitochondrial DNA, which is a difficult concept to understand, is not part of the understanding of people who react in that way.

I just do not know why that section of the bill was placed there, unless it was specifically to prevent cytoplasmic transfer. To me, it means that I will not to be able to investigate cytoplasmic transfer in the part it plays both in families that suffer from rare but unable to be treated in any other way mitochondrial genetic diseases and in why older women from about

the age of 35 completely otherwise unexplained infertility begins to occur. By the early 40s, that affects the great majority of women—in other words, well before the menopause. IVF is making no inroads into that at the moment, whereas in every other cause of infertility spectacular inroads have been made. We cannot do so unless we understand which cytoplasmic factor is the limitation. We do not know whether that is the mitochondrial DNA itself or some other catalytic component of the cytoplasm of the egg that is missing. Until we can do that investigation, we will not be able to answer that question and advance the management of such unexplained infertility in women in their latter 30s.

Two steps are prevented: one is even investigating the problem in the laboratory, because the experimental fertilisation of eggs is going to be banned under the legislation if it is not amended; the other is in the actual clinical practice of cytoplasmic transfer. As I understand the criticisms of it, they are mainly based on the fact that we do not know why it helps. We do not know if it helps because mitochondria are being added with the DNA that goes with them or whether it is some other component of the cytoplasm that is being brought to bear. But at least 15 children have been born as a result of the procedure in the United States. It clearly is not an obviously abnormality evoking procedure. While I am not saying that it is ready for clinical practice, I do not think that it is out of the ordinary as a subject for scientific and clinical investigation.

**Senator STOTT DESPOJA**—From your response to my question, it is clear to me that the book is not closed on saying that mitochondrial DNA does play more of a role in contributing to an individual's DNA. There is another stream of thought which is that maybe it just goes to the energy levels of the developing cell. You make it sound as if there is not one stream of opinion, that it is still an open debate.

**Prof. Jansen**—We know that the embryo does not make new mitochondrial DNA for about two weeks. This is probably because it would be wasteful; it is so busy making new DNA for the nucleus, which has to double every time one cell becomes two, that it would be a shame for the embryo to use resources to replicate mitochondrial DNA until it is well and truly embedded in the uterus. So there is a halt put to new mitochondrial DNA and the egg must save up. As it develops, it accumulates this additional mitochondrial DNA way beyond its own needs, and that is then distributed to the daughter cells as the egg divides and the embryo forms. After two weeks or so, those cells begin to replicate the mitochondrial DNA and look after their own requirements. If there has been introduced mitochondrial DNA, it will be in a sense metabolically indistinguishable to the embryo, we believe, and the embryo will not care which egg it comes from.

The very small proportion of the DNA that does not code for genes is called the D-loop, which is of great interest to anthropologists and to people studying matrilineal descent because it is very variable—it is like the junk DNA that is used for DNA fingerprinting in the nuclear genome—but not of any particular interest, clinically, to the woman. It is of interest forensically—for instance, in immigration testing to see if a woman is related to people who have migrated to Australia and are claiming they want to bring their mother. How do you prove that the mother is related? You do it through typing the mitochondrial DNA from this small region. But it is a non-coding region, so it is not a gene. While it may have these forensic and anthropological uses, it is not really clinically important. The 15 babies that have been born in the US do show small quantities of the donated DNA tested for by this mechanism. But, our understanding of the inheritance of mitochondrial DNA from generation to generation is that that quite rapidly gets diluted to zero with one or two generations. Occasionally it might take over, but that is of no clinical importance.

**Senator STOTT DESPOJA**—Thank you; you have pre-empted my last question on that issue. In terms of the legislation, what is it exactly that you are arguing for? Are you suggesting that that provision should be removed from the bill, or are you suggesting even a moratorium? You made clear in your opening remarks to my question that there are a lot of things we do not know. Are you arguing that research should be allowed to take place so that we do know the answers to that question?

**Prof. Jansen**—I will refer to my submission.

**CHAIR**—While you are looking for that, Professor Jansen, I will ask members of the committee for approval to have Dr Pope's statement incorporated into the transcript of evidence. There being no objection, it is so ordered.

*The statement read as follows—*

Senators,

Thank you for the opportunity to address this Senate Committee today. I would like to commence by outlining who I am and what my interests are in the Research Involving Embryos and the Prohibition of Human Cloning Bill 2002.

I am a scientist with 16 years experience in clinical IVF. I am the Chairperson of the Scientists in Reproductive Technology, a subgroup of the Fertility Society of Australia, representing scientists involved in ART. I am also a director of the Fertility Society of Australia and a scientific representative on the Reproductive Technologies Accreditation Committee.

I am certainly not opposed to this Bill. I feel society has a right to determine the safe guards for future technology. The ART industry has embraced legislation and regulation over the years. However, I believe the Bill has not considered the implications on future advances in ART and has focused purely on stem cell research. I have watched as the Committee has considered many varied opinions over the last few weeks and I do not envy your responsibility. It is crucial that the discussions do not become embroiled in the assignment of "life status". This question can never be answered. Society accepts the life and death of embryos. It is important to focus on how to ensure that individuals are not coerced by technology into generating embryos as a commodity.

I asked to address you today in view of the potential impact this Bill may have on the future of ART in Australia. The discussion thus far has highlighted stem cell research and has made little comment on the broader spectrum of the Bill, which is "research on embryos". The IVF community has undertaken varying degrees of research or investigation on embryos as part of the evolving nature of the infertility treatment for the last 24 years. During that time both Government legislation and self regulation have unfolded and worked well hand in hand. The Research Involving Embryos and the Prohibition of Human Cloning Bill 2002 will have an impact on material available to IVF researchers and to couples wishing to donate embryos in the future.

Over the last 24 years a number of significant advances have occurred in the treatment of infertility. These have involved a two step process of assessment and verification. The Bill as it stands today would have hindered those advances: The three examples I use are that of embryo freezing; (the very reason we are here today!); blastocyst culture and Fluorescent In Situ Hybridisation, a process for identifying abnormal numbers of chromosomes in cells.

A need was identified in each of these cases - the need to minimise the number of embryos transferred into the uterus and how to maximise treatment options and value for the health dollar. An animal model was used to determine a process and finally human embryos were utilised to assess the procedure and verify the safety.

The benefits include;

- Reduced need for additional surgical procedures
- Allowed for increased pregnancy opportunities
- Reduced medical costs

- Reduced risks of multiple pregnancy

These advances would be difficult to undertake today in view of the proposed legislation. Would the Senate allow for material destined to succumb to be utilised for ART research? The material that would be available in future will be limited to embryos frozen prior to 5th April 2002. This includes embryos frozen up to 5 or 10 years ago depending on the State in which they were frozen. Recent advances in embryo culturing provide a very different cohort of embryos in 2002 than in 1997 or 1992. What impact this may have on future research or development is unknown.

I would like to encourage the committee to consider

- the implications of the Bill on those couples who are responsible for the generation of "donated" embryos;
- the implication of this Bill on IVF treatment in Australia;
- the clarification of the use of genetically abnormal or arrested embryos for destructive research or training of embryologists.
- the need to ensure that the "sunset" clause is upheld. It is vital to constantly review the impact of new legislation on emerging and established technologies and finally,
- I would endorse the Gambaro amendment.

I thank you for your time and consideration.

**Senator BARNETT**—Professor Illingworth, you referred to the research being undertaken on non-viable embryos.

**Prof. Illingworth**—That is correct.

**Senator BARNETT**—How many non-viable embryos are there in Australia, say, per year?

**Prof. Illingworth**—Dr Pope may like to comment on that; it is in her area of expertise.

**Dr Pope**—It is a very difficult question to answer, unfortunately, because it is very dependent on the number of genetically abnormal embryos that may result, which we have no control over; it is literally the roll of the dice as to how they fertilise, if they fertilise correctly. We also have numbers of embryos that actually fail to continue developing so they have an arrested development at around day 2 or day 3. With some people, a large percentage of their embryos may occur in that way.

**Senator BARNETT**—More than 50 per cent?

**Dr Pope**—More than 50 per cent could do that. In others, you may have none—they may all progress as you would expect. It is impossible to predict from cycle to cycle exactly what will happen. It is not even unique to the individual, so it is possible to stimulate a woman in one particular cycle and get a number of abnormal embryos.

**Senator BARNETT**—Can you give us an estimate, based on your many years of experience?

**Dr Pope**—I can talk about two things. I would say that probably 30 per cent of embryos do not progress or have that capability. There are figures that talk about genetic abnormalities—and I am talking about those embryos that may end up with an additional set of chromosomes, so instead of having 23 chromosomes from the female and 23 from the male they may have an additional 23—and that can be quoted as high as 80 per cent in human embryos. Humans do not reproduce particularly well. Our natural pregnancy rate is 25 per cent, so you can see that 75 per cent of all embryos may indeed not be genetically viable.

**Prof. Illingworth**—If I could have a quick stab at a number, I would guess about 40,000 per annum, on the basis of about 20,000 IVF cycles and roughly two abnormal embryos per IVF cycle.

**CHAIR**—Thank you. Professor Jansen?

**Prof. Jansen**—I can answer Senator Stott Despoja's question about the sections of the bill which would require alteration in order not to prevent such research. For section 15, which prohibits 'creating or developing a human embryo containing genetic material provided by more than 2 persons', the insertion of the words 'other than mitochondrial DNA' after 'genetic material' would effect that. For section 18(1), which prohibits altering the genome, the words 'prohibit altering the nuclear genome in a way that is heritable' would correct that. In section 22(4), which defines various embryos as prohibited embryos, again, the words 'other than mitochondrial DNA' after 'genetic material' in 22(4)(c) would—

**Senator STOTT DESPOJA**—I am aware of the sections to which you referred earlier. I just want to clarify whether or not you would like those sections removed. Are you suggesting amendment or removal?

**Prof. Jansen**—I think section 15 could be removed, but it could also be repaired by excepting mitochondrial DNA from 'genetic material'.

**CHAIR**—Professor Jansen, in the interests of time, would you be kind enough to provide to the committee a written explanation of your request?

**Prof. Jansen**—Yes.

**Senator STOTT DESPOJA**—That last statement was exactly what I was after, Professor Jansen, thank you very much. Dr Pope—and, indeed, Professor Illingworth—you referred to the distinction between abnormal and normal embryos. I think we have covered that, but I will first ask you to explain that distinction. In your comments it is almost as if we should know, but I understand that some abnormal embryos are easy to spot as a matter of course but others require an experienced practitioner to make a judgment call. Dr Pope, in your submission you refer to a proposed amendment to distinguish between the two for the purposes of this legislation. Can you tell us more about that?

**Dr Pope**—Certainly. I hope that you have all now received a copy of my written statement, which has arrived, with me, very late. In it I have tried to make this as straightforward as possible, because it is much simpler if you can have a visual idea of what I am talking about. There are two areas which are quite obvious to a scientist undertaking IVF that signify that things may not be functioning as we would expect. The first is what I referred to a few minutes ago as polyploidy. Five pages in, I have outlined what a polyploid embryo looks like. That represents the third set of chromosomes that I talked about. When the egg and the sperm come together, the egg carries 23 chromosomes, the sperm carries another 23 and they come together to form the normal 46 chromosomes that you would find in most of us. On occasions, the egg continues to hold on to 23 of its chromosomes, so you end up with 69 chromosomes instead of 46.

As you can see from this diagram, at the time that we would look at an egg to determine whether or not fertilisation has occurred, these pronuclei—these little dots—are very obvious. If there are two pronuclei there, we know that the egg has fertilised and has the right number of chromosomes in place. If we see three, four or more pronuclei, which we can see on occasion, it is very clear precisely what has gone wrong. Is that clear to you at this stage?

**Senator STOTT DESPOJA**—Does this occur naturally?

**Dr Pope**—It does, yes.

**Senator STOTT DESPOJA**—The reason I wanted to pursue your suggestion is that, if we did that, obviously we would have to come up with a definition as to what constitutes

'abnormal'. Is there a chance that in attempting to do that we would come up with quite an ambiguous definition that would create perhaps more problems than it solves?

**Dr Pope**—I would hope not, because we have gone through the process now of defining an embryo and we have used this definition; we have used the two pronuclei as part of the definition of an embryo. Using that definition allows us to then say that if there are three or four pronuclei, or one pronucleus, it is not what we would consider a normal embryo. So I do not think there would be any confusion on that side of it. Where it does get a little more confusing, I am afraid to say—let me take you back a page—is with embryos that fail to continue to divide.

When fertilisation occurs and those two pronuclei fuse, the whole cell goes on to divide so that that single cell becomes two, then four, then eight and then continues. The first three divisions, through to around eight cells, are driven by the egg, not by the actual embryo. So it takes a number of divisions before the male genomic material kicks in and it truly becomes an embryo. We have embryos in our laboratory, and you will see examples of these, that may get to day 3 and remain as a four-cell or a three-cell or they could get to a five-cell; I have given you some examples of some five-cells here. They begin to fragment and they do not progress any further. By observing these embryos over time, you realise that they do not have the potential to keep dividing. So this is another group that I would look at as abnormal embryos in that they will not continue dividing; they will not make the 128 cell divisions necessary for an embryo to differentiate into the foetus and the placenta. In the laboratory, when we would do a day 3 or a blastocyst transfer, these embryos would not divide that far, and it would be blatantly obvious that they did not have the potential, so we would not transfer these embryos. As such, they fall under that definition of embryos that would not be suitable for transfer back into the uterus.

**Senator STOTT DESPOJA**—Thank you, that is very useful. May I ask one more question?

**CHAIR**—We are running a bit short of time.

**Senator STOTT DESPOJA**—I will put it on notice.

**Senator HARRADINE**—How would you define a normal human embryo then?

**Dr Pope**—It is when two pronuclei are seen. At that first image, where I showed you the three pronuclei, you would see two. I can show you one of those; it is four pages from the back, on a page called 'Fertilisation'. The top image shows an egg with two pronuclei in it, which we predict to be an embryo that is going to continue dividing. It may still arrest before it continues to the eight-cell stage and onwards. The next image is an unfertilised egg, so there are no pronuclei in there; it is perfectly clear. The third image shows again three pronuclei, where you have that extra set of chromosomes. These are the markers we use to determine that fertilisation has occurred. We then wait for cell division to progress. These are quite clearly the parameters that we are using at this point.

**Senator HARRADINE**—In other words, from day 1?

**Dr Pope**—This would be approximately 18 hours after the sperm had been added to the egg.

**Senator HARRADINE**—From that stage you have a distinct individual human embryo?

**Dr Pope**—At that stage you have the genetic material together. It is yet to fuse so that you actually have the combination of the genetic material. There must be a combination of the male and female; they must join together. That is driven by the egg. It divides to two cells,

then to four cells, and then, once it reaches around the eight-cell stage, that is when the male genetic material kicks in. Theoretically, the embryo is not created until around that third phase of division, which is around day 3. Egg and sperm meet together and then the embryo is created from around day 3 on.

**Senator HARRADINE**—But at that stage it has its own DNA, doesn't it?

**Dr Pope**—Yes, it has a combination of the DNA from the male and female.

**Senator HARRADINE**—Professor Jansen, why do you think that Victoria, South Australia and Western Australia have prohibited cytoplasmic transfer—that is to say, the importation of DNA from three persons?

**Prof. Jansen**—I am afraid I cannot answer your question. I do not know why those states have done that, if they indeed have done that.

**Senator HARRADINE**—You do not know that they have done it?

**Prof. Jansen**—I do not know why they have done it.

**CHAIR**—He cannot explain a reason for the state governments having a particular view.

**Prof. Jansen**—Correct.

**Senator HARRADINE**—Do you think it might have had something to do with the mixing up of parentage?

**Prof. Jansen**—No.

**CHAIR**—That is a hypothetical question.

**Senator HARRADINE**—I will ask the professor about his own views on this. Have you no concern about the fact that this is mixing up of parentage?

**Prof. Jansen**—I do not believe it has a mixing-up effect of any importance to families.

**Senator HARRADINE**—But you did say that there have been 15 children in the UK—

**Prof. Jansen**—The United States, yes.

**Senator HARRADINE**—and that does not follow through after two generations. Is that right?

**Prof. Jansen**—This DNA is only detectable by highly sophisticated testing. It has absolutely zero effect on the genes that function in those people. This is non-coding DNA. It is comparable to someone who has had a blood transfusion having a DNA test which reveals the blood of a third person, a third party.

**Senator HARRADINE**—That is certainly not the information that I have in respect of this whole area—the question of the DNA coming from three different persons.

**Prof. Jansen**—Unless you articulate and detail what your information is, then I cannot comment.

**Senator HARRADINE**—I will be able to do that in due course. I do need to get on to the submission that was given by Professor Jansen, rapidly backtracking from what he said to the Senate Select Committee on Human Embryo Experimentation.

**Prof. Jansen**—Sorry, is a 17-year period a rapid backtracking, Senator?

**Senator HARRADINE**—I did not say rapid.

**Prof. Jansen**—My apologies.

**Senator HARRADINE**—Before I go to that, could I point out to you that the parliament did not, as you suggest, refuse to endorse the bill. The committee made its decision, and that decision was that the human embryo deserved respect such that it should not be experimented upon. Given what you have quoted—that is to say, the minority view of Senator Zakharov and the then view of Senator Crowley; and I would suggest you have a word with Senator Crowley as to her current view—

**CHAIR**—Former Senator Crowley.

**Senator HARRADINE**—It is on the record. Given their statements, do you favour the use of human embryos or embryonic stem cells for the testing of drugs?

**Prof. Jansen**—Correct. I do not favour that.

**Senator HARRADINE**—You do not favour the use of human embryos to test drugs?

**Prof. Jansen**—Correct. Unless you define the culture medium for developing embryos for infertility as a drug, but for drugs that are unrelated to embryo culture medium I do not favour the creation of embryos for the testing of pharmaceuticals, cosmetics or any substance that is not considered essential for the development of an embryo for clinical purposes.

**Senator HARRADINE**—Thank you. I want to go to the statement that you made:

It is a fallacy to distinguish between surplus embryos and specially created embryos in terms of embryo research ... any intelligent administrator of an IVF program can, by minor changes in his ordinary clinical way of going about things, change the number of embryos that are fertilised.

You went on to reaffirm that in the evidence, saying:

It would be but a trifle administratively to make those embryos surplus rather than special.

You have given a long discussion about a woman's eggs here, but you were not referring to that when you made that statement.

**Prof. Jansen**—Senator Harradine, you also made those comments on 29 August. I have specifically addressed those in my submission and I believe that my submission adequately informs you and other senators that I no longer hold the view which you attribute to me from 1985, that it is within the power of the treating physician to make a material difference to the number of eggs or embryos available within a woman's IVF treatment cycle.

**Senator HARRADINE**—I attributed those words to you because you made them.

**Prof. Jansen**—Correct. They were made in 1985 and I am no longer of that view.

**Senator HARRADINE**—But you stated at that stage:

It would be but a trifle administratively to make those embryos surplus rather than special.

What has that got to do with the explanation that you have given us here? It has nothing whatsoever to do with it. We are talking at cross-purposes. You then give a dissertation about what is known today about the number of eggs and a lot of other points which appear to me to have nothing really relevant to do with what you stated to the committee.

**Prof. Jansen**—I do not have a copy of the words I used. I am happy to take it on notice and to provide you with a written response.

**Senator HARRADINE**—You quote the words.

**Prof. Jansen**—Can you draw my attention to where I quote those words?

**Senator HARRADINE**—Yes, in your submission to us in the first paragraph.

**Prof. Jansen**—The quote to which Senator Harradine is referring is:

... there was no problem for an IVF practitioner to increase the number of 'excess embryos'.

**Senator HARRADINE**—I was referring to the statements that you made here. I again state that you repeated that in more simple terms. You said:

It would be but a trifle administratively to make those embryos surplus rather than special.

**Prof. Jansen**—I do not recall those words.

**Senator HARRADINE**—It is in the transcript.

**Prof. Jansen**—As I have mentioned, I am very happy for you to provide that quote and its source to me and for me to provide you with a written response if you believe that the general matter to which you refer has not been adequately addressed by me in my submission.

**CHAIR**—Senator, could we move on please, because we are running short of time. Senator Boswell and Senator Bishop want to ask questions as well.

**Senator HARRADINE**—The witness has devoted two pages to that and almost all of that seems not to be related to the statement he made.

**CHAIR**—Professor Jansen has offered to have a look at the comparison between the two statements and to provide an adequate answer to you but we seem to be going around in circles. If you have further questions that you would like to address to the witnesses, please ask them or we can move to Senator Boswell and Senator Bishop.

**Senator HARRADINE**—Professor Jansen, you referred to reproductive cloning in your initial statement.

**Prof. Jansen**—Yes.

**Senator HARRADINE**—I notice you did not refer to destructive cloning for the use in therapy.

**Prof. Jansen**—So-called somatic cell nuclear transfer?

**Senator HARRADINE**—Yes.

**Prof. Jansen**—I have not addressed that in my statement.

**Senator HARRADINE**—Are you opposed to that?

**Prof. Jansen**—I am not opposed to that; no, not as a matter of principle. I accept that, because of perhaps incomplete understanding of the issues, a suspension of activity in that area for three years might be reasonable. I do not have strong views.

**Senator HARRADINE**—But you have always had a view of support for specially creating embryos for the purposes of destructive experiments.

**Prof. Jansen**—The area of clinical activity that Senator Harradine is referring to—somatic cell nuclear transfer, sometimes referred to as therapeutic cloning—is a way of expressing the nucleus of an adult cell in such a way that it becomes undifferentiated and is then capable of forming a stem cell that may be used in treatment. I do not have any particular new issues to raise on the matter.

**Senator HARRADINE**—Are you suggesting that that process is only the process for the type of cloning that you are talking about?

**Prof. Jansen**—Correct. The same process can be used for human reproductive cloning but that is a different purpose. The same step of somatic cell nuclear transfer underlies human reproductive cloning also—

**Senator HARRADINE**—Exactly.

**Prof. Jansen**—to which I am opposed.

**Senator HARRADINE**—But it is the same process, isn't it?

**Prof. Jansen**—It is not the only step in the process for either of the possible ends, which are the production of stem cells that are histocompatible with the person who has provided the material for the process and the human reproductive cloning that we all agree ought to be stopped. There is no ethical or medical justification for human reproductive cloning.

**CHAIR**—Senator Harradine, Senator Boswell wants four minutes and Senator Bishop wants three minutes. It will then be twenty to six, which is exactly the time that we have allocated.

**Senator HARRADINE**—I am sorry, I think this is a very important question to ask so that we have it perfectly clear. Cloning is cloning is cloning.

**Prof. Jansen**—No, it is not.

**Senator HARRADINE**—There is some difference, is there, for—

**Prof. Jansen**—I am happy to provide a written account of what cloning is.

**Senator HARRADINE**—I am perfectly aware of what cloning is. Are you suggesting that there are two types of processes adopted as opposed to one? Somatic cell nuclear transfer is the development of a human embryo and at a particular stage in that development of the human embryo—at whatever stage it would be in the sense of extracting stem cells from one, to its destruction—transferring it into the womb of a woman or to some culture instead in reproductive cloning. It is exactly the same process.

**Prof. Jansen**—I think you have just made the difference perfectly clear in that the difference is those two fates.

**Senator HARRADINE**—But it is exactly the same process.

**Prof. Jansen**—Yes, in the laboratory; you and I agree on that, Senator.

**CHAIR**—Before Senator Boswell begins questioning, I understand that you have to leave very soon, Ms Dill, to catch your flight.

**Senator BOSWELL**—My questions do not relate to Ms Dill.

**CHAIR**—Senator Bishop, could you be quick and ask your questions to Ms Dill?

**Senator MARK BISHOP**—Yes. Ms Dill, I read your submission, and at the bottom of the page it refers to ACCESS as an:

> ... independent, consumer based organisation providing support, education and advocacy for infertile people.

Your submission also shows that you have an extensive organisation across all states of Australia. Without asking you to give particulars, what are the sources of finance for your organisation?

**Ms Dill**—I am perfectly happy to discuss that. We get our funding from a number of sources: from people who join ACCESS to acquire our services; if we have particular educational projects such as fact sheets or seminars we approach pharmaceutical companies, who have their own ethical guidelines, and there are certain things that they can provide; and some clinics make donations to ACCESS. Importantly, though, ACCESS is a limited company. Our memorandum and articles require that a majority of our board of directors and our board of governors, which is an advisory body only, shall always be consumers. In that

way, we maintain the independence and the consumer base of the organisation, which is essential to the work that we do.

**Senator MARK BISHOP**—But you accept donations from industry clinics and pharmaceutical companies?

**Ms Dill**—Absolutely.

**Senator MARK BISHOP**—That is okay. You accept donations from universities?

**Ms Dill**—I would happily accept them if they offered them.

**Senator MARK BISHOP**—And you accept donations or contributions from consumers who seek advice as to particular circumstances.

**Ms Dill**—People join up to belong to ACCESS. They pay $50 a year. The sorts of things that pharmaceutical companies would contribute toward—

**Senator MARK BISHOP**—That is okay, we have not got much time. How many members do you have who have joined for $50 a year?

**Ms Dill**—We have around 5,000 individuals and then we have linked to that some large support groups, each with about another 2,000 members each. They have linked up via their groups but the individuals have not paid their $50; those groups actually support us as corporate benefactors—they make donations.

**Senator MARK BISHOP**—So the 5,000 individuals do not pay the $50—

**Ms Dill**—Yes, they do.

**Senator MARK BISHOP**—Sorry, I misunderstood you.

**Ms Dill**—Some of those are couple memberships, and we will accept $50 for a couple. Sometimes an individual will join and sometimes a couple will.

**Senator MARK BISHOP**—So you would have an income then which was well in excess of half a million dollars per year?

**Ms Dill**—No, we do not. Not all of those people will pay that amount. Last year, our income was—if I had known I was to be asked this, I would be able to tell you—in the area of about $180,000. I am really guessing there, but it is in that vicinity.

**Senator MARK BISHOP**—Say it is in the vicinity of about $180,000, can you tell us in percentage terms how much of that comes from individual contributions?

**Ms Dill**—I think it would be probably only about 20 to 30 per cent. It is a small percentage because we keep our memberships—

**Senator MARK BISHOP**—From pharmaceutical companies?

**Ms Dill**—I guess the balance of our support comes from people who donate—so that would be all corporate benefactors, whether clinics or pharmaceutical companies—for the purposes of attending conferences.

**Senator MARK BISHOP**—That is what I am trying to establish: the amount—

**Ms Dill**—We would not be able to exist and do the work that we do without it. For example, to go overseas to attend a conference, we do not have that kind of money but that falls within the ethical guidelines of the pharmaceutical—

**Senator MARK BISHOP**—I am not—

**CHAIR**—Senator, we are running very short of time and Ms Dill has to go.

**Senator MARK BISHOP**—Yes. I have never heard of a consumer organisation that receives extensive funding from industry bodies and then advocates self-regulation. That is what I am trying to explore.

**CHAIR**—I am just concerned about Ms Dill's flight. Would you like to put those questions on notice?

**Senator MARK BISHOP**—Ms Dill has to go, doesn't she?

**CHAIR**—That is right.

**Ms Dill**—I would be happy to answer that quickly if you wish. So you do not understand why we support self-regulation? The key factor of that is that we are included in—

**Senator MARK BISHOP**—No, I did not say that. I just said I have never heard of a consumer organisation that is so heavily funded by industry bodies. That is my first point. The second point is this: in all the time that I have been here, I have never heard any consumer organisation advocate self-regulation; they all come to seek a degree or a form of regulation. It is new to me—that is all.

**Ms Dill**—We are involved in this regulatory process, which we see as crucial, and that is important to us. That is why we support that.

**Senator MARK BISHOP**—And you are funded by industry.

**Ms Dill**—Consumer organisations around the world receive donations for educational projects. They do not provide core funding. Those decisions are made by the ACCESS board. So they do not stipulate how our money should be spent.

**Senator MARK BISHOP**—You have just told us that 70 per cent of your funding comes from corporate benefactors, and we have had a myriad of them come to us in this inquiry pushing a point of view, one of which is represented by Dr Pope at the end of the table.

**Ms Dill**—None of those people that have appeared here have given us money. We are not involved with stem cell research—absolutely not.

**Senator MARK BISHOP**—I did not say you were.

**CHAIR**—Senator Bishop, may I proceed?

**Senator MARK BISHOP**—Yes.

**CHAIR**—Thank you very much for your time, Ms Dill, as you need to leave.

**Ms Dill**—Thanks for having me here.

**Senator BOSWELL**—Professor Jansen, time is short, so the chairman is being pretty ruthless.

**CHAIR**—No, the timetable is really ruthless and we are now very far over time.

**Senator BOSWELL**—Professor Jansen, you were recently quoted as saying that you wanted to be allowed, under the national law, to do research on fresh IVF embryos. How does this bill help you if you want fresh, not frozen, embryos?

**Prof. Jansen**—I think I was referring to, in certain circumstances, investigating ways in which IVF might be improved. It is necessary, just as it was widespread in the 1970s and the 1980s, for the development of IVF to fertilise eggs and allow their development in circumstances where the chance of pregnancy is low. It is where eggs might become available. I stress it is not a terribly common thing but in investigating the future questions that Senator Stott Despoja was referring to and in effecting maturation of eggs in vitro then

immature eggs, for instance, which are retrieved at the time of a clinical egg retrieval and which have not reached the stages at which they are fertilisable, can be matured in vitro—

**Senator BOSWELL**—Yes, but my point is that this bill will only release frozen embryos.

**Prof. Jansen**—That is the embryo bill. I am talking about the provisions in the cloning bill that prevent the experimental fertilisation of eggs.

**Senator BOSWELL**—We are not talking about that. What I am saying to you briefly is that you say you want fresh embryos, but the bill will only release frozen embryos.

**Prof. Jansen**—I am not sure that I said that.

**Senator BOSWELL**—You are down as saying that.

**CHAIR**—I beg your pardon?

**Senator BOSWELL**—I am sure that we could find your quote in your submission, Professor. You didn't say that in your submission?

**Prof. Jansen**—I do not think I particularly addressed that in a submission.

**Senator BOSWELL**—Okay.

**CHAIR**—Can you point to it in the submission?

**Senator BOSWELL**—I cannot at the moment. If Professor Jansen has not said it then I apologise. I am sure that we may be able to find it somewhere but I may be wrong. This question is to Professor Jansen and Dr Pope. How many embryos will you use and for what purposes?

**Prof. Jansen**—This information has been made available to the Australian Health Ethics Committee in an annual report.

**Senator BOSWELL**—But I do not know that. Could you tell me roughly how many? Is it 10, 20 or 100?

**Prof. Jansen**—In the development of culture medium for meaningful results then we are talking about hundreds.

**Senator BOSWELL**—Hundreds.

**CHAIR**—If you wish to gain an accurate answer, Professor, you are entitled to take the question on notice.

**Prof. Jansen**—You need to have statistically valid numbers to draw conclusions from.

**Senator BOSWELL**—Do either of your organisations have any financial relationship with Professor Trounson? Is he a shareholder or a director? Similarly, is there any relationship with Mr Bob Moses, who is chairman of the National Stem Cell Centre?

**Dr Pope**—Professor Trounson is on the board of Monash IVF. At this point, however, we do not have any arrangements with the stem cell companies. Alan Trounson is the scientific director of Monash IVF and has been now for many years due to his very great involvement in IVF initially.

**Senator BOSWELL**—Does he get a financial retainer or does he do it for love?

**Dr Pope**—He would be on a financial retainer from Monash IVF. I am unaware of what that is.

**CHAIR**—Professor Trounson went through all of that the other day, Senator Boswell. He put it all on the table.

**Prof. Jansen**—I am happy to answer that.

**Senator BOSWELL**—He said he was going to put it on the table.

**CHAIR**—He put virtually all of that on the table in his oral submission the other day.

**Senator BOSWELL**—I thought he was going to put it on the table.

**Prof. Jansen**—Professor Trounson has been a shareholder in Sydney IVF almost since its inception. When we began senators will appreciate that IVF techniques were in their infancy, there was a long waiting list for treatment for couples and many IVF programs went for months and months, even a year or more, without pregnancies. When Sydney IVF started in February 1986 we wanted to be sure that we would not compromise our position in relation to our patients by having to persist in circumstances where pregnancy rates were low and problems in the laboratory required repair. Generally, we would need then a consultant experienced in IVF to help us through those difficulties. We considered that the ethically correct or better way to go was to invite Professor Trounson to become a shareholder and acquire shares in Sydney IVF, rather than have an emergency where we would have to discontinue the program and thus not have payments from patients for medical treatment during a time that problems needed repair. Professor Trounson became a shareholder at that time. He is still a shareholder and is not active in any managerial way at Sydney IVF.

**Senator BOSWELL**—Are either of your organisations associated with IVF America?

**Prof. Jansen**—No.

**Dr Pope**—IVF America was a spin-off from IVF Australia, which was set up by Monash University many years ago, but the company is no longer part of the Monash University companies at this stage. I believe it was bought out by an American consortium. That has not been in place for many years now.

**Senator BOSWELL**—There is no direct relationship between IVF America and Sydney IVF?

**Prof. Jansen**—That is correct.

**Senator BOSWELL**—Is Professor Trounson a director of your clinic?

**Dr Pope**—He is the scientific director.

**Senator BOSWELL**—That is of Monash IVF. Professor Jansen?

**Prof. Jansen**—Professor Trounson was scientific director at Sydney IVF in the late 1980s and perhaps into the early 1990s but not since.

**Senator BOSWELL**—But he is not a director now?

**Prof. Jansen**—That is correct. He is not a director now.

**Senator BOSWELL**—Does he get any remuneration in any other way from your organisation?

**Prof. Jansen**—Not other than dividends from shares, as any shareholder does.

**Senator BOSWELL**—We can look up the shareholding.

**Senator HARRADINE**—You are the director, aren't you, Professor Jansen?

**Prof. Jansen**—I am the medical director, Senator Harradine, and I am the managing director of the company.

**CHAIR**—We are a long way over time. Thank you very much for your input and the time that you have given to the Senate committee today. We are very grateful.

[5.52 p.m.]

**NEVILLE, Dr Warwick John, Research Fellow, Australian Catholic Bishops Conference**

**RIORDAN, Ms Marcia, Executive Officer, Respect Life Office, Archdiocese of Melbourne, Australian Catholic Bishops Conference**

**WILSON, Archbishop Philip Edward, Archbishop of Adelaide, Australian Catholic Bishops Conference**

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

**SOLOWIEJ, Ms Aileen Antonia, Communications Officer, Catholic Women's League Australia Inc.**

**UHLMANN, Mrs Mary Rose, National Bioethics Convenor, Catholic Women's League Australia Inc.**

**CAMPBELL, Mr Raymond Paul, Director, Queensland Bioethics Centre, Catholic Archdiocese of Brisbane**

**CHAIR**—I welcome you all to the committee. Witnesses are reminded that the giving of evidence to the committee is protected by parliamentary privilege. However, the giving of false or misleading evidence may constitute a contempt of the Senate. As you are probably well aware, the committee is conducting these inquiries in a panel type forum. We have before us your submissions. If you would care to make any additional comments you are more than welcome to do so. I do not know whether the representatives from the Australian Catholic Bishops Conference or the Catholic Women's League want to make one additional comment or whether you all want to make comments. That is entirely up to you to decide. Archbishop Wilson, maybe you would like to begin the comments.

**Archbishop Wilson**—Thank you very much. I will make an opening statement, then other members of the group will make further statements. I thank the senators and the committee for giving us the opportunity to come today. The Australian Catholic Bishops Conference appreciates the opportunity to comment on the legislation currently being examined by the committee concerning cloning and destructive embryo research. My colleagues today will offer their own observations from their particular vantage point within the church. My remarks are limited to the fundamental flaw in the legislation before the committee, namely the abrogation of the foundational principle of law and public policy regarding the uniform protection of all human life and putting in its place the deliberate destruction of human life for radically utilitarian, commercial purposes. This debate is about the formulation of public policy and the development of law. Its background is of fantastic, but contentious, claims made by a very small, selective group of scientific researchers, almost invariably without formal medical training, who seek to establish, as a legislative and medical precedent, the destruction of human life. The tools sought by these researchers, and offered now by governments, are embryos created solely to provide children to childless couples.

Frailty and suffering are part of the human condition. It is right and just to seek to alleviate suffering and promote research for cures but, throughout history, research has never been done with a 'blank cheque', either in dollar terms or in the provision of innocent human life as human guinea pigs. Legislators today tread the difficult path of discerning fact from fiction and myth from truth in emotionally charged circumstances—circumstances comprising a volatile mixture of persons with rare and debilitating medical conditions, of money, of politics and of law. These circumstances place high demands on legislators to decide with justice and

wisdom. Accordingly, the role of legislators is to be mindful of the common good and to recognise always that law has a protective, regulative and educative function, in accord with the philosophical and jurisprudential traditions of longstanding in our culture and history.

However, there is a danger in this debate that business, industry and the paradigm of humanity as 'resource, production, property and market forces' might prevail. There is a choice. A line can be maintained, as it was in the euthanasia debate in 1996-97, which says that we ought not make one section of humanity a disposable, marketable commodity and do so for substantial financial gains for a select few who are protected by intellectual property rights. In 1994, the House of Lords Select Committee on Medical Ethics reported on euthanasia. It said:

> ... to create an exception to the general prohibition of intentional killing would inevitably open the way to its further erosion whether by design, by inadvertence, or by the human tendency to test the limits of any regulation.

To a significant degree, the Commonwealth parliament in 1997 agreed with this, and other opinions, that are contained in that report.

Human nature is the same today. It has not changed since 1997. Moreover, in the euthanasia debate there were no readily apparent financial interests at stake. Here, there are vast sums of money in taxpayer funds and via patents. If this parliament decided in 1997 that euthanasia could not adequately be regulated, by what measure can it fairly be said today that embryo experimentation can be 'strictly regulated'? In the Biotechnology Centre of Excellence papers, cost recovery, commercialisation and intellectual property rights figure prominently. It is a matter of public record that a patent lawyer has been recruited from the United States to facilitate the operations of the centre. He is in charge of a biotechnology centre of excellence. It raises questions, symbolically and practically, about the priorities of that organisation.

We know that research for cures for all kinds of conditions will continue even if embryos are not in such an abundant supply. So why are we having this debate about the use of the 'frozen generation'? It seems that there could be two reasons. Firstly, it could be because the IVF industry has stockpiled embryos. Accordingly, some contemplate using these embryos simply because they are said to be surplus. But we know that the industry manipulates the production of embryos. There has been a rise in the number of embryos frozen since 1994, from approximately 22,000 to approximately 72,000 at the present time. The second reason could possibly be that these embryos do not look like us, even though all of us once looked like them.

This legislation purports to enact the COAG agreement of 5 April 2002. The COAG communique states that access to surplus IVF embryos is predicated upon, among other things, research which may lead to medical breakthroughs in the treatment of disease. That is to say, that the legislation proposed is founded upon two things, both of which are highly contentious: firstly, the hypothesis that some treatment of disease might be discovered from the destructive use of so-called excess frozen embryos; and, secondly; because IVF units have stockpiled a large bank of frozen embryos.

We note that Germany has followed a different course. In 1990, Germany enacted its Embryo Protection Act. According to the British Embassy in Berlin's *Fact sheet: biotechnology, medical and life sciences report* of 4 December 2001, this act bans the fertilisation of human eggs for any purpose other than reproduction. In order to avoid the creation of stockpiling of surplus embryos, it bans the implantation of more than three eggs through IVF in one cycle. It outlaws egg donation. It bans human cloning and it outlaws the

creation or use of human embryos for research purposes. Perhaps the legislation in Germany is based on the consciousness of the history of the country, a history which reveals many difficulties in the past with the vagaries and excesses of medical research. Accordingly, it has enacted legislation which accords with the factual reality that the embryo is human. 'Embryo' is defined as 'a fertilised egg cell in which the sperm and egg nuclei have merged and which therefore have the capability to develop into a human being' and are therefore worthy of some basic protection. By way of contrast, the legislation before this committee provides minimal protection for embryonic human life. All that stands between the continued life of an embryo and a researcher's commercially exploitable dissection is a licensing committee.

In passing this bill, Australia will have crossed a line which major international medical research protocols have all said must never be crossed. Embryos created with the sole intention and purpose to remedy the childless state of certain couples are now to be handed over to researchers, under licence, to be used as human guinea pigs. Public policy and legislation based on the deliberate destruction of human life is unworthy of support.

Any possible good end does not justify the use of any means, especially when it is deliberately destructive of human life. Moreover, the radically utilitarian public policy which supports this legislation creates a significantly dangerous, if not chilling, precedent.

**Ms Riordan**—The church provides health care and welfare services to the Australian community, to people of all faiths and none. Many of these services are specifically for women. My colleagues here are better able to detail these services. It is important to note, however, as Archbishop Francis Carroll did in his letter of 13 September, and the Archdiocese of Melbourne did in its submission to this committee, that the concern of the church regarding the exploitation of women as a sole source for eggs is shared by many others in the community.

Women's experience provides evidence of consistent exploitation by certain sections of the medical research community but especially by certain IVF practitioners. I can provide the committee with a short list of relevant references, but I would simply remind senators of the Allars report in 1994 into CJD and the exploitation of women in the extraction of human growth hormone. The church is concerned that women risk being further exploited and pressurised to provide eggs if ES cell research is expanded. More and more eggs will be required from more and more women. It is a concern that we share with many others.

I would like to quote two women legal academics in the United States, published in the 21 March 2001 issue of the *Journal of the American Medical Association*. Cynthia Cohen, from the Kennedy Institute of Ethics, Georgetown University, Washington, DC, wrote:

> Producing eggs engenders increased risks for women. Hyperstimulation can lead to liver damage, kidney failure, or stroke, and ovulation-stimulating drugs have been associated with ovarian cancer, according to some studies. Although women might be willing to undergo such risks for the sake of having a child, it seems clear that either payment from eggs or coercion would have to be used to persuade women to produce eggs for stem cell research. … Thus, before considering embryonic stem cell research, procedures need to be developed to protect women's health and freedom from overbearing financial or other pressure.

Rebecca Dresser, from the Schools of Law and Medicine, Washington University, St Louis, noted in the same journal:

> Creating human embryonic stem cell lines from somatic cell donors would require a large supply of oocytes. Experience in infertility treatment indicates that obtaining such oocytes will not be easy.

These basic issues have never been addressed either at all or satisfactorily by advocates of stem cell research. To my knowledge, they have not been addressed directly in evidence

before this committee. These fundamental issues are not addressed in the legislation under consideration. Unless and until they are adequately addressed, it is in our view completely premature to advance consideration of legislation that, for many other reasons, is founded upon completely selective arguments from a selective group of researchers. Thank you.

**Dr Neville**—Most of my comments are directed to matters of law. The only ethically coherent and ethically consistent course in relation to the legislation under consideration would be to ban destructive research on human embryos. This would be consistent with the approach taken regarding the Euthanasia Laws Act 1997: just as committees of inquiry worldwide held that, firstly, it would be impossible to regulate euthanasia effectively so as to ensure that the human tendency to test the boundaries of regulation would be contained and that, secondly, the uniform protection of all human life was the cornerstone of the common law, so it is with respect to the regulation of embryo research. Where vast sums of money are at stake, it would be impossible to regulate such research so effectively as to prevent more and more destructive research, requiring more and more embryos, be they bar-coded, fresh, frozen or what have you.

On 30 May this year, the Biotechnology Centre of Excellence was announced, as is well known. The central focus of that centre is outlined in the documentation released by the government:

> ... the field of stem cell research has excited significant investment globally because of its capacity for potential returns from all phases of research.

The documentation continues:

> ... the novel fields—

'novel' fields, I emphasise—

> that constitute the Centre's research strategy will generate a variety of discoveries that have significant commercial potential with the capacity to generate substantial benefits. To protect its inventions, and to maintain its brand and reputation in biotechnology, the Centre will actively protect its intellectual property, including patents, copyright and know-how.

There is significant evidence that the commercial emphasis, especially regarding the use of patents, employed in the legislation and by the Biotechnology Centre of Excellence provides a flawed basis for research. This is so for a number of reasons. Firstly, empirical research suggests only a weak correlation between patent rights and innovation. Secondly, there is substantial doubt whether the traditional equilibrium that patent law seeks to strike between private monopoly and public accountability works to maximise innovation in the biomedical field. Thirdly, patent law is centred on economic or market values and has difficulty dealing with ethical and social issues. In an article in a book devoted to this subject called *The Commercialization of Genetic Research: Ethical, Legal and Policy Issues*, Professor Richard Gold from the Faculty of Law, University of Western Ontario, states:

> Since human biological materials are infused with ethical and social concerns, allocating ultimate control over these materials through a system that ignores these very concerns is likely to lead to unfortunate results.

The Biotechnology Centre of Excellence's thrust for the commercialisation and commodification of life, with its concomitant entrepreneurial focus, does not take into account the literature which highlights that patenting in biomedicine does not enhance trust, among other things. Surveys have found that patenting has led to reductions in openness and data-sharing, delays in publication and tendencies to select research projects of short-term commercial interest.

Even more troubling is evidence that corporations with vested interests have tried to suppress the publication of research findings that were not in their interests. For example, in 1997 Craig Venter separated from Human Genome Sciences. He said the move was prompted by company pressure to delay publication of his results to influence his scientific findings. In another example, a British hospital that tested a patient for cystic fibrosis was asked to pay royalties because a private company held a patent on the gene. These matters are documented in an interesting article in the *Hastings Center Report* called 'Homo Economicus: Commercialisation of Body Tissue in the Age of Biotechnology'. That article has been out in the public arena since 1998.

In short, the use of patents and other intellectual property rights has at least two negative consequences. Firstly, it promotes a view of medicine and the provision of therapy solely as a commercial business. This has implications for those without adequate financial resources to gain access to developments and innovations. Thus, there are very significant questions of justice and equity, not to mention discrimination. Secondly, contrary to standard medical research practice and codes of research, patenting and IP rights actually inhibit the distribution of research benefits. Indeed, as Richard Gold states in a book that he has devoted specifically to this, *Body Parts: Property Rights and the Ownership of Human Biological Materials*, some writers have noted:

> ... property interests have skewed research toward biotechnological cures—

because that is where the money is—

> rather than more conventional therapies or efforts to determine the underlying social and environmental causes of disease.

There is some hope of regulation, perhaps. Notwithstanding the pro-research utilitarian philosophy, especially in the research on embryos part of the bill, recent academic legal writings, which were published some months before the legislation saw the light of day, highlight that the Commonwealth Trade Practices Act 1974 might assist the general public from having visited upon them outrageous claims by researchers. How so? In the April 2002 issue of the *Biotechnology Law and Policy Reporter*, in an article entitled 'Commercialisation and misleading and deceptive conduct', one practitioner notes that in addition to the tort of negligent misrepresentation:

> ... a person who acts honestly and reasonably may, despite this, engage in conduct that is likely to mislead or deceive. Intention is not relevant. It is the conduct that is considered by the courts, not the reason for it.

He continues:

> ... a representation can be a statement expressly made or even implied from conduct. A scientist must be aware that an opinion, a forecast, and even silence in some circumstances, can constitute misleading and deceptive conduct.

I have a copy of the article which I will give to the committee secretariat.

Given the accent in the Biotechnology Centre of Excellence papers on commercialisation, cost recovery and protection of discoveries by the use of intellectual property, and given that the legislation provides significant opportunity for concealment under the confidential commercial information provisions, it is at least helpful to know that there are some avenues of protection via the Trade Practices Act which might make the regulation of this burgeoning industry a genuine possibility.

But there is another avenue which, to my knowledge, has never been explored in evidence before this committee—although I have not had the opportunity to go through all of the

submissions. That is, to date there is no discussion of antidiscrimination legislation. Perhaps this is because of the speed with which the legislation is being prosecuted. For example, if it were found that biotech companies were selecting embryos according to their genetic composition—via, say, pre-implantation genetic diagnosis—would not the lapsed Genetic Privacy and Non-discrimination Bill 1998 [2002], promoted by a member of this committee, inquired into and reported on by one of this committee's sister committees, namely the Senate Legal and Constitutional Legislation Committee, be of some relevance? At the same time, would not the current Australian Law Reform Commission and the Australian Health Ethics Committee's 900-page discussion paper, *Protection of Human Genetic Information*, be of some relevance?

In our rush to enshrine in legislation the commercialised access to the frozen generation by a few prominent non-medically qualified researchers, we have not allowed any of these ethical and legal matters appropriate attention. This legislation will set the unheard-of precedent for the statutory creation of a biological underclass—namely, those unworthy of life but worthy of sacrifice on the commercial slab of experimentation. That is the precedent that would be set by this legislation. And what of the inchoate rights of embryos already recognised by the Supreme Court of Tasmania in the landmark case in 1996 of Re K? The frozen generation will be denied the ultimate right of having those rights ever crystallised.

There is a growing body of literature which questions the impartiality of scientists with financial interests at stake. This has been canvassed by the committee at some length, I know. It is a question at stake for academic journals, though, which increasingly are requiring disclosure of all relevant interests of those contributing articles. There are a growing number of articles, such as 'Can you believe what you read?' Increasingly, mandatory disclosure laws are seen as one reasonable way of promoting trust and the sharing of information among researchers and the public. Some go so far as to say that:

> ... disclosure has been embraced as a tool to empower consumers and enhance competition in the heath care marketplace.

Significantly, feminist writers—some of whom have already been referred to—have articulated similar and related concerns for some time. I will give you one example only. In an impressive collection of data back in 1989, Patricia Spallone says:

> Scientific concepts and technologies are being used as the basis for setting the standards of making moral and social judgments about human reproductive practice and so about women's behaviour. In the past, this was the role of religion. Today, science acts as a kind of religious belief in industrialised societies where scientific knowledge is considered superior, 'objective' and closer to the truth.

In 1989, that was an extremely prescient piece by Patricia Spallone. But as medically qualified researchers have said often and forcefully to this committee and elsewhere, there is no proof of principle for destructive embryonic stem cell research. As Professor Rowe, amongst others—and I trust I heard him correctly—stated, the claims made for human ES cell research were 'fairyland stuff'. This is no basis for legislation which sets the precedent of the deliberate destruction of human life.

**Senator STOTT DESPOJA**—Obviously I am biased in relation to the private member's bill to which you referred, but I am just wondering whether this is also an argument, either within this bill or in accompanying legislation, to ban patenting of genes and gene sequences? Is this in any way relevant to this legislation before us?

**Dr Neville**—The short answer is I think it is something which requires significant discussion. I would have thought certainly that it is one of the things that has to be put on the table and, to my knowledge, it has not been.

**Senator STOTT DESPOJA**—You foreshadow the issue of the ALRC review and the inquiry that has just reported and you also refer to the private member's bill—which I hope has not lapsed; I thought I had reintroduced it. Are you talking about that as accompanying legislation—it does not have to be a private member's bill, obviously—or do you envisage a regulatory scheme within a bill such as this that outlaws discrimination on the basis of your genetic information, or at least something in the bill that guarantees genetic privacy?

**Dr Neville**—If there were such a thing as a short answer, I would say yes. I think it has to be out on the table but it is somewhat premature, given that we have a 900-page discussion paper to plough through before we get to making any formal recommendations. The range of things that are canvassed in the report, such as genetic databases and all these other kinds of things—matters of privacy, discrimination and international law—are matters that it would seem to me must be part of the deliberations on this legislation. I therefore think that it is incredibly premature when the two peak bodies, AHEC and the Australian Law Reform Commission, are taking a very long time—there has been an information paper and now there is a 900-page discussion paper—and doing an enormous amount of consultation, and this will be over in the blink of an eye if we are not careful.

**Mr Campbell**—The Queensland Bioethics Centre, of which I am the Director, is an agency of the Catholic Archdiocese of Brisbane. The position put forward in my submission accords with the teaching of the Catholic Church. However, the position that I put forward is not peculiar to the Catholic Church, nor is it based upon some kind of special revelation available to the Catholic Church. The position that I have put forward is based upon science and reasoning. I do not seek to impose upon this parliament some belief peculiar to the Catholic faith. I emphasise this point because, as most of you would be aware, the media have often delighted in portraying this debate as a clash between religion and science and, even in this place, the Catholic Church in particular has come in for special mention.

The position in my submission is put forward as being the most reasonable position for this parliament to adopt—a position founded upon science and philosophical reasoning. It takes into account the wellbeing of all citizens and does not sanction injustice to some members of our community. It is a radical position—it is the position that all human beings should be treated equally before the law. You as legislators had the opportunity to enforce that principle or to deny it. In the end, it is as simple as that. In my submission I have focused upon the issues of the status of the embryo and the distinction between allowing the embryo to succumb and destroying the embryo because, from my reading of the debate both in the media and in the lower house, it appeared to me that there was a great deal of confusion regarding those particular issues. I hope that the discussion in the Senate will not be marked by the same degree of confused thinking as was present in the lower house.

**Mrs Ulhmann**—I would like to make a correction to our submission. On page 2, 'mouse video' should read 'rat video'. I apologise for the error. CWLA is an organisation of some 8,000 women in rural and city areas across the nation. We welcome members from other faiths and we very much appreciate the opportunity given to us to attend this Senate hearing. Our members have been involved in the stem cell debate since it began. We were represented at the human cloning inquiry in support of the submission and in the consultation on the Research Involving Embryos and Prohibition of Human Cloning Bill 2002. We applaud the splitting of the bill and the vote against human cloning. Our members have followed the debate very carefully and have spent many hours studying the papers and articles written on stem cell research. We are totally in favour of stem cell research; the problem is the source of the stem cells. We cannot support the use of embryonic stem cells which results in the death of the embryo or the creation of embryos for the purpose of obtaining stem cells. We fully

support the use of adult, mature stem cells, which are also found in children, or of stem cells obtained from cord blood.

The continuing success with patients using stem cells from these sources—as well as the discovery of multipotent adult progenitor cells by Dr Catherine Verfaille—supports our position, whereas not one person has yet been helped by embryonic stem cells. The claims made by those supporting this research appear to have been exaggerated and misrepresented. For example, the now discredited video shown to politicians would have played a big role in influencing their decisions, as were the claims that embryonic stem cells would cure many serious illnesses. This must surely be a matter of grave concern and it calls into question other statements and claims that have been made. It has also misled the public. False hope has been given to many who are hoping for quick answers to their medical conditions. It is becoming apparent that their best hope lies with adult stem cell research which is ethical, compatible and available now.

We would like the bill to contain the words 'human embryo', to remind those who vote that we are dealing with human life. The question of when life begins has featured greatly in the decision making. It would appear that it is okay to destroy embryos to obtain stem cells, as it is done very early and they are not human. If they are not human, why are they wanted? We all began as a cluster of cells. If implanted, a foetus would develop; we did not begin on the 14th day. Without this simple beginning, there would be no life. Life begins at the moment of conception and fertilisation. This is not only a religious argument but is backed up by the work done by Richard Gardner, an embryologist at Britain's Oxford University, which is mentioned in our submission.

As a person who has been part of a heart transplant research program for six years, I would readily accept adult stem cell therapy. But I would reject the use of embryonic stem cells, as I believe it will be many years before they can be used safely on human subjects, if ever. They have the potential to cause tumours. I doubt very much whether they can grow me a heart in a Petri dish.

If this bill is passed, we predict that, as mentioned in the media almost as a throwaway line, the embryos now in storage will not be sufficient for scientists' needs, and access to embryos created after April 2002 will be asked for. This could in fact be on the COAG agenda for 2003, as the NHMRC are going to review it in a year.

We are very concerned about the possible exploitation of women which will occur if the number of eggs needed to provide embryos for the provision of stem cells is to be achieved or if embryos are to be created by nuclear transfer. Will poor women be encouraged to sell their eggs? Will IVF patients be given drugs to overstimulate egg production, and at what risk to their personal health and safety? Will therapeutic cloning come on the agenda at the next COAG conference, or will it appear under a more acceptable name—nuclear transfer? Will states that are not satisfied go it alone? If the bill is passed, how will it be adequately policed? As scientists gain one point, there always seems to be another; they are constantly pushing the barriers.

This is not a good bill. The rights of inspectors to enter premises and the commercial-in-confidence clause seem to very much advantage those involved in the enterprise. How can we be sure just what is happening? Do we know now? Will parents be fully informed of the possible uses their embryos will be put to? Huge sums of money are involved and it is more likely that embryos will be used for testing pharmaceuticals or for other research. It will be many years before embryonic stem cells can be used on humans. There are only limited funds for stem cell research. Let them go to the area where results are being achieved now; namely,

adult stem cell research. Please vote no to this bill and allow time for the work being done to be more thorough and for claims to be verified. The research will continue, just as in the United States, using existing stem cell lines. Thank you.

**CHAIR**—Do you wish to make any additional comments?

**Ms Solowiej**—From the point of view of the CWLA, we did not have a lot of time to respond in the time given for submissions. Just from a personal point of view, a lot of people in the community whom I have spoken to do not really have a fully informed idea of exactly what this bill is about.

**Mr Sullivan**—As senators may well know, the Catholic Church is the single largest provider of non-government owned health care services in Australia. Along with the direct provision of services from conception to natural death, the church also conducts world-class medical research institutes and bioethics centres. This is a tangible and substantial commitment to protecting and enhancing the dignity of life and the value of every person, regardless of their circumstance and degree of sickness, disability or suffering.

It is within this context that I make the following observations regarding the Research Involving Embryos and Prohibition of Human Cloning Bill 2002. When the Prime Minister, state premiers and chief ministers convened at the Council of Australian Governments on 5 April 2002 to discuss stem cell research, they did so amidst a public debate concentrated on the veracity or otherwise of the use of adult and embryonic stem cells. This debate was fuelled by the proposition that such stem cell research may lead to the alleviation of some degenerative diseases at some point in the future. The decision taken was to ban human cloning but permit the harvesting of stem cells from embryos. Why?

Put simply, there is a ruse being perpetrated by members of the scientific and business community. I would go so far as to suggest that a deliberate campaign of misinformation is being conducted. They have built up false expectations that miracle cures are just around the corner, if only experimentation on embryos can be permitted. Their spin works something like this: 'Of course no-one in their right mind would suggest anything as ghastly as seeking permission to clone embryos and humans, but to be able to experiment on unwanted frozen embryos will give enough scope for the promise of cures to be advanced.' As a consequence, we have COAG making an illogical and rushed decision. They banned human cloning and received almost universal approval, but they permit destructive experimentation on surplus embryos, even though there is almost universal acceptance that these embryos will not be suitable for proper research if the aim is to advance the search for cures to Parkinson's disease, Alzheimer's disease, motor neurone disease, diabetes, spinal injuries and heart failure.

This is a very important issue. The surplus embryos available for research will not be suitable if the end game is the pursuit of treatments and cures of degenerative diseases. Firstly, scientists already realise that the current techniques for culturing stem cells from embryos are unsuitable because they have been grown on mouse tissue. This means that there is a high risk of virus transfer from animal to human species. Therefore, it is pointless earmarking surplus embryos for research, given how any extracted stem cell lines from these embryos will be cultured and the risk of xenotransplantation. It will take little time before researchers are looking for more reliable subject material. Secondly, the embryos in question are surplus to IVF needs because they have been deemed less than suitable for implantation. These embryos have some irregularity in their texture or shape or in the way they have divided, such that they were considered inappropriate for implantation.

For similar reasons, they are not likely to be the preference of embryonic stem cell researchers. They may be preferable for other embryonic researchers but that is not the intent of the COAG decision. Many of the frozen embryos have been stored for extended periods. They will need to be thawed before being dismembered. This further compromises their usefulness. Moreover, these embryos are of a different genetic type to the likely recipients of the cells and tissues generated. The risk to recipients is still too unknown. Frankly, a more logical position would be to undertake human cloning so that properly cultured and immunologically suitable embryos could be created to harvest stem cell lines.

Interestingly, Professor Trounson was reported in the *Australian* on 27 March this year as not only calling for destructive research on embryos but also seeking no ban on what is euphemistically called 'therapeutic cloning'. This means creating cloned embryos out of the body of cells of a patient and donated nucleated eggs and then dismembering these customised embryos to generate the stem cells specific to the patient. It still involves destroying human embryos, but it deals with the issue of immunological rejection and genetic differences. There is little doubt that the real agenda is to create a permissive environment to push for the legalised cloning of embryos to advance the pursuit of cures of degenerative diseases. In the meantime, the permission to conduct research on surplus embryos is broadened to allow for other than stem cell extraction such as training and speculative experimentation, which caters to the commercial needs of the industry, to be advanced almost through the back door. It beggars belief that these facts were not placed before the COAG leaders. If they were, you would wonder why they were prepared to pursue such an illogical and fraught strategy.

Despite all COAG leaders recognising the contentious nature of this debate and the lack of clarity surrounding the science and the complex ethical issues involved, the briefing papers that supposedly assisted the leaders to come to their decisions have never been released. Moreover, it has never been clarified whether the particular interests or utilitarian bias of some health department officials, particularly at the state government levels, did not sway the provision of information in the process that led to the COAG decision. Furthermore, COAG has not made available any comprehensive information that would better enable members of parliament to inform their consciences on this most contentious issue. When you consider the growing public disquiet over the possible military action against Iraq and the calls for a demonstration of proof to justify such action, the lack of any objective, broadly accepted information to justify the deliberate destruction of human life at the embryonic stage is chilling. I urge the Senate to call for these papers so that in the interests of public scrutiny the degree of objective information available to elected members and the community in general can be improved.

The bill before you goes far beyond the intent of the COAG decision. COAG made a decision concerning stem cell research. It focused on the lawful use of human stem cells for research. It restricted the involvement of frozen embryos to those that existed at the time of their decision. It did not sanction the creation of legislation to enable excess embryos per se to be destroyed in the interests of research and diagnostic testing in the broad. Yet this bill has taken a licence to not only extend the notion of what is an excess embryo but has left the door open to the possibility of future embryo farming. It includes a sunset clause which makes possible the legal destruction of embryos created after the date of the COAG decision.

It is also obvious that agendas beyond stem cell research are being contemplated. The NHMRC, in its selective and non-transparent consultations, listed a range of procedures and techniques to be performed on embryos that go far beyond the accepted understanding of stem cell research. Why have the NHMRC and the drafters of this bill been given a wide brief?

Have they been taken in by the commercial agenda and ruse being perpetrated by elements of the scientific and business community? Do they realise that researchers want to utilise surplus embryos in ways other than stem cell research? There is clear evidence that the research community is divided over the likelihood of breakthroughs concerning treatment of diseases with respect to embryonic stem cells. Researchers who also have formal medical qualifications confirm that, firstly, human embryonic stem cell research is highly problematic due to tissue rejection problems and the development of teratomers; secondly, there is no 'proof of principle', or evidence of the efficacy of human embryonic stem cell research; and thirdly, adult stem cell research provides an ethically more prudent and medically more significant course of research for the treatment of disease.

This is a very contentious and divisive bill. It is being pushed through the parliament with inordinate haste. It lacks anything near the public scrutiny and information sharing, let alone the appropriate parliamentary processes, that were afforded the euthanasia issue. Even at this late stage, confusion rather than clarity reigns. We urge you to hasten slowly before you enshrine in law a dangerous precedent which permits the deliberate destruction of human life and discriminates against one stage of life in favour of others.

**Senator BARNETT**—Firstly, thank you for your submissions and the arguments that have been put. It is very much appreciated. In a previous submission made this afternoon, Professor Illingworth advised that research was currently being undertaken on non-viable human embryos as well. He advised that in his estimation there could be somewhere around 40,000 non-viable embryos in Australia per year and that would be in addition to the 71,000 currently in storage. Based on that advice, is it your understanding, Dr Neville, or whoever would like to respond, that that would be the number available for research—the 40,000 plus the 71,000?

**Dr Neville**—That would certainly be my understanding, subject only to any new sort of regulation that might be put on that by the licensing committee.

**Senator BARNETT**—Exactly, and that is the point that I am coming to—that is, the regulation of the research under the consent provisions. The consent provisions under the bill are basically very limited. It could be a one-line consent made available by the donors. Under the bill, it refers to the ethical guidelines on assisted reproductive technology or any other ethical guidelines that are provided by the NHMRC. I do not know whether you have had a chance to have a look at these guidelines but, with respect to the consent provisions, 3.2.5 says that it provides consent 'for specified research' and it says, 'see guideline 6.4'. If you turn to clause 6.4 of this particular guideline, which will then be the regulations that apply, it says:

Approval requires:

> A likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed research.

Would you care to enlighten us on your views of the definition of 'significant advance in knowledge or improvement in technologies for treatment as a result of the proposed research'?

**Dr Neville**—There are a couple of aspects that arise here. One is that, as you would be aware, those guidelines were published in 1996 and they are the subject of review at the moment. So, again, it only adds to the speculative nature and, therefore, also the difficulty of this committee and the parliament to enact legislation when, as it were, all of the balls are still in the air. The second thing is that similar imprecise language is in the draft legislation. When you have terminology such as 'significant', to a researcher a 0.5 per cent increase in whatever

may be regarded as very significant but to others it is not significant at all. The imprecision which is introduced is like: how long is a piece of string?

**Senator BARNETT**—Exactly, and I will come to page 5 of the submission. I think you have made a very sensible point in regard to the guidelines—that is, that they were finalised in 1996, six years ago. They are currently under revision and, according to the previous witnesses and the advice that we have received, that revision is currently on hold. If we legislated, we would be signing into effect a law which said that there are consent provisions and regulations and that the regulatory framework for this research is actually in guidelines which are currently in revision. Is that the way you see it?

**Dr Neville**—Certainly, and also, as everyone is aware, guidelines are by and large unenforceable.

**Senator BARNETT**—Exactly, and that draws me to guideline 6.5, which says:

Protocols for ART in any clinic should take account of the success rates of fertilisation typically achieved in that clinic and, on that basis, seek to avoid the likelihood of production of embryos in excess of the needs of the couple. Techniques and procedures which create embryos surplus to the needs of the infertility treatment should be discouraged—

not disallowed, not prohibited but 'discouraged'. Does that concern you?

**Dr Neville**—Yes, I think again that, as the archbishop mentioned, it stands in significant contrast to the way legislation has in fact passed in Germany, where only three eggs are able to be fertilised in any treatment cycle, specifically with a view to avoiding the stockpiling of embryos. Presumably—although I have not checked this—their levels of success in relation to IVF are little different from those in Australia, where we do not have that same regulation.

**Senator BARNETT**—Thank you for that. In the submissions from the Australian Catholic Bishops Conference, on page 5, there is reference to the regulatory impact statement, which details a large range of matters for which a licence can be granted. It talks about the definition of research, including 'to train clinicians in microsurgical ART techniques' or 'for improving ART techniques'. Then, a few sentences later, it talks about the embryos being sought by researchers for drug testing and toxicology studies. On the definition of research, is that the sort of thing that can happen under this bill—that there would be drug testing and toxicology studies?

**Dr Neville**—Given the open-endedness of the legislation, it seems to be quite clear that the only regulation could conceivably come through any conditions that might be imposed by the licensing committee. Otherwise, it is basically open slather.

**Senator BARNETT**—I want to focus on your amendments in part 2 on page 11 of this submission regarding clause 24(2)(b) about informed consent, limitation of consent and variation of consent. We had some discussion about the consent provisions with the previous witnesses. Can you expand on your preferred amendment in clause 24(2)(b)? Do you have that there?

**Dr Neville**—Sorry, which page of the submission is it?

**Senator BARNETT**—It is on page 11 of the submission of the Archdiocese of Melbourne. I am not sure who would like to respond to that. It is 24(2)(b).

**Ms Riordan**—We might hand over to the lawyer present, if that is okay.

**Dr Neville**—Could we take that on notice and get back to you?

**Senator BARNETT**—Yes, just think that through. Mr Sullivan, in your submission you have referred to your concerns about the granting of licences in clause 36(4)(b):

Moreover, by citing the advancement in knowledge or improvement in technologies, the legislation will permit destructive activity loosely associated with objectives of stem cell research ...

You go on to talk about the testing of technologies. Can you expand on that and on your concerns?

**Mr Sullivan**—Yes. It goes back to what was said in the opening statement. If you go back to both the implied and explicit intent of the COAG decision, they were talking about the use of embryonic stem cell research for preventative and, hopefully, curative treatments in degenerative diseases. There was no explicit brief to move into areas of research on embryos per se. There was no brief to go into areas of diagnostic procedures on embryos. Frankly, that whole area of licensing has expanded the brief far beyond COAG and far beyond even the current public debate.

**Senator BARNETT**—So you are saying that the bill as it stands at the moment basically makes certain restrictions but then it sets up this regulatory regime which is in the land of the never-never.

**Mr Sullivan**—The reality is—and I am happy for Dr Neville to add to this—that the structure of the licensing authority is very open-ended. I am not sure—and I will take advice from the Senate—whether in setting up regulations in guidelines those guidelines will be disallowable instruments.

**Senator BARNETT**—Regulations are disallowable instruments, but if it is in the hands of the committee that makes the regulations or makes the guidelines then it is in the hands of that committee. That is the way I read it at the moment, but that is obviously a matter for the committee.

**Mr Sullivan**—In our draft we also question the composition of the committee and the degree to which there would be enough objectivity on the part of the committee to ensure that decisions taken were again in line with the supposed intent of COAG.

**Senator BARNETT**—I realise that time is short and other senators would like to have a go so I will finalise my questions. On page 11 of the submission from the Archdiocese of Melbourne you have recommended a whole range of amendments. Did you want to comment on clause 24(2)(b), the informed consent recommendation? In addition, would you like to highlight which of those amendments are the most important to you?

**Dr Neville**—Could we make some written comments in answer to those questions to expedite the hearing?

**Senator BARNETT**—Certainly.

**Senator WEBBER**—Senator Harradine took us through an interesting process with some of the witnesses we heard from earlier. Dr Pope from Monash IVF went through a detailed definition of where in the fertilisation process she thought the creation of an embryo occurred. Could those of you who particularly said you had a more scientific basis to your evidence give me a definition of where in the process you think the embryo is created.

**Ms Riordan**—We could go into a lot of definitions, but the simplest one is that the embryo is created at the beginning of conception.

**Senator WEBBER**—Right.

**Mr Campbell**—In response to your question, I refer to a few quotes in my submission, but the places to go to are the books on embryology—the textbooks that are used in our medical schools: what people are taught. If you can find me one that says anything other than that an embryo is formed at fertilisation, I would be very interested to see it.

**Ms Riordan**—We refer to that in our submission from the Archdiocese of Melbourne as well. We refer to most of those embryology textbooks that say exactly that.

**Senator HARRADINE**—Could we have the page reference for that?

**Ms Riordan**—It is on page 4 of the submission from the Archdiocese of Melbourne.

**Senator WEBBER**—The recommendation that we allow the freezing of embryos prior to implanting was made in the previous report that Senator Harradine refers to quite often. That was not seen as the ideal solution; it was seen as being the best of a bad lot. Would it not be fair to say that allowing the freezing of embryos prior to implantation has opened the door to the debate as to what we now do with these embryos? If we did not freeze them, if we just created them and immediately implanted them, we would not be having this debate at all.

**Dr Neville**—That is exactly right, which is why the German Embryo Protection Act was enacted so as to limit the use of only 'fresh', as it were, embryos so that there could be no cryopreservation.

**Senator WEBBER**—Can I take it, then, that you are actually opposed to the freezing of embryos?

**Dr Neville**—Yes.

**Senator WEBBER**—I am just trying to get all these issues clear in my mind. It is interesting having a discussion that is not entirely scientific. I have not looked at science since I left high school so the rest of it has been a bit challenging. Given the fact that you are opposed to the freezing of embryos but that it is currently allowed in Australia, even if we restricted the number of eggs that we took in any treatment cycle to try to deal with some of those other ethical issues, what do you think we should do with those frozen embryos? If they do not all need to be used, even if we take three eggs and we treat them but do not implant them all, what do we do with the others?

**Mr Sullivan**—I would suggest that they be allowed to naturally succumb, because, really, the principle we are talking about here is that it is unnecessary to take so many. The whole point is that the motivation in the first place for why they ended up being—for want of a better term—surplus embryos was for the convenience of those running the industry not for the convenience of those seeking to become pregnant.

**Senator WEBBER**—So you would see it as being a greater moral problem to take embryos—because the parents can die or there may be other medical reasons why it is not possible for them to pursue IVF, even if we restrict the number that can be taken—a greater moral dilemma to do something further with embryos that you have conceded would succumb anyway? If they are going to succumb, they are going to die.

**Mr Sullivan**—Yes.

**Senator WEBBER**—So if we accept that, isn't it a moral dilemma if we allow that to happen?

**Mr Sullivan**—I will answer for myself because obviously everyone else will want a go on this one.

**Senator WEBBER**—I do not mind who answers.

**Mr Sullivan**—The issue is, and the dilemma we now find ourselves in—and this is something that not only the Prime Minister but others have said—is that people find no distinction between allowing natural death to occur as opposed to a deliberate action that destroys, in this case the embryo. In our introduction we say that we find that puzzling

because the same ethical distinction was made during the euthanasia debate. We said as a community that we were not prepared to go to the space in law where a direct action that would kill a patient would be condoned. We have said, though, that allowing a patient to die naturally is obviously ethically sound. The parliament made that distinction through a conscience vote, yet we now have people saying that the distinction does not exist, even though through your question you have revealed that there is quite clearly a moral dilemma at that point. So our position is that there is a distinction between a direct action to kill and making a precedented law about that, as opposed to allowing the natural process of death.

**Mr Campbell**—I tried to address this issue at some length in a couple of pages in my submission. I am trying to highlight the different kinds of acts which are involved in taking an embryo from the freezer to allow it to thaw and allowing it then to die because it can no longer survive in the environment, as distinct from allowing it to thaw and grow and then extracting the stem cells, which is a destructive act. The thing about moral acts is not simply the end result; you get a dead embryo, if you like, either way. But the thing about a moral act is what I choose to do—morality is about choices. If my choice is to destroy the embryo then that is one kind of moral choice, in the same way as if I choose to kill a person who is terminally ill rather than let the terminal illness run its course. You still end up with a dead person, but two different moral choices are involved.

**Senator WEBBER**—Indeed. But if it is an embryo that is not going to be used for implantation, for a variety of reasons, aren't we making the decision to kill it as soon as we take it out of the freezer?

**Mr Campbell**—You are not doing the act of killing.

**Senator WEBBER**—But we are not implanting it—

**Mr Campbell**—But the embryo is going to be taken out of the freezer—

**Senator WEBBER**—I hope not too many people are watching this; it is not a very nice discussion to be having. It seems to me that that is a conscious decision, particularly with those embryos that are not being used for implantation.

**Senator MARK BISHOP**—But it is the consequence of the decision, not the decision itself that is important. When you thaw the embryo, it will expire in the course of time. The purpose is not to kill it.

**Mr Campbell**—If you are going to implant the embryo—

**Senator WEBBER**—Mark and I can probably have this argument during the debate rather than now. But if you know that by removing it from the freezer that is the consequence of your decision, then it is a decision to—

**Mr Campbell**—Every day in our hospitals, doctors turn off life support systems knowing people are going to die, but they are not killing those people. We do not bring them up before a court of law and charge them with having killed someone. Those doctors would be very distressed if you started to tell them that they were killing those patients. There is a very distinct decision and a very distinct action.

To highlight it for you, no matter what you are going to do with the embryo you are going to remove it. If you are going to implant it, you are going to remove it from the freezer, allow it to thaw and allow it to begin to develop and then implant it. If you are going to use it for embryonic stem cell research, you are going to remove it from the freezer, allow it to thaw and allow it to develop—because they are not at the stage of having the cells that they are wanted for as stem cells, so they are allowed to develop further—and then the stem cells are

harvested, destroying the embryo. If you are going to allow it to succumb, it is the same action. You remove the embryo from the freezer, put it back in the environment and it will begin to develop again. Then it will reach a stage where it can no longer survive in that environment and it will die if it is not implanted. I would suggest that they are three very different kinds of actions.

**Senator WEBBER**—That is the kind of clarification I am after in my quest to become a little better informed on this issue. I will wrap it up here but, to solve that moral dilemma, wouldn't it be better just to leave them in the freezer?

**Mr Campbell**—No, there are regulations. We would go back to your earlier question regarding whether we should freeze them in the first place. I would agree with, I think, every other member here before you at the moment that the actual process of freezing the embryo is itself an act which is not respectful of the dignity of a human being. When we began freezing we were in actual fact experimenting with embryos, because the process of freezing was experimental and, of course, the embryo was not consenting to that experimentation. So, first of all, yes, the freezing itself is questionable as something that has respect for the dignity of a human being. The maintaining of the embryo in that state is still questionable as respectful of the dignity of a human being.

On top of that, we do not know the long-term effects. The longer an embryo is frozen, the more harm that could be caused, and prospectively this is an embryo that could be implanted. Another side of the argument that comes in there is: does anyone have an obligation to maintain it in that frozen state? I cannot see that anyone has. It is what we call 'maintaining the extraordinary means of life'. I cannot see that anyone has an obligation to maintain that embryo in that state. Hence, we are left with the only unfortunate alternative, given the fact that this has been allowed to develop. It is a moral dilemma, but that is the only humane solution, it seems to me, that is respectful of all the goods involved.

**Senator WEBBER**—I accept what you are saying about it being incredibly unfortunate and difficult that we have these supposedly surplus embryos and that we seem to have collected them by the thousands, and I accept that they exist. So your view on what we do with them—and correct me if I am wrong—is to allow them to succumb?

**Mr Campbell**—It is the situation which exists at the moment in Victoria and other states that have regulations.

**Dr Neville**—Two wrongs do not make a right. It is the least worst scenario.

**Senator HARRADINE**—The distinguished Chair of the Select Committee on Human Embryo Experimentation, ex-Senator Michael Tate, is in the audience. On this question of freezing, is it less of a problem to freeze embryos? Wasn't that the recommendation of a number of the committees that considered—

**Mr Campbell**—Do you mean to freeze eggs rather than embryos?

**Senator HARRADINE**—Yes, to freeze eggs rather than embryos. Obviously it is a problem, but is it less of a problem? That process was recommended by the committee that Senator Webber referred to, and in the interim it recommended that freezing should occur only in certain circumstances—for example, if a woman happened to be suddenly ill and her eggs could not be transferred immediately, they could be frozen. That is what the committee said. Do you see that as a problem but perhaps as less of a problem?

**Mr Campbell**—Definitely. From the moral point of view, freezing eggs is less problematic. Scientifically, I think there have been problems with freezing eggs, but my opinion is that from the moral point of view it is less problematic.

**Senator HARRADINE**—On the question of drug testing and the utilisation of human embryos or embryonic stem cells for testing of drugs and for toxicological studies, could I ask you, Mr Sullivan, as you are from the Catholic Health area: if in the future as a result of this legislation you are going to have numbers of embryos used to test drugs and, as a result of that, new pharmaceutical products are produced, doesn't that raise a moral question from the hospital's point of view? This is going to happen fairly soon if this legislation goes through. Further down the track, if a pharmaceutical product is developed because of the testing of human embryos or the use of human embryos or human embryo stem cells for the testing of that drug, doesn't that raise a moral question for the hospital? I would like to ask that of the Archbishop too, if possible.

**Mr Sullivan**—I will quickly give one answer—yes. The question, for example, about the testing for pharmaceuticals in general—not even worrying about embryonic research—is a moral question, because we already know in Australia that we are facing big questions about how we fund the pharmaceutical industry and our benefit schedule. So the allocation of scarce resources in health care is a moral question anyway. The question you put to me is extremely hypothetical and I think it goes to the heart of this whole debate. What we are facing is an extremely hypothetical set of propositions to do with embryonic stem cell research that may lead sometime in the future to some types of cures. Therefore, it is a similar scenario. If you want to take it simply from the point of view of the allocation of scarce resources across health and research, you would argue that we are certainly not justified in pursuing this.

**Senator HARRADINE**—It was not meant to be a hypothetical question at all. It is to do with the development of the use of human embryos in the development of pharmaceutical products not necessarily associated with stem cell therapy. I have a letter from the minister, but he had asked BresaGen to answer the questions I had asked. I asked a question about this, and he responded:

If your question refers to the potential use of human ES cell lines for drug screening, this could be a major advantage, and is well appreciated by many pharmaceutical and biotechnology companies worldwide.

**Mr Sullivan**—Senator, the obvious moral question that comes to my mind is that we already have pharmaceutical testing on other than embryos and other than human subjects. What we would simply be doing in this case would be relegating human subjects to the level of guinea pigs.

**Archbishop Wilson**—Indeed, there would be a moral problem with that. People already have some moral difficulties with the testing that goes on with cosmetics in the way that animals are used to do that. It would seem to me that we enter into a new order of our relationships with our fellow human beings if there is a special group of human lifelines, or whatever, set up and used for experimentation for the benefit of the rest of the community. I think that would be a major moral issue.

One of the fundamental moral principles behind all of this of course is that in our human history most of the terrible things that we have been able to do to people have been based on the fact that we have convinced ourselves that they are not human. Last year I went to the Ukraine on a visit with the Pope. I did a private tour while I was there to a place called Ari Bar that I had read about and wanted to get to. Ari Bar was a ravine outside the city of Kiev, where 35,000 people were shot in two days by the Nazis. The Nazis returned later and filled up the ravine with another 25,000-30,000 people over the years. I stood there and I thought: how can people do this? How is it possible? I have seen the photos and the movies of the people lined up along the cemetery fence as though being led off. It was really chilling to

stand there and see the same fence, the same road, and then all that was there, and the thought that occurred to me then—which really haunted me before that and has since then—is the fact that you can only do that sort of thing once you convince yourself that those you are dealing with are not human. I think that comes up again and again in the judgments we make about other people. Sometimes it shows itself in racism. Sometimes it shows itself in the phobias that develop about particular races or all races and so on. I think that is the major moral issue here as well. If you can convince yourself that you are not dealing with human life, then you can do whatever you like. What we are saying is that we are very much involved with human life here and therefore there is a set of principles that follow from that. Every question you might ask will take us back to that major moral issue. We believe we are dealing with human life and therefore a whole range of responsibilities and reactions emerge from that.

**CHAIR**—There being no further questions, I thank you all for giving us your time today.

**Proceedings suspended from 7.16 p.m. to 8.16 p.m.**

**TATE, Reverend Professor Michael Carter AO, former Chairman, Senate Select Committee on Human Embryo Experimentation**

**CHAIR**—With the agreement of the committee, and the kind agreement of our next group of witnesses, I call former senator Reverend Professor Michael Tate for what he has guaranteed me—gilt-edged—will be a quick five minutes. Welcome, Reverend Professor Michael Tate. We would like to hear your comments.

**Rev. Prof. Tate**—Thank you for your special concession to your normal mode of operation. Given the fact that there has been such a turnover of the Senate membership, I thought that it might be useful to prod the corporate memory of the Senate as to the major findings of the Senate Select Committee on Human Embryo Experimentation in Australia, which reported in September 1986. After listening to some of the debate this evening, I want to emphasise two or three matters. One is that the nine senators on that committee—and it spanned all political parties, including Senator Harradine, Senator Macklin from the Democrats and the major parties—agreed the definition of a human embryo to be:

... genetically new human life organised as a distinct entity oriented towards further development.

In a pluralist society, we recognised that we could not adopt a philosophical, theological or legal definition of the embryo which would call it a person, and we did not talk about killing when it came to destruction. We simply said that it is genetically new human life from the moment of conception. That was right across the board. Senator Crowley and Senator Zakharov dissented on the question of the significance of the marker event of 14 days. They thought that it was important as up to that time, they said, the gamete donors or the intended social mother had the right to determine the fate of the embryo. But, even there, it is important to note that in paragraph 39 of their dissent they said:

While this dissenting report concludes that implantation is a marker event of ... significance, it does not conclude that there should be no constraints on what can be done to the pre-implantation embryo. We support the view in the Report that prohibits cloning of a human embryo, and any procedure under which the gametes of a man or a woman are fertilised by the gametes of an animal ... Further, we recommend that where other avenues of research are open, eg. to determine chromosomal patterns by use of adult tissue, such avenues are to be used, rather than creating embryos for such purposes.

So even the two dissentients, my colleagues and friends Senators Zakharov and Crowley, as a matter of caution and prudence, suggested that where an alternative was available—in this case, adult stem cell research—that should be preferred to human embryo experimentation which destroyed the embryo, in the course of, in this case, extracting the stem cells.

I think it is important that the Senate had two big-picture frameworks in mind. One was the 1964 Declaration of Helsinki, which as you know distinguished therapeutic and non-therapeutic experimentation. The main clause in that biomedical ethical principle, which has international commendation and significance, states:

Concern for the interests of the subject must always prevail over the interests of science and society.

Our committee never said that those who drafted that declaration had the human embryo in mind. We have never tried to push definitions beyond what was in the minds of the framers but we found that at some stage, of course, everyone would regard the embryo as a human subject. We found that no marker event was of such tremendous significance that different principles should apply as to its destruction before that marker event occurred. The 14-day marker event did not seem to us to be compelling. We never said that it may not be the case that compelling evidence could emerge. We said that common prudence dictated that until the

contrary was proved beyond reasonable doubt the embryo of the human species should be regarded as if it were a human subject for the purposes of biomedical ethics. That is a cautious, prudent approach that should commend itself to the committee.

I could talk also about the fact that we decided that guardianship rather than property was the legal framework in which one should comprehend society's dealing with the embryo. It does not belong to the gamete donors; it does not belong to the intended social mother, if she is not one of the gamete donors. It is a question of guardianship towards the embryo and in that case the guardian could not assume that the embryo, if given the choice, would donate itself to medical science. Finally, I want to briefly deal with the question of freezing and what the committee said, because a senator who is not present at the moment brought it up.

**CHAIR**—That would have been Senator Webber.

**Rev. Tate**—Chapter 5.12 of the report said:

> ... there may be cases of an embryo existing as a result of in vitro fertilisation and where, if the aim is to give that embryo the best chance of being implanted and being successfully carried to term, then freezing may not only be desirable but necessary ... it could occur when the uterine environment was considered to be unreceptive to implantation at the time of intended transfer.

In other words, given the fact of an in-vitro fertilised embryo, it would be ethically better to give it a chance of implantation by freezing than to allow it to immediately succumb. But if there were some surplus embryos which had been frozen, we would need to consider the question that the senator raised about long-term or indefinite freezing as being perhaps the ethically more proper course of action. In the view of the committee, long-term—I mean 20, 30, 40 or 100 years—freezing would be an extraordinary means of support for that embryonic human life which is not ethically required by almost every ethical principle. You need not take extraordinary means of support for a human life. The conclusion stated:

> ... where there is no reasonable means of sustaining the life of an embryo, there is an ethical distinction between allowing it to succumb and deliberately destroying it either outright or during the course of destructive non-therapeutic experimentation.

That is in paragraph 5.16. In fact many of the questions that have been raised even in this evening's evidence have been considered by that committee. I commend some of those paragraphs, even the cautious remarks of the dissentients in that report about experimenting on the human embryo where there are alternatives that are reasonably available. They thought to experiment on the human embryo in that case would be beyond the pale. Thank you for my five minutes of glory.

**CHAIR**—Thank you very much. That was a very useful contribution and I am very grateful for it.

[8.25 p.m.]

**HARPER, Mr Greg, Deputy Chief Executive Officer, Australian Research Council**

**SAWYER, Professor William Hugh, Executive Director, Biological Sciences and Biotechnology, Australian Research Council**

**HARTLAND, Ms Kerri, Executive General Manager, Biotechnology Australia**

**SWANTON, Dr David John, Manager, Industry Development, Biotechnology Australia**

**CHAIR**—Welcome. Witnesses are reminded that the giving of evidence is protected by parliamentary privilege and that the giving of false or misleading evidence may constitute a contempt of the Senate. We have been running this as a panel style of committee process. We have before us your submissions. If you would like to briefly add anything to those, you are welcome to do so, and then the senators will be asking you some questions.

**Ms Hartland**—I have a very brief opening statement. First of all, I would like to thank the committee for this opportunity to comment on the legislation relating to embryo research that is currently before the parliament. Biotechnology Australia have responsibilities relating to the management and oversight of Australia's biotechnology activities. Along with the Australian Research Council we have joint responsibility for establishing the Biotechnology Centre of Excellence that culminated in the grant of $43.55 million being awarded to the National Stem Cell Centre, as announced by the Prime Minister on 30 May. Biotechnology Australia, along with the Department of the Prime Minister and Cabinet and the Department of Health and Ageing, were also a member of the Commonwealth steering committee, chaired by the NHMRC, which oversaw the development of Commonwealth policy on human cloning, ART and related matters. Commonwealth, state and territory government officials constituted the COAG implementation working group, and we were involved with that in an observer status. The working group worked on the implementation of the 5 April 2002 COAG agreement with respect to the establishment of the national scheme for the regulation of the use of excess ART embryos, including the drafting of the bill.

Biotechnology Australia support the legislation introduced into parliament. We believe the legislation allows, within a robust regulatory framework, excess ART embryos to be used to develop new embryonic stem cell lines. As the committee knows from its hearings, the prevailing view of stem cell scientists is that research needs to continue on both adult and embryonic stem cells. Our submission outlines our key arguments. I would like to stress that Australia is currently a world leader in embryonic and adult stem cell research—research that has the potential to offer significant health, social and economic benefits.

We are all aware that developments in stem cell science are occurring very rapidly. A number of overseas jurisdictions have, and are likely to have, less restrictive legislative schemes than that which is currently before this parliament. If Australia is to reap the benefits from this technology, we need to be at the forefront of any developments; otherwise, investment will flow out of Australia. The bill is one part of a nationally consistent regulatory system that will allow Australia to remain internationally competitive, but one that we also believe addresses community concerns.

**Mr Harper**—We have little to add to the submission that we made to the committee other than to repeat what Ms Hartland has just said—that we and Biotechnology Australia are jointly responsible for the establishment of the National Stem Cell Centre.

**Senator HUTCHINS**—My question is to the representatives of Biotechnology Australia. On page 4 of your submission, you state:

> Embryonic stem cells have the unique ability to proliferate indefinitely and to differentiate into almost all of the more than 200 different cell types found in the body.

On page 6, you refer to Dr Catherine Verfaillie's research on multipotential adult progenitor cells obtained from bone marrow. Can you tell me why research on those cells could not produce the same results?

**Dr Swanton**—Dr Verfaillie's work was on particular cells co-purifying with mesenchymal stem cells. As our submission states, at the moment those stem cells cannot produce heart cells, blood cells or insulin secreting cells. They may well in due course but, until we know definitively, we recommend that research continue on both embryonic stem cells and adult stem cells.

**Senator HUTCHINS**—So you are sure it can happen with embryonic stem cells?

**Dr Swanton**—By definition, embryonic stem cells are pluripotent, which means that they can produce all the cell types in the body. Adult stem cells have yet to show true pluripotency.

**Senator HUTCHINS**—How quickly could research using multipotential adult progenitor cells progress to the stage that research using embryonic stem cells is at now?

**Dr Swanton**—That is a scientific question; I suspect you should address it to scientists. Dr Verfaillie would indicate that more research would be needed at this time.

**Senator HUTCHINS**—What sort of doctor are you?

**Dr Swanton**—I am not a biotechnologist; I am a theoretical chemist.

**Senator HUTCHINS**—What sort of scientist do we need to ask that question of?

**Dr Swanton**—A biotechnologist—someone like Alan Trounson, Catherine Verfaillie or Martin Pera. They are the experts in the field.

**Senator HARRADINE**—Sheep in what field?

**CHAIR**—Order!

**Senator HARRADINE**—They are sheep in what field?

**Senator BOSWELL**—That is the most outrageous thing—

**Senator HARRADINE**—Expert in what field?

**CHAIR**—Order!

**Senator HUTCHINS**—Dr Swanton, the submission said you are the manager of industry development. Is that correct or are you the marketing manager?

**Dr Swanton**—No; I was very much involved in the establishment of the Biotechnology Centre of Excellence in a secretariat support role, providing support to the advisory panel.

**Senator HUTCHINS**—So you have come here today in the capacity of an industry representative; would that be right?

**Dr Swanton**—I think that would be right; yes.

**Senator HUTCHINS**—We get intimidated by titles like Doctor, Professor and all that.

**Dr Swanton**—We are just ordinary people.

**Senator HUTCHINS**—We just had a professor here, but he was a professor of theology. You are a doctor and I asked what sort of doctor you were, but you are more in the business side of the company.

**Dr Swanton**—No; I am a scientist, but I am not a biotechnologist.

**Senator HUTCHINS**—So you act as a scientist for the company?

**Dr Swanton**—No. Biotechnology Australia is a government agency. I am here today in my capacity as a member of Biotechnology Australia, which is a division within the Department of Industry, Tourism and Resources.

**Senator JACINTA COLLINS**—What is your job description?

**Dr Swanton**—I am the manager of industry development in the Biotechnology Australia division of the Department of Industry, Tourism and Resources.

**Senator EGGLESTON**—This is obviously a very complex and controversial subject. You are representing the biotechnology industry, with something of a vested interest in seeing this bill passed, but how will Australia be disadvantaged if the bill is not passed?

**Ms Hartland**—As we said in our opening statement, Australia has leading edge researchers in both adult and embryonic stem cells. In other jurisdictions around the world legislation is in place to allow research to go on in both those fields. We believe that, if this bill is not passed, a number of those researchers are likely to leave Australia and take with them potential for investment and for cures and benefits for Australians.

**Senator EGGLESTON**—You mentioned cures, which are what we expect this to be all about. What kinds of treatments are available now—from adult stem cells, firstly, and, secondly, from embryonic stem cells?

**Ms Hartland**—We are certainly talking about potential. I might pass that to one of my scientific colleagues here who might be able to speak a little bit more about it. What I could say is that embryonic stem cells have not been used to treat human disease; however, there are some proof of concept studies to date that have been promising. We certainly have a number of studies—

**Senator HUTCHINS**—Proven concept studies?

**Ms Hartland**—Proof of concept stage.

**Senator JACINTA COLLINS**—They have proven the concept; it is not an established concept. We have to understand the language quite clearly here. You have said that they have proven promising, not that they have proven concept.

**Dr Swanton**—I suppose the exact term that one would use is that proof of concept has been shown in mice for treating many of these diseases.

**Senator MARK BISHOP**—In mice, yes.

**Senator HUTCHINS**—What document are you reading from anyway, Ms Hartland?

**Ms Hartland**—This is just a document of some notes that we have compiled. In fact—sorry—this is from our submission.

**Senator MARK BISHOP**—I think Senator Eggleston was talking about human embryonic stem cells.

**Senator EGGLESTON**—I was indeed.

**Senator MARK BISHOP**—So that is the context, not mice.

**Senator EGGLESTON**—I believe there are some treatments available from adult cells but, as you said, from embryonic cells they are only potential. You mentioned that immunorejection was a major problem. I would have thought that is quite a big hurdle to overcome, in terms of providing ongoing treatment for any condition at all, because you would need the same kind of immunosuppression that you use with transplants to use embryonic cell treatments, would you not?

**Dr Swanton**—Not necessarily.

**Senator EGGLESTON**—Well, something very similar.

**Dr Swanton**—Immunosuppression is obviously a very big problem, and the normal transplants that apply—kidney transplants or whatever—require the use of immunosuppressant drugs. This is a typical practice at the moment. However, there are some possibilities of other options at the moment. There is the option of nuclear reprogramming, which I thought Professor Pera talked about the other day and the issue of tolerising the immune system via creation of a new thymus—developing a thymus and inserting it with embryonic stem cells that matched a similar nuclear type that is producing, say, the pancreas cells. This would allow the pancreas to be recognised as 'self' and therefore there would be no need for immunosuppressant drugs. This has been shown in mice to be a satisfactory way of approaching this problem. We have references in peer reviewed literature for that.

**Senator MARK BISHOP**—Which references? Can you give us the references?

**Dr Swanton**—This one is published in—

**Senator MARK BISHOP**—Whose paper is it?

**Dr Swanton**—This paper is by Jason Gill, Mark Malin, Georg Hollander and Richard Boyd, published online on 17 June 2002 by the Nature Publishing Group. I have the World Wide Web address—http://immunol.nature.com—so it looks like it is *Nature*.

**Senator EGGLESTON**—Nevertheless, all of those things are potential, aren't they? You have not got an established method of overcoming the immune problems. You are talking about potential nuclear transfers—

**Dr Swanton**—This is all research that has potential.

**Senator EGGLESTON**—and thymus glands atrophy when people are 18 and that sort of thing.

**Dr Swanton**—As a scientific theory, it is worthy of being explored.

**Senator MARK BISHOP**—Could you table that document?

**Dr Swanton**—Yes, most certainly.

**Senator MARK BISHOP**—I would like to have it, if it can be tabled.

**Senator EGGLESTON**—The immunological issue is a big issue, anyway. Tell me: will the National Stem Cell Centre be able to operate if the bill is not passed?

**Ms Hartland**—Yes. The members of the expert panel that were responsible for recommending the National Stem Cell Centre as a successful operator of the centre of excellence actually asked that question of those that were interviewed from the centre. They indicated that, particularly given that about half of the research they are doing is adult stem cell—so I assume that we are referring to the other half of the research—they would be able to continue their research if the bill was not passed.

**Senator BARNETT**—Sorry, I did not hear the answer.

**Ms Hartland**—They said that they would be able to continue.

**Senator EGGLESTON**—They would, but largely with adult cells. That is what you are saying.

**Ms Hartland**—Certainly half of the research that was always envisaged that would be done by the centre was adult stem cell work, so obviously that could continue. They would be looking at using existing stem cell lines. At least in the short term, they certainly said that they would be able to continue. I am not sure what their long-term sustainability is.

**Senator EGGLESTON**—Has the Commonwealth got an agreement with the National Stem Cell Centre?

**Ms Hartland**—Not yet. A deed of agreement is under negotiation.

**Senator EGGLESTON**—What do you anticipate that that will contain? What sorts of issues will it address?

**Ms Hartland**—It will address all of the sorts of terms under which monitoring would be done; it will address key performance indicators; it will be linked to a business plan; it will set down areas where, if there were problems, there would be termination of Commonwealth funding—those sorts of things.

**Senator EGGLESTON**—Earlier tonight we heard about the German legislation, which is fairly restrictive, I think. You have made comment about Australia losing out in the scientific race if this legislation is not passed, and yet the Germans, who, as a country, devote a lot of money and time to scientific research, seem to be happy with the form of legislation they have. Would you like to comment on the comparison between Australia and Germany in terms of biotech legislation?

**Ms Hartland**—I am not familiar with the German legislation per se, but I would note that Australia does have some leading researchers in the adult and embryonic stem cell fields. I do not know about the levels of expertise in Germany, but there are certainly other countries that have got legislation that is more lenient, if you like, than the suggested legislation here.

**Senator EGGLESTON**—Do you have a view regarding the restriction on the destructive uses of embryos to those embryos created before 5 April 2002, as contained in this legislation?

**Ms Hartland**—We have had input from industry, but the actual date was decided by COAG. Our role is to abide by the COAG decision and implement that, so I would not put a view forward on that.

**Senator EGGLESTON**—It is not the date we are talking about, it is the destructive use of embryos.

**Ms Hartland**—My apologies. As the committee has heard, there have been various views on this from industry. Some industry people are saying that the 5 April date does create a problem for them. Others are saying it does not. On balance, we have come down as supporting the legislation, so I believe that 5 April can be lived with.

**Dr Swanton**—Senator Eggleston, did you say 'before 5 April' or 'after 5 April'?

**Senator EGGLESTON**—I said 'before 5 April'. In other words, the embryos you are allowed to use, but there are restrictions on the destructive use of them, I understand.

**Dr Swanton**—I think BresaGen might have indicated to you that they would prefer that the 5 April deadline be lifted sooner rather than later, so that embryonic stem cell lines could be established according to current good manufacturing practice guidelines.

**Senator BARNETT**—I did not quite hear that. Are you saying that you recommend the lifting of that date?

**Dr Swanton**—No, I think BresaGen, the company, proposed that in their submission.

**Senator BARNETT**—But what is your position? I thought the senator was asking what your view was.

**Senator EGGLESTON**—What is the view of Biotechnology Australia?

**Ms Hartland**—Biotechnology Australia, as a government agency, does not have a view, but we are saying that we believe that the view that has been put forward to us by industry, on balance, is supportive of the 5 April deadline.

**Senator EGGLESTON**—What about the banning of somatic cell nuclear transfer under the proposed legislation?

**Ms Hartland**—I would give a similar response on that. On balance, the industry view that has been put to us is that the legislation as it exists is appropriate.

**Senator BOSWELL**—On page 10 of your submission, you state that there are three Australian companies operating in the area of stem cell research—Stem Cell Sciences, BresaGen and ES Cell International. Stem Cell Sciences have a patent on cloning, so they are out. BresaGen might be Australian, but the CEO is based in the United States. That is correct, isn't it?

**Ms Hartland**—Yes, that is correct.

**Senator BOSWELL**—Then we come to ES Cell International. Why do you describe that as an Australian company?

**Dr Swanton**—Do we describe that as an Australian company? I am not sure.

**Senator BOSWELL**—Yes, you do.

**Dr Swanton**—It has an Australian shareholding, yes.

**Senator BOSWELL**—But it is registered in Singapore.

**Dr Swanton**—There are Australian shareholders.

**Senator BOSWELL**—But it is majority foreign owned.

**Dr Swanton**—Do you know it is majority foreign owned?

**Senator BOSWELL**—Yes, I do. You should know too, if you did your research on it.

**Dr Swanton**—When we contacted ES Cell International, they indicated that their share ownership was confidential.

**Senator BOSWELL**—You cannot have a confidential share ownership. If you have got a public company, that is open to anyone and if you are allocating $45 million, I would have thought that that was page 1, paragraph 1, first word that you would check.

**Dr Swanton**—I was not aware that it was a public company.

**Senator BOSWELL**—You were not aware that it was a public company, and you gave them $45 million. My God!

**CHAIR**—Senator, please.

**Senator BOSWELL**—Madam Chair, do you realise what this is about? This is a public company.

**CHAIR**—Senator, I just want all witnesses to be treated with respect, that is all.

**Senator BOSWELL**—All right, I will contain myself if I can.

**Ms Hartland**—Chair, I do not think that we have actually given any money to anybody, in fact, at this stage.

**Senator BOSWELL**—No, but the recommendation is that you do, isn't it?

**Ms Hartland**—Yes, but it is very unclear about whether ES Cell International is part of a consortium or not.

**Senator BOSWELL**—You have suggested a grant be made to a commercial arm in a majority foreign owned company. I would like to know how that helps the Australian biotechnology industry.

**Ms Hartland**—I have not recommended that, nor has Biotechnology Australia recommended it. It was recommended by a panel of experts and then it went through a ministerial process.

**Senator BOSWELL**—Who was on the panel of experts?

**Dr Swanton**—There were 10 members originally. Seven members ended up making the decision. The panel of experts was chaired by Dr Peter Jonson.

**Senator BOSWELL**—He is the person in business with the stem cell secretary.

**Dr Swanton**—What stem cell secretary are you talking about?

**Senator BOSWELL**—Dianna DeVore.

**Dr Swanton**—Dr Dianna DeVore is the chief operating officer of the national stem cell centre.

**Senator BOSWELL**—And she is in business with Peter Jonson. It is a cosy old relationship in there.

**Ms Hartland**—I think you are referring to the MNT Innovations Ltd, which is the newly formed—

**Senator BOSWELL**—I am talking about two people being in business—one receiving a grant for $45 million from the other. I would suggest you do not give up your day job and go into business.

**CHAIR**—Senator, excuse me!

**Senator JACINTA COLLINS**—You are not containing yourself, Senator Boswell.

**CHAIR**—I would like the witnesses treated with respect. Ms Hartland is trying to add something, and you are talking over her. If you ask the questions, please let someone respond. Ms Hartland, please continue.

**Ms Hartland**—Thank you, Chair. I do have some information on that issue, that MNT Innovations Ltd is a newly formed commercialisation arm of the CRC for Microtechnology. It is a non-operating company. It does work in the field of applications of biotechnology but it is not doing stem cell work and does not have any stem cell work on the horizon.

**Senator BOSWELL**—I know that, but they are still in business together.

**Ms Hartland**—I do not think there was any conflict of interest there.

**Senator BOSWELL**—Of course there is a conflict of interest.

**Senator BARNETT**—Senator Boswell, I think the chair has some objective and fair comments to make, but you asked the question about the list of the panel members and Ms Hartland was going to respond with the list. I was wondering if she can have that opportunity.

**Senator BOSWELL**—Yes, Ms Hartland.

**Ms Hartland**—As Dr Swanton said, the chair was Dr Peter Jonson. The deputy chair of the panel was Professor Merilyn Sleigh.

**Senator HARRADINE**—Would you also say who they are in their capacities outside the panel? Dr Jonson is the Chair of the Institute of Commercialisation. Would you mind giving their titles?

**Ms Hartland**—Professor Merilyn Sleigh is the deputy chair and she is the CEO of a company called EvoGenix.

**Senator HARRADINE**—That is a biotech company.

**Ms Hartland**—Professor Denis Wade is the Chairman and Managing Director of Johnson and Johnson Research Pty Ltd.

**Senator HARRADINE**—A pharmaceutical company.

**Ms Hartland**—Professor Grant Sutherland is the former Director of the Department of Cytogenetics and Molecular Genetics at the Women's and Children's Hospital in Adelaide. Dr Ian Pitman is now retired but was the former Research Director of F.H. Faulding Co. Ltd.

**Senator HARRADINE**—A pharmaceutical company.

**Ms Hartland**—John Stonier is the Director of Davies Collison Cave, which is a patenting lawyer.

**Senator HARRADINE**—Patent lawyer.

**Ms Hartland**—Professor Vicki Sara is the CEO of the Australian Research Council, and there were a number of additional advisers to the panel.

**Senator BOSWELL**—Is Professor Saunders in there?

**Dr Swanton**—There is no Professor Saunders.

**Ms Hartland**—There is no Professor Saunders, no. Sorry, do you mean Professor Vicki Sara?

**Senator JACINTA COLLINS**—No, there was an earlier one.

**Senator BOSWELL**—Saunders.

**Ms Hartland**—Sleigh, Wade, Sutherland, Pitman, Stonier.

**Senator BOSWELL**—It was Professor Sutherland.

**Ms Hartland**—There were two additional advisers to the panel: Professor George Petersen, who is a New Zealand professor—sorry, I do not have his full title here—and Dr Paul Tolstoshev, who is with a consulting firm called PT Biotech.

**Senator HARRADINE**—They were not members?

**Ms Hartland**—No. They were brought on as additional referees.

**Senator HARRADINE**—Is it Professor Sutherland's attitude that the place would be better off if those with disabilities had not been born? Are you aware of that statement?

**Senator McLUCAS**—Excuse me, Chair. I am not sure how that is particularly relevant to the bill.

**Senator HARRADINE**—I am sorry, but Kerri Hartland mentioned the committee; I did not.

**Senator McLUCAS**—I am not referring to you, Senator. I am just talking about this whole discussion and how—

**Senator BOSWELL**—The whole discussion is absolutely crucial. We have the people who made a grant of $45 million—

**Senator HARRADINE**—It was $46.5 million.

**Senator BOSWELL**—Brian, don't argue with me about a million and a half! These people made this grant, and here we are, interviewing them and asking them why they made the grant. This discussion is absolutely essential.

**Senator McLUCAS**—I think it should be discussed in estimates.

**Senator BOSWELL**—No, it should not be discussed in estimates.

**Senator McLUCAS**—We are discussing the bill here.

**Senator BOSWELL**—We are going to pass a bill on $45 million—a lot of which, I maintain, has gone overseas to an international company registered in Singapore. Don't you understand that it has to be discussed?

**Senator McLUCAS**—This bill is not about $45 million.

**CHAIR**—Senator Boswell, please stop speaking like that to witnesses and to your colleagues. I have given you due latitude—

**Senator BOSWELL**—Can I ask my question?

**CHAIR**—Senator, I am speaking! I have given you due latitude to ask a series of questions that do not relate to the bill. Senator McLucas's point of order is quite valid: this does not relate to the bill. If you want to move on to other issues, you can. But I ask you to do it with respect.

**Senator BOSWELL**—With respect, Madam Chair, I will ask the remainder of these questions—if I may.

**CHAIR**—You have canvassed a whole range of questions that do not relate to the bill. Do you have any questions that do relate to the bill?

**Senator BOSWELL**—They do relate to the bill.

**Senator JACINTA COLLINS**—Madam Chair, I raise a point of order. As you expressed a moment ago, Chair, you have given a fair range of latitude about how something might relate to the bill. I respectfully suggest to you that this session demonstrates that point. Now that the committee has decided to have the session with these particular witnesses, I suggest that we move on and that senators ask questions relevant to these witnesses, rather than arguing about why they are here in the first place when they are already here.

**CHAIR**—The funding issue is not the only reason why I would have thought these witnesses are here. They are here to talk about the issues relating to the bill. If one wants to ask further questions about funding issues, then they are questions for another time and place. I have raised that issue repeatedly, but I have attempted to try and give latitude. That latitude is being abused now.

**Senator BOSWELL**—I am sorry, but the latitude has not been abused. Concerning the point of order, some very serious information is required. We are spending $45 million of taxpayers' money. I am trying to establish whether that money is going overseas to an

international company registered in Singapore. These witnesses are the people that made the recommendations. I would respectfully suggest that I am asking for information that is absolutely essential to the bill.

**CHAIR**—Senator, if you can point out to me the clause in the bill that relates to the questions you are asking, I will quite happily allow you to continue to ask these particular types of questions.

**Senator BOSWELL**—Madam Chair, are you going to allow me to ask my three remaining questions?

**CHAIR**—I have made a ruling. I have allowed you to ask many questions on this issue.

**Senator BOSWELL**—I want to ask three more questions on this issue.

**CHAIR**—You can put the questions, but the witnesses are not obliged to answer them.

**Senator BOSWELL**—I want it put on the record—

**CHAIR**—I do not mind what you put on the record.

**Senator BOSWELL**—that you are refusing to let me ask a question on this bill.

**CHAIR**—No, I am certainly not. I am happy for you to ask any question you would like on the bill. If you can tell me where these particular questions relate to the bill, then I am quite happy for you to ask them. I am not preventing you from asking any question at all—far from it.

**Senator JACINTA COLLINS**—Can I suggest that this line of questioning relates to potential amendments in relation to commercialisation of this research.

**CHAIR**—That is a very long bow to draw.

**Senator JACINTA COLLINS**—It is not a long bow. I might be moving such amendments, and I would like to explore those issues.

**CHAIR**—That is a discussion for the chamber; that is not a discussion for here.

**Senator JACINTA COLLINS**—No, it is not; it is quite relevant to the bill.

**CHAIR**—Senator Collins, if you or Senator Boswell can point out to me the relevant clauses in this bill—

**Senator JACINTA COLLINS**—I do not need to draft an amendment before the committee stage deliberation of a bill.

**CHAIR**—I have not suggested that. It is quite wrong to suggest that I have.

**Senator JACINTA COLLINS**—Precisely where my amendment would fit into the current bill is a matter for the clerks to determine.

**CHAIR**—I am simply asking where these questions relate to the bill.

**Senator JACINTA COLLINS**—And I have given you a very clear indication. It would be far more fruitful if we just continued.

**CHAIR**—I have the bill here, if you would like—

**Senator JACINTA COLLINS**—I would seek advice from the clerks on this point.

**CHAIR**—If you want to, that is fine.

**Senator JACINTA COLLINS**—I suggest you seek advice from the secretary on the nature of your ruling and that we seek advice from the clerk on my point of order.

**CHAIR**—That is fine. The committee is suspended and we will seek advice from the clerks.

**Proceedings suspended from 8.56 p.m. to 9.02 p.m.**

**CHAIR**—The committee will reconvene. Senator Boswell, have you decided which of the options I put you are prepared to accept?

**Senator BOSWELL**—This bill works within an environment of some money going to stem cells and some money going to adult stem cells and to embryo stem cells. Within that context, I think money is relevant. I have another two questions to ask on this, which would take about 30 seconds, and I seek your indulgence.

**CHAIR**—Senator Boswell, I have already made an offer to you, which I will make again: you can ask the questions; the witnesses are not obliged to answer them, because they do not pertain to their submissions or to the bill.

**Senator BOSWELL**—Thank you. Ms Hartland, you have recommended a grant, which has not been made—

**Senator HARRADINE**—Not them; the expert panel.

**Senator BOSWELL**—What is your role, if the expert panel makes the grant?

**Ms Hartland**—Our role was just as a secretariat to the panel, so we had nothing to do with the decision making.

**Dr Swanton**—The decision was made by Dr Nelson and Mr Macfarlane.

**Ms Hartland**—On a recommendation from the panel.

**Senator BOSWELL**—What was your role in that?

**Ms Hartland**—We provided a secretariat to the panel.

**Senator BOSWELL**—I thought—

**CHAIR**—Senator Boswell, you have asked a question. Please let the witnesses answer.

**Ms Hartland**—We helped organise things like papers for the panel and their meeting schedules—all of the paperwork and those sorts of things.

**Senator BOSWELL**—All right. I will just have a look at this and try to frame my questions. Does anyone else want to ask a question?

**Senator McLUCAS**—I have a question for the ARC. In your submission, you canvass the issue of the 5 April cut-off date. I think you express a view that you would prefer that there was not that cut-off date and suggest that there would be other methods of managing embryos that are produced in an ongoing way. How do you think the legislation could be amended, if at all possible, to ensure the prevention of embryos being created for the purposes of research, which I think is generally accepted as a sound principle? Is there a way to amend the legislation and delete the 5 April cut-off date?

**CHAIR**—Can I put a rider on that: bear in mind that you are being asked for an opinion of your organisation, not for a personal opinion.

**Prof. Sawyer**—I think the view of the ARC at the moment is that the proposed legislation is prudent in this respect and it does provide a breathing space of two years before that legislation is reviewed again. I do not wish to forecast the outcome of that review, but I am sure that the issue of the 5 April date will be discussed at that time. I think that within those

two years there will be significant progress in the science in this area which might change the views we have.

**Senator JACINTA COLLINS**—You expressed the view that alternate means of preventing the creation of embryos for this work could well be developed, rather than the 5 April cut-off. Do you have an understanding of what destructive embryonic work has been done to date?

**Prof. Sawyer**—I should say that I am not a stem cell scientist.

**Senator JACINTA COLLINS**—Does the ARC have an understanding?

**Prof. Sawyer**—The ARC takes advice on these sorts of issues from its scientists and members and from its board.

**Senator JACINTA COLLINS**—Do you know whether the ARC agrees with Professor Trounson that there is, for all intents and purposes, no difference between embryonic stem cells and germ cells?

**Mr Harper**—The ARC is conscious of a variety of documents which suggest that the term 'embryonic stem cells' can cover cells derived from blastocyst and stem cells derived from the gonadal ridge of foetuses. In particular, there is a recent peer reviewed article in the *Journal of Pathology* that notes that embryonic stem cells can come from the ICM, inner cell mass, of the early blastocyst or foetal gonadal tissue.

**Senator JACINTA COLLINS**—I am exploring a different issue here, rather than exploring what loose language might have been used within scientific journals. The issue I am exploring is whether, for scientific research purposes, the two are interchangeable—which is what Professor Trounson suggested—and, if that is the case, whether there is not already a current alternative source of the material that is being sought under this bill.

**Mr Harper**—I need to qualify my response by saying that I am not a stem cell scientist either. My understanding is that the term 'embryonic stem cell' can cover material which is sourced from either of those two sources that I mentioned earlier.

**Senator JACINTA COLLINS**—But you are still not answering the question I am asking, which is a different issue, which is: can the two, for all intents and purposes, be used to achieve the same research objective?

**Dr Swanton**—As far as we are advised, that is indeed the case.

**Senator JACINTA COLLINS**—It is indeed the case, is it?

**Dr Swanton**—Yes. One piece of advice is that the major difference between an embryonic stem cell and a germ cell is the tissue from which they are isolated. There are also some very minor differences between the two cell types in growth regulation during expression. But they are referred to in the article by Allison as the same thing.

**Senator JACINTA COLLINS**—I also want to go to the Biotechnology Australia submission. Firstly, when you talk about the rationale in support of the bill—on page 12 of the Biotechnology Australia Division, Department of Industry, Tourism and Resources submission—you refer to the Andrews committee report, but you do not refer to it as a majority-minority report. Is there a reason for that?

**Dr Swanton**—I understand that there was a 6 to 4 split. We indicated the majority recommendation there. There was, of course, a minority view as well.

**Senator JACINTA COLLINS**—I am curious as to why that was not expressed.

**Ms Hartland**—We have just put down the majority view.

**Senator JACINTA COLLINS**—The reason I raise this concern is that when I go further through your submission I find that you talk about policies from other countries in a far more limited way than even the NHMRC refers to international experience. As far as I can see—and correct me if I am wrong—you make no reference to the EU experience in relation to handling these matters.

**Dr Swanton**—That is correct. We make no reference to the EU.

**Senator JACINTA COLLINS**—Why is that?

**Dr Swanton**—We need to draw the line somewhere. We have referenced the US, the UK and Singapore and some implications for Australian companies.

**Senator JACINTA COLLINS**—As far as I can see, all you reference are those countries that have, in a sense, already crossed the line. You do not bother referencing any other country that might have made an alternative decision.

**Ms Hartland**—The point that was trying to be made was that, given the expertise in Australia in terms of stem cell research, these were countries with more lenient environments where those researchers may well go.

**Senator JACINTA COLLINS**—With respect, the section that this is under is 'Rationale for Support of the Bill'. It is not really a balanced rationale, is it?

**Dr Swanton**—The key issue is Australia's international competitiveness.

**Senator JACINTA COLLINS**—So the key issue for you is Australia's international competitiveness—that is fine; I completely understand your submission now.

**Senator BOSWELL**—I have considered what you said, Chair, and I will ask questions straight out of the witnesses' submissions. So if you rule my questions out, then I believe you are going to have to rule out every submission.

**CHAIR**—I will be happy if you can point to anywhere in a submission that has referred to the funding.

**Senator BOSWELL**—On page 10 of the Biotechnology Australia submission they say:

... these companies are well placed to realise significant royalties and licensing income from third parties who have derived products based on Australian-owned human embryonic stem cells, with additional revenue streams to be derived from the sales of research reagents, growth factors etc.

**CHAIR**—That has not got anything to do with specific issues raised in the bill.

**Senator BOSWELL**—Yes, but my submission to you is that, if you rule me out of order in asking a question on their submission—

**CHAIR**—Senator, do you want to ask the questions or not?

**Senator BOSWELL**—But you have just ruled me out of order.

**CHAIR**—I have made four offers to you to ask the questions, and you keep wanting to debate the issue.

**Senator BOSWELL**—No, I do not. I just wanted to let you know where I am coming from—that is, I think I—

**CHAIR**—Do you really want to go ahead? The witnesses can decide whether they want to answer the questions. I have made that offer to you, I think, four or five times now.

**Senator BOSWELL**—Thank you. Is it not true to say that BresaGen and ES Cell International are well placed to make a lot of money because you put them there and gave them a huge start of $47 million?

**CHAIR**—Senator, I will not allow that type of claim to be made. The witnesses have not given anybody any money. They have repeated that ad nauseam.

**Senator BOSWELL**—Well, they have recommended it. What due diligence procedure and checks of company searches did the people on the controlling panel do, or did you do that for them? Who did all the due diligence testing, the research, company searches and so forth? Who was responsible for that?

**Ms Hartland**—There was a consulting firm by the name of Acumen Alliance that was contracted to do that work and report to the panel.

**Senator BOSWELL**—My question was: how much scrutiny did the expert panel give to the commercial interest of the people in the National Stem Cell Centre proposal? Your answer to that is that they passed that over to—

**Ms Hartland**—There was a consulting firm that was employed to look at governance and financial issues, and it reported to the panel.

**Senator BOSWELL**—Thank you. There was a grant made to the centre, whose commercial arm is majority foreign owned. How do you believe that helps the biotech industry?

**Ms Hartland**—There is no grant to ES Cell International, and it is not clear whether ES International will, in fact, be a partner in the centre—it is still under deliberation.

**Senator BOSWELL**—Who makes that decision?

**Ms Hartland**—As we have mentioned before, the deed of agreement was being worked through with the centre. We are waiting on business plans and we will look at those in conjunction with a legal team and the ARC.

**Senator BOSWELL**—My last question is: is there a guarantee in the grant that has not been given but will be given—or has been recommended—that no Australian taxpayers' funds will go to foreign overseas companies?

**Ms Hartland**—I think that Bob Moses may have addressed the committee on this the other evening. He said that he did not believe that would be the case. But, from the government perspective, we will see all of the audited statements that come through and there are key performance indicators that we will be assessing. We will look through where funds are going and where research is being done.

**Senator BOSWELL**—There is nothing to stop embryonic products going to other countries where there are little or no regulations on the kind of experiments that can be done, including cloning and animal-human experiments. Would you agree with that statement?

**Ms Hartland**—The business plan, including the research, will be approved through an executive committee with the government, so we will know what research is being done and where things are happening.

**Senator HARRADINE**—I want to clear one thing up. Did I hear you say that ES Cell International is not a partner?

**Ms Hartland**—It is still being negotiated.

**Senator HARRADINE**—A document called 'Biotechnology National Centre of Excellence'—and I think this is your own document—mentions 'initial call centre partners' and one of those is ES Cell International Pty Ltd.

**Ms Hartland**—That is true, but I do not believe there are any agreements in place with partners at this stage. There are no deeds signed, so we will not know for sure who those partners are until we have the business plan from the centre. My understanding is that at this stage there is no agreement.

**Senator HARRADINE**—I am sorry, wasn't that matter put to the panel that you were the secretary of? It is all here.

**Ms Hartland**—That is true; it was in the initial proposal that came forward. It is still being negotiated, but there is no agreement at this stage.

**Dr Swanton**—There are likely to be changes to many aspects of the original application, subject to negotiation between the centre and all the participating bodies.

**Senator HARRADINE**—In your submission you say:

The great potential benefits to the community offered by the development of stem cell technologies mean that Australia's participation in this area of biotechnology should be fostered.

What benefits—I am talking in the context of commercial benefits—would be available to Australia?

**Ms Hartland**—The commercial benefits that would be likely to flow from the centre?

**Senator HARRADINE**—Yes, I mean from patents and all the rest of it.

**Ms Hartland**—I think that is yet to be seen, obviously, but in the medium to long term we would hope that there would be therapeutic—I am trying to think of the word—

**Senator HARRADINE**—Pharmaceuticals?

**Ms Hartland**—No, not necessarily, but some health benefits are likely to flow for the Australian population.

**Senator BARNETT**—I would like to follow on there. Ms Hartland, you have used an example about diabetes in your submission, in the last paragraph of page 10. In your submission you specifically say:

... an ... example of their potential value is to consider that if an Australian company utilised their current scientific and commercial advantage to produce a single commercial cell therapy product—for example in the area of diabetes—with a conservative estimate of a 5% market share, an annual sales revenue in the order of AUS$500m would be realised in 2010.

What on earth are you talking about? Can you expand on that and explain that to the committee?

**Ms Hartland**—It is basically extrapolating from the figures that have been provided about the therapeutic benefits from cell therapies and the level of the problem. If you extrapolate from the global figures and take a figure from Australia—

**Senator BARNETT**—Ms Hartland, I know quite a lot about diabetes. When you say 'five per cent of market share', what market share are you talking about?

**Dr Swanton**—A market share of $US5 billion in 2010 has been predicted, and we have the reference in our submission.

**Senator BARNETT**—Of what? I have seen the reference. You tell me what we are actually talking about here—what sort of market share?

**Dr Swanton**—The global value of the diabetes market—that is, treatments for diabetes.

**Senator BARNETT**—Treatments for diabetes?

**Dr Swanton**—I imagine that would be the case.

**Senator BARNETT**—You imagine that is the case?

**Dr Swanton**—I would have to go back to the original report and check that.

**Senator BARNETT**—Thank you for your answer.

**Senator HARRADINE**—The web site of Biotechnology Australia—and this is also referred to in the submission—talks about the potential use for stem cells. It says:

Another potential use for stem cells is the generation of new nerve cells for the treatment of Alzheimer's disease, Parkinson's disease and paralysis.

Let us take Alzheimer's. Wherever did you get that idea from?

**Dr Swanton**—There is quite a bit of information on that.

**Senator HARRADINE**—Like what?

**Dr Swanton**—First of all, there was a letter by 80 Nobel laureates to President Bush indicating that insulin-producing cells could be used to treat or perhaps even cure patients with diabetes and so on, and it mentions Alzheimer's as well. I would have thought a letter from 80 Nobel laureates would have had some credibility.

**Senator HARRADINE**—So you are basing that—

**Dr Swanton**—I had not finished my answer.

**Senator HARRADINE**—So you are basing that on a lobbyist's attempt to get President Bush to act in a certain way?

**Dr Swanton**—That is one letter from 80 Nobel laureates, which I think would have some credibility. In addition, the National Institutes of Health noted the same thing in its document:

Spinal cord injury, multiple sclerosis, Parkinson's disease, and Alzheimer's disease are among those diseases for which the concept of replacing destroyed or dysfunctional cells in the brain or spinal cord is a practical goal.

In addition, the Andrews committee report mentions Alzheimer's as a possible use of embryonic stem cells. Furthermore, we have recently found two papers in the peer review press. The cause of Alzheimer's, as you would probably know, Senator Harradine, is unknown. However, we have a peer reviewed article that indicates that, in Alzheimer's disease patients, cholinergic neurons are affected. We also have another peer reviewed paper that indicates that embryonic stem cells can be used to develop cholinergic neurons. That certainly would be a reasonable theory to explore as a scientist. All that evidence, while obviously not conclusive, certainly supports the idea that embryonic stem cells could be used to treat Alzheimer's.

**Senator HARRADINE**—You are basing that on what you have just told us?

**Dr Swanton**—Indeed, yes.

**Senator HARRADINE**—Have you not seen the submission by the foremost scientist in this field in Australia, Professor Colin Masters?

**Dr Swanton**—I have not seen what Professor Masters has to say.

**Senator HARRADINE**—May I quote it to you? Professor Colin Masters said:

I am the Professor of Pathology at the University of Melbourne and my expertise is limited to the study of brain diseases, Alzheimer's and other neurodegenerative disorders in particular. My observations on the current stem cell debate relate to the misrepresentation which has occurred over the potential therapeutic benefits of stem cell therapies, especially in the areas of Alzheimer's disease, Parkinson's disease, motor neuron diseases and other causes (traumatic and non-traumatic) of spinal cord paralysis.

I have been concerned that advocates of embryonic stem cells as a therapy have created false expectations in the mind of the general community. The difficulties in developing these cells for therapeutic purposes in the brain pose immense scientific difficulties which require much more developmental research. The real value of stem cells for drug discovery has been almost overlooked in the public debate.

My general view is that stem cell research should be allowed to flourish. However, in the initial phases of this endeavour, emphasis should be given to adult stem cells for a variety of scientific reasons. Research on embryonic stem cells could easily be restricted to rodents or other species until such time as the true potential of these cells is realised.

And on the ABC *Science Show*, he stated that to suggest that stem cells would be suitable for that purpose, as you are suggesting, is fanciful.

**Ms Hartland**—We have some alternative views. Dr Swanton was just raising a number of peer reviewed articles and documents from the National Institutes of Health that held other views.

**Senator HARRADINE**—Those articles don't go anywhere, do they?

**Dr Swanton**—I did not say these people had found a cure for Alzheimer's disease. What they are indicating is that it is a worthwhile theory to propose that embryonic stem cells could provide assistance in the treatment of Alzheimer's and are certainly worthy of further research. Professor Masters said, as you quoted, that more developmental research was required. He also indicated that he thought adult stem cells would be useful but he did not give the reasons why they would necessarily be better than embryonic stem cells in the treatment of Alzheimer's.

**Senator HARRADINE**—Are you saying—

**Dr Swanton**—I am just reading back from your quote.

**Senator HARRADINE**—I see. It will be very interesting for him and others to see what you have said today. In the submission that you have made to us—and I invite you to recall what I did say about the *Science Show* and what Professor Masters said on that re embryonic stem cells, not adult stem cells: that it was fanciful.

**Dr Swanton**—Why would embryonic stem cells be more fanciful than adult stem cells, given that embryonic stem cells have—

**Senator HARRADINE**—You had better ask Professor Masters that, and obviously you have not. What you have said stands there, and that will be very interesting. The statement that you make in your document that you have presented to us talks about the limitations of adult stem cells. In your document to us you should be serving us as we should be serving you. That document says nothing about the more than 100 peer review articles detailing successful adult stem cell treatments. Why didn't you put that in here?

**Dr Swanton**—This submission is on the bill. The bill concerns the destructive use of embryos to create embryonic stem cells; it does not explicitly refer to adult stem cells. There is no need to make a case for adult stem cells. Professor Paul Simmons the other day indicated that adult stem cells were very useful in many circumstances. We do not resile from that. In

fact, the National Stem Cell Centre actually does much work on adult stem cells and embryonic stem cells. The work on adult stem cells is recognised.

**Senator HARRADINE**—I will come to that in a moment. But there is a discussion at the moment about the relative merits in respect of embryonic stem cells and adult stem cells. Nowhere have you proven or shown anything here which talks about any cure for those diseases, but I referred to a document which did. Don't you read the documents that come to the parliament, to inform your minds about these matters?

**CHAIR**—What has that got to do with the bill?

**Senator HARRADINE**—It has got a lot to do with the bill.

**CHAIR**—But relate the question to the bill. That is a very open-ended question and it could be interpreted as asking, 'Do you read notices of motion coming through the parliament?'

**Senator BARNETT**—You have to identify the document you are referring to.

**CHAIR**—What are you referring to when you are asking the witnesses the question: 'don't you read stuff that comes through the parliament?'

**Senator HARRADINE**—The subject matter of this discussion at the moment is the clear push by Biotechnology Australia to try and get the committee to agree to allow scientists to access frozen embryos for the purpose of embryonic stem cell research and other matters. Is that right?

**Dr Swanton**—Yes.

**Ms Hartland**—Yes.

**Senator HARRADINE**—So that is where you come from. But you have not indicated the alternatives which are far better and proven to have cured a large number of diseases.

**CHAIR**—But no-one is obliged to write an alternative as a commentary, because it is not contained within the bill. This bill does not deal with adult stem cell research. This bill deals with embryonic stem cell research. So no-one is obliged to write a commentary on a comparison or an alternative.

**Senator HARRADINE**—Professor Sawyer, what is your view on experiments on human subjects? What are the protocols?

**Prof. Sawyer**—The protocols were laid down by the NHMRC rules on those issues.

**Senator HARRADINE**—Isn't it a protocol, as Professor Colin Masters says in one of the submissions to our committee, that you need to undertake experiments on animal models over a period of time until you have established the proof of concept completely? Isn't that normally the situation?

**Prof. Sawyer**—That is generally the situation, yes.

**Senator HARRADINE**—Madam Chair, that is why I am asking the question. If the Senate has a piece of legislation before it that allows scientists to access 70,000 frozen embryos, clearly the onus of proof is on them to say that it is necessary to have that access. That is the purpose of my question. All I am asking is to show that it is not necessary. If Biotechnology Australia were even-handed and professional in giving us the information we need so that we can make up our minds, they should have provided information about the cures that have actually been found, for a whole range of diseases, by the use of adult stem cells.

**CHAIR**—That is a problem in the wording of the reference because the reference asked any witness to comment on the bill, not on all of the other issues surrounding the bill.

**Senator HARRADINE**—I do not have to have this argument with you. Are you suggesting that I cannot ask questions about this very vital issue: is it necessary for scientists to be given access to 70,000 human embryos?

**CHAIR**—No, I am not suggesting that you cannot ask that question at all.

**Senator HARRADINE**—That is what I am asking.

**CHAIR**—I am suggesting that you cannot ask the witnesses why they have not put something in their submission which does not relate to the bill.

**Senator HARRADINE**—Are you suggesting that the issue as to whether or not it is necessary does not relate to the bill? If you are talking about whether or not it is necessary, why have they not provided us with the information about the use of adult stem cells so that we can examine the matter properly?

**Ms Hartland**—We believe that the work on adult stem cells is very important. As we have said, half of the research that is expected from the National Stem Cell Centre will be on adult stem cells. We have taken information from a range of sources, from people, for example, at national institutes of health. The UK Royal Society states:

It is often presented that there is an either/or choice between adult versus embryonic stem cell research. The Royal Society believes that adult stem cell research and embryonic stem cell research **are not alternatives** and **both** must be pursued. In all likelihood each will yield distinctive therapeutic benefits but (i) we cannot predict which will be first or better and (ii) work on one system may help work on the other.

**Senator HARRADINE**—Would it help to know that I am a republican—the Royal Society! Are we supposed to bow and scrape?

**Dr Swanton**—The Royal Society is the UK's eminent science body.

**Senator HARRADINE**—I know it, but you have not provided information on the question of necessity.

**Dr Swanton**—We have indicated that adult stem cell work is necessary on page 7. We have also indicated why embryonic stem cell work is necessary in the four dot points on page 7.

**Senator HARRADINE**—I am not talking about adult stem cells. You have not provided us with the information that would reasonably be expected from an organisation like yours. What is meant by the use of some of these embryos and embryonic stem cells in the testing of drugs? What advantages are expected from their use in the testing of drugs and the examination of toxicology?

**Dr Swanton**—Are you making a specific reference to something we said in our submission, Senator?

**Senator HARRADINE**—I am asking you a question. If you put it in your submission, well and good, but I did not see it there. I am wondering why you didn't, if you didn't put it in there.

**Dr Swanton**—From what I understand, many have proposed that embryonic stem cells, when further differentiated, could be used for drug testing. Stem Cell Sciences is a company that does this or would like to do this and uses mouse embryonic stem cells at the moment.

**Senator BARNETT**—What was the point you were making about drug testing? You support drug testing under the definition of research?

**Dr Swanton**—From what I understand, Stem Cell Sciences is not going to be using embryos but embryonic stem cells or further differentiated stem cells. They do this at the moment in mice and I think they would like to do it—but you need to ask Stem Cell Sciences yourself—in humans.

**CHAIR**—Dr Swanton, you are not really qualified to answer that question, are you?

**Dr Swanton**—No.

**Ms Hartland**—You would not have a specific view on it. Any of the views we are putting forward here are those that have been put forward to us on the industry development side of things. If that has not been put to us, then I do not think we would have anything further to offer.

**Senator HARRADINE**—Could I put that to them then, from no less than the Minister for Industry, Tourism and Resources in a letter that presumably you prepared for him in answer to me? This is a letter dated—there is no date on it; that is interesting. The answers have been prepared also by BresaGen. I raised with the minister the question about the potential use of human embryo stem cell lines for drug screening. The response was:

If your question refers to the potential use of human ES cell lines for drug screening, this could be a major advantage, and is well appreciated by many pharmaceutical and biotechnology companies worldwide.

**Ms Hartland**—I am not familiar with the letter that you have, Senator Harradine, but I can take it on notice.

**Senator HARRADINE**—I was asked to source it back to your department, so I am sourcing it right back to your department. You should know it. I refer also to the $5.5 million that was set aside for the National Centre for Advanced Cell Engineering. That is in your portfolio, isn't it?

**Ms Hartland**—No, it is not, Senator.

**Senator HARRADINE**—It is not? Which portfolio is that?

**Ms Hartland**—It is in DEST—Department of Education, Science and Training.

**Senator HARRADINE**—DEST now? But when this grant was made? It was Industry, as I understand it.

**Ms Hartland**—It may well have been, Senator, but it is not under my responsibility. It is certainly looked after by DEST.

**Senator HARRADINE**—The area of drug testing, is that part of the national centre?

**Ms Hartland**—I think that they mention drug testing in one of the programs. We will have to take that on notice. I do not know.

**Dr Swanton**—Without recalling the whole application, I do not think drug testing was in there at all.

**Senator HARRADINE**—It is in the National Centre for Advanced Cell Engineering. That is part of this new centre.

**Dr Swanton**—So what is in that national centre?

**Senator HARRADINE**—I have information that says that the facility, that is, the National Centre for Advanced Cell Engineering—

will supply academic and commercial research centres, nationally and internationally, with human stem cells for use in research as assay systems for assessment of gene function or for drug screening and toxicology, and for recombinant protein …

DNA.

**Ms Hartland**—That is the NCACE, as distinct from the National Stem Cell Centre.

**Senator HARRADINE**—It is rolled into the National Stem Cell Centre now.

**Ms Hartland**—I think they are talking about the use of facilities at the NCACE, but I cannot tell you about the linkages with the programs.

**Senator HARRADINE**—Would you take that on notice and tell us?

**Ms Hartland**—I can, but we are waiting on the business plan and I just do not know of the timing for that—but yes, I will take that on notice.

**Senator HARRADINE**—Can you provide that information within the next two weeks?

**Ms Hartland**—I doubt it, because I am certain that within that time we will not have a business plan or a deed of agreement in place with the National Stem Cell Centre.

**Senator HARRADINE**—What about the question of program 15 of the centre?

**Ms Hartland**—Which is?

**Senator HARRADINE**—It is the integration of embryonic stem cell research and adult stem cell research.

**Ms Hartland**—What was the question?

**Senator HARRADINE**—The question goes to the issue of conscience, which is of extraordinary importance in this as well as in other matters in the parliament. What is meant by 'integration' of embryonic stem cells and adult stem cells?

**Ms Hartland**—I think you raised this issue at estimates as well, and we certainly took that on board. I am aware that the NHMRC's guidelines have a clause that talks about no researchers being forced, if you like—I will find the exact wording—

**Senator HARRADINE**—I am not talking about their being forced; I am talking about researchers on adult stem cells, students and so on being disadvantaged in any way, in both their current employment and their future employment.

**Ms Hartland**—We have certainly discussed this. The activities of the centre do come within that ambit. The NHMRC's ethical guidelines on assisted reproductive technology say:

Those staff who conscientiously object to research projects or therapeutic programs conducted by institutions that employ them should not be obliged to participate in those projects or programs …

We have taken on board your comments on this and we will ask our legal drafters to incorporate an express provision in the funding deed that goes to the heart of the issue.

**Senator HARRADINE**—But that does not cover the situation. You are saying, 'We'll give money for the integration of these things'—what does that integration mean? What does program 15 mean?

**Ms Hartland**—We are yet to see the business plan that will outline that, so I cannot crystal ball gaze on that one. But we have raised this issue already with the people who intend to be involved with the centre, and they have given us guarantees that no-one will be forced to do anything. It will not be career-limiting if they say they do not want to do particular work. Certainly no-one will be forced to do anything.

**Senator HARRADINE**—If there is integration of the two, that would be a serious question in the minds of some of the researchers and scientists in that their opportunities will be limited by that very fact.

**Ms Hartland**—An education and communications officer has also been put in place who is there to ensure that those sorts of things do not happen.

**Senator HARRADINE**—Is it an education media officer?

**Ms Hartland**—No, it is not a media officer; it is an officer to whom students and others can go if they believe that there are any issues that are being raised along those lines. We have tried to put in three layers of protection, if you like, to guard against that very point.

**Senator HARRADINE**—But you are going to have the integration of embryonic and adult stem cells. In that particular case, a scientist with a conscientious objection would be then forced into a situation of continuing or resigning.

**Ms Hartland**—I do not believe that to be the case.

**Prof. Sawyer**—That program is just one program in a large number. There are alternative areas where such people can work. I could give you my experience in a slightly different area, namely animal experimentation. As someone who has had over 30 years experience in academic research, if there are students—either undergraduates or postgraduates—who do not wish to take part in such activities, they are not disadvantaged; alternative areas are found for them. I am sure that that would be the case in these new centres, particularly if we have guidelines within the deed of agreement which deal with this specifically.

**Senator HARRADINE**—Thank you, Professor. But in this particular case—where I am talking about scientists who are specialists in the area of, say, adult stem cell science—it is proposed that they be forced to integrate their work with that of the embryonic stem cell work. That raises serious questions, clearly. In one particular instance, they may not then have to physically engage in embryonic stem cell research, but they will be required to compare their work with embryonic stem cell research work, which, as I understand it, raises questions about conscience in those areas. Are you looking at that?

**Prof. Sawyer**—It is my belief—

**Senator HARRADINE**—Is that your area? No, that is the biotech area.

**Mr Harper**—In the funding deed which is still under negotiation, the National Stem Cell Centre will be required to comply with the NHMRC guidelines.

**Senator HARRADINE**—Don't tell me that.

**Mr Harper**—Those guidelines require that such people not be obliged to participate in projects or programs to which they object.

**Senator HARRADINE**—Look, that is not the point—

**CHAIR**—We are now well and truly over time.

**Senator HARRADINE**—if that is the way you are dealing with it.

**Senator BOSWELL**—Madam Chair—

**Senator HARRADINE**—No, let it go; he is on record.

**Senator BOSWELL**—I wonder whether you could allow Senator Barnett to ask one question. He has been waiting for a long while.

**CHAIR**—I thought he had asked a few questions, but if he wants to ask one more—

**Senator BOSWELL**—He has been deferring to his senior colleague here.

**CHAIR**—We are now over time. We have accommodated Professor Tate, and so forth. Most certainly, you can ask one question.

**Senator BARNETT**—I would like to ask more than one question. We started 15 minutes late with Professor Tate.

**CHAIR**—No, we did not; we started 10 minutes late, and that is why I am keeping the clock.

**Senator BARNETT**—It was 10 to 15 minutes. With your leave, I would like to ask just a few questions; it would be more than one. I will try and be as brief as possible. Chair, are you feeling generous?

**CHAIR**—But not too long—five minutes.

**Senator BARNETT**—I thought I would change tack a little bit, in the sense of a change of scene. I will start with the ARC, if that is all right—one question for the ARC. You say in the second last paragraph:

... research into embryonic and adult stem cells is at an early stage.

Can you advise what evidence you have to support that claim?

**Prof. Sawyer**—At the present time it is our understanding that, whether you are talking about adult stem cells or embryonic stem cells, there are considerable problems in their use in terms of application for the relief of certain conditions. That is why we say that we believe this research in both areas really is at an early stage.

**Senator BARNETT**—I have no further questions for the ARC. My next question is to Biotechnology Australia. In your opening remarks, Ms Hartland, you said that half of the money intended for the National Stem Cell Centre was for adult stem cell research. Just to confirm for the record, does that mean that the other half is for human embryo stem cell research?

**Ms Hartland**—That is correct. I do not have exact figures, but it is about half.

**Senator BARNETT**—It is about half each; two halves make a whole.

**Dr Swanton**—And subject to what happens in the business plan.

**Senator BARNETT**—Sure. But at this stage, based on your understanding, out of $46-odd million half is for adult stem cell research and half is for embryo stem cell research?

**Ms Hartland**—That is correct.

**Senator BARNETT**—The regulatory regime that we are looking at in this bill obviously has to go through the Senate and get passed, but what happens if it does not get passed? What happens to the National Stem Cell Centre and the work they do on embryo stem cell research and adult stem cell research? Are there interim guidelines set up by the NHMRC to set up an interim regime, or will the work on embryo stem cell research not go ahead?

**Ms Hartland**—I answered this question before—Senator Eggleston asked it. Obviously, adult stem cell research can go ahead. There is no problem with that.

**Senator BARNETT**—Yes, I accept that.

**Ms Hartland**—So that is approximately half of the work. The people involved with the centre were asked this question by the panel of experts at the interview phase.

**Senator BARNETT**—What did they say?

**Ms Hartland**—They said that they could operate if the legislation did not go through; they would use existing stem cell lines, for example. I cannot comment about the long-term viability or in what direction their business plan would move.

**Senator BARNETT**—Would there be any interim guidelines set up by the NHMRC to regulate that program?

**Ms Hartland**—You would have to ask the NHMRC that. The centre will be—

**Senator BARNETT**—But you are providing $20-odd million dollars for that. You must know what sorts of guidelines would apply to the research.

**Ms Hartland**—They will follow all laws and guidelines that are existing at the time.

**Senator BARNETT**—This is not a law yet; it is a bill.

**Ms Hartland**—That is true. But at the point at which we come to an arrangement with a deed of agreement and money passes over, whatever the guidelines are at that stage, including interim guidelines that may be in place, they will be obliged to fulfil those.

**Senator BARNETT**—On page 15 of your submission you said, 'in Clause 36, proper informed consent'. Can you advise what that means?

**Ms Hartland**—We were referring to consent as it appears in the bill.

**Senator BARNETT**—What sort of consent is required?

**Dr Swanton**—I am trying to look for the clause in the bill, but whatever is defined in the bill.

**Senator BARNETT**—In the bill under clause 36 it says:

... that appropriate protocols are in place:

Do you know what protocols you are talking about? You are supporting this in your submission. Can you defend your submission?

**Dr Swanton**—Clause 39 of the bill indicates:

... each responsible person in relation to the excess ART embryo must have given proper consent to that use;

It goes on to indicate other requirements.

**Senator BARNETT**—It sets up a protocol. Do you know what the protocol is? Are you aware of the protocol?

**Dr Swanton**—I am not.

**Senator BARNETT**—Okay, let me show what the protocol is. This is it here—Ethical Guidelines on Assisted Reproductive Technology. Clause 3.2.5 talks about specified research. It then goes to guideline 6.4, which says:

Approval requires:

... a likelihood of significant advance in knowledge or improvement in technologies for treatment ...

So it is pretty broad, and I was wondering, to confirm for the record, if you support that definition and that particular guideline.

**Dr Swanton**—Generally, yes.

**Senator BARNETT**—What is your definition of 'significant advance in knowledge'?

**Dr Swanton**—I do not think that is a question for us; it is probably better directed to the NHMRC.

**Senator BARNETT**—Okay, thanks.

**Senator McLUCAS**—You were saying before that, essentially, half of the funds were going towards adult stem cell research and half towards embryonic stem cell research. The other day, when we were talking to Professor Trounson, he talked about there being four primary research areas in the National Stem Cell Centre and he described them. Can you tell me how you came to that statement that half of the funds are going towards adult stem cell research and half towards embryonic stem cell research, when there are in fact four programs and two of them are quite differently named?

**Ms Hartland**—It was a question that was put to the centre by the panel. We certainly asked the question ourselves and that was the answer we have been provided with.

**Senator McLUCAS**—From the National Stem Cell Centre?

**Ms Hartland**—From the people who put the proposal forward, yes.

**Senator McLUCAS**—You are going to provide us with some documentation to support that, is that right?

**Ms Hartland**—I do not have anything specifically on that. They have certainly said that to us on a number of occasions. I can talk to them further about that. What documentation did you want?

**Senator McLUCAS**—You said you had spoken with them.

**Ms Hartland**—We can have a look back to see if we have any information that is written on that. I know that the panel asked that of the applicants at the time and that we certainly asked that, because it has come up numerous times so we wanted to know the answer.

**Dr Swanton**—Although the business plan has not been finalised and the research programs have still to be finalised, the views we have obtained already from the draft submission and material provided by Professor Trounson have indicated that it will be roughly half and half. He may well now be going off on a slightly different tangent, and we need to get his views on what the National Stem Cell Centre will actually do. That will be in the business plan which is still to be determined.

**Ms Hartland**—Certainly that is the information that we have had all along.

**Senator McLUCAS**—If you have any more information on that split, I would be very interested in it.

**Ms Hartland**—Yes, certainly.

**CHAIR**—May I thank you all very much indeed for coming along tonight and spending as much time as you have with us and also for allowing us the courtesy of inviting Professor Tate to join us in advance of your scheduled time.

[10.03 p.m.]

**BREEN, Dr Kerry, Chair, Australian Health Ethics Committee, National Health and Medical Research Council**

**MATTHEWS, Ms Andrea Paulette, Consultant, Matthews Pegg Consulting, contracted to the National Health and Medical Research Council**

**MORRIS, Dr Clive Michael, Executive Director, COAG Implementation Taskforce, National Health and Medical Research Council**

**CHAIR**—Welcome. I remind you again that witnesses are protected by parliamentary privilege but any giving of false or misleading evidence may constitute a contempt of the Senate. The primary purpose of this session is to provide an opportunity for the NHMRC to comment on or clarify any issues that have been raised in evidence before the committee. This is the usual practice of this committee in bill inquiries. I will invite you to do so but, before I do, I would also like to recognise that Dr Breen was specifically called by some members of the committee and has made a significant effort, at some inconvenience, to be here this evening. The committee is very grateful to you for making that effort, Dr Breen. Dr Morris, do you wish to make any comments?

**Dr Morris**—Thank you very much for the opportunity to speak again with the committee. I would like to clarify a few matters relating to the role of the NHMRC in developing the legislation, the role of the NHMRC in the existing system for the oversight of research, the legislation before parliament and certain comments made in the testimony of one of the witnesses before this committee about advice provided by the NHMRC. Firstly, in relation to the role of the NHMRC in developing the legislation, I would like to reiterate that, following the 5 April meeting of COAG, the NHMRC was given the task of developing the legislation for introduction into parliament by the end of June. The parameters for the legislation were provided by the decisions of COAG as set out in the COAG communique. The legislation was developed in consultation with all states and territories, relevant Commonwealth agencies, the National Health and Medical Research Council and the executive committee of the Australian Health Ethics Committee. A national program of consultation was also undertaken in all capital cities with people nominated by each jurisdiction. The final legislation as introduced into federal parliament faithfully reflects the COAG agreement. However, parliament will determine its final outcome.

Secondly, I would like to clarify the role of the NHMRC in the current voluntary system of regulation, since it has been raised a number of times over the past few weeks. Senator Collins has put a number of questions on notice requesting information from the NHMRC about the approvals made by human research ethics committees within research organisations and institutions relating to research involving embryos. We have now provided a response to Senator Collins. However, it is useful to make a couple of points. AHEC conducts an annual survey of HRECs that have notified AHEC of their existence, and AHEC reports on their compliance with the NHMRC's *National statement on ethical conduct in research involving humans*. While documented compliance with NHMRC guidelines is a requirement for receipt of research grant funding from the NHMRC, all other institutional human research ethics committees notify their existence to AHEC and submit annual reports on a voluntary basis.

The annual AHEC survey does not include details of individual research protocols, nor the grounds on which approvals are granted. The survey focuses on information relevant to human research ethics committee procedures, such as membership, confirmation of

participation by required categories of members and the number of protocols approved or rejected. Thus the NHMRC does not hold information about individual projects approved by HRECs, including those relating to research involving embryos. To obtain such information, the NHMRC could only request it from HRECs that have notified their existence to AHEC and would only be able to enforce compliance with such requests where the institution also receives funding from the NHMRC. Research involving excess ART embryos is likely to occur in ART clinics, which are not generally funded by the NHMRC.

One of the major improvements proposed under the legislation before parliament is that the NHMRC will be empowered to collect detailed information about all proposals involving the use of excess ART embryos. Such information would be reported publicly. During the committee hearing on Thursday, 19 September both witnesses and senators expressed concern that the legislation would permit unrestricted trade in human eggs, sperm or embryos. This is not the case. The legislation prohibits the giving or receipt of valuable consideration for the supply of a human egg, human sperm or human ovum. Valuable consideration is further defined to include any inducement, discount or priority in provision of a service, and it is intended that this would include such things as a handling fee.

Lastly, I would like to comment on two comments made by Dr Chris Juttner during his testimony to this committee. During his testimony, Dr Juttner indicated that he had had discussions with me and Professor Pettigrew about some NIH discussion paper and that Professor Pettigrew and I had been in agreement about strengthening the bill along the lines that he discussed. I would like to say that this is not the case. I understand that Dr Juttner has since written to the secretary of the committee explaining this. Dr Juttner also noted that, on the issue of putting the nuclei of adult cells into embryonic stem cells that had had their nucleus removed:

... we have had advice from NHMRC and the people drafting the legislation that these do not constitute embryos because they cannot produce babies.

Again, this was not the case.

**Senator BARNETT**—I did not quite hear what you said then. Who made that statement?

**Dr Morris**—Dr Juttner, during his appearance before the committee, said:

... we have had advice from NHMRC and the people drafting the legislation that these do not constitute embryos because they cannot produce babies.

That is a direct quote from *Hansard*. I would just like to say that, during consultations with Dr Juttner on the exposure draft of the bill, Dr Juttner did raise these examples of putting adult cells into embryonic stem cells that had had their nuclei removed and, at the time, it was concluded that, on the basis of a definition in the exposure draft of the bill, it did not appear that this would constitute an embryo.

**Senator BARNETT**—To clarify, what is your position on that? Do you agree or disagree with Dr Juttner?

**Dr Morris**—In relation to the current bill, Dr Juttner was referring to having had advice from us on the definition in the current bill, and it was actually on an exposure draft of the bill during our consultations that the matter had occurred. Finally, I am aware that the committee has received a number of submissions and heard testimony from a range of experts and that, as their submissions are analysed and the committee develops its report, additional issues may come up over the next few weeks. In regard of the time available tonight and to help facilitate the work of the committee, we would be pleased to received questions on notice if this is felt to be helpful to the deliberations of the committee.

**CHAIR**—Thank you, Dr Morris. Dr Breen.

**Senator BARNETT**—I look forward to Dr Breen's contribution, but the witness referred to a letter that Dr Juttner sent to the secretary.

**CHAIR**—That was circulated earlier today.

**Senator BARNETT**—Some of us have been in committee meetings since 3.30, and we certainly do not have a copy of it. I have been in this room, the dining room or elsewhere. Could that be distributed to the committee members, please?

**CHAIR**—It can be redistributed, I suppose.

**Senator BARNETT**—Thank you. I am just trying to help you, Dr Morris, so that we know where you are coming from.

**Dr Morris**—Thank you.

**Dr Breen**—My preliminary statement will be fairly brief. The Australian Health Ethics Committee is a principal committee of the National Health and Medical Research Council. Its membership, terms of reference and statutory responsibilities are laid down in the National Health and Medical Research Council Act 1992. In relation to the matters at hand, it is important to note that the Australian Health Ethics Committee cannot issue ethical guidelines via the council without undertaking public consultation on a well-developed draft set of guidelines. In addition, AHEC is obliged under the NHMRC Act to have regard to submissions received for issuing the guidelines, and I refer to the NHMRC Act section 13.

The present AHEC was appointed in mid-2000 and its members hold office until mid-2003. At the commencement of this triennium, AHEC advised in its strategic plan that the task of revision of the 1996 *Ethical guidelines on assisted reproductive technology* was to be undertaken in the current triennium. This decision was consistent with the NHMRC policy that guidelines be reviewed or revised when they have been in existence for over five years. The process of revising these guidelines was initially deferred, as AHEC felt that it should await the outcomes of the inquiry then being conducted by the House of Representatives Standing Committee on Legal and Constitutional Affairs, namely the Andrews committee. However, in August 2001 it was decided to establish a working party to undertake this work on behalf of AHEC. The working party consists of four serving AHEC members—one of whom is the chairperson and three other persons with a range of expertise relevant to the task. I am not a member of that working party. The committee has been given the name Committee to Review the Ethical Guidelines on Assisted Reproductive Technology, which we abbreviate to CREGART. I have attached to this statement the membership of that working party and its terms of reference.

During the process of preparing a revised draft set of guidelines—a process that is continuing—a number of parallel developments took place of which this Senate committee is aware. Especially relevant was the COAG decision announced on 5 April 2002 and the subsequent work by staff of the NHMRC to assist in drafting legislation to bring the COAG decision into law. At the same time as CREGART was undertaking its first round of public consultation, considering submissions and producing a first draft of the new ART guidelines for AHEC, AHEC via its executive committee was invited to provide comments on the draft legislation and associated documents which were being developed by the COAG implementation working group headed by Dr Clive Morris. The AHEC executive were thus in a similar position to various stakeholders in the states and territories—that is, we were asked to provide input and comment but we did not have responsibility for finalising the draft bill for the relevant ministers. During the time from which parliament commenced debate of the

bill, AHEC considered carefully the timing of the release for consultation of the revised guidelines, which are presently entitled *Ethical guidelines on the use of reproductive technology in clinical practice and research*. It is the belief of AHEC that, even if the draft were ready for release for public consultation, it would be inappropriate for AHEC and the NHMRC to release the document before parliament has completed its current task. This belief has been formed out of respect for parliament and because some aspects of the draft guidelines are premised on the decision of COAG. In addition, I in particular was acutely aware that a Canadian counterpart to the NHMRC had been severely criticised by the Canadian parliament for releasing draft policy on embryo research before parliament had debated the matters. That is the completion of my statement, and I am very pleased to be here and to answer your questions to the best of my ability.

**CHAIR**—Ms Matthews, do you wish to add anything?

**Ms Matthews**—No.

**Senator JACINTA COLLINS**—I would like to thank the NHMRC for responding to the questions that I put on notice to aid the understanding of the public or anyone who might be trying to follow the context of this discussion. I would also like to thank AHEC for making themselves available today. For the benefit of the other senators, the context of the questions that I put on notice arose from the NHMRC submission, which stated:

It is anticipated that these guidelines will include information about the types of matters that should be considered in order to establish that certain uses of excess ART embryos are likely to result in a significant advance in knowledge, or improvement in technologies for treatment as a result of the use of excess ART embryos.

This is what I referred to earlier, senators might recall, as it appears in this case that the cart is before the horse. As I understand the situation, we are advised that how terms in the bill such as, 'leading to a significant advance in knowledge' might be interpreted are awaiting the result of the review of the guidelines. It is near impossible for us as parliamentarians to understand how it is envisaged that those terms may in fact be applied. Dr Breen, was there a meeting of the full AHEC in September this year?

**Dr Breen**—Yes, we held a meeting on 3 and 4 September.

**Senator JACINTA COLLINS**—Did AHEC consider the revised guidelines with a view to public consultation at that meeting?

**Dr Breen**—Yes. An updated version of the guidelines was tabled and debated at great length. I am guessing the total, but at least 20 alterations were requested by the full AHEC to the drafting group. The drafting group have gone back to do some further work on that.

**Senator JACINTA COLLINS**—So there is still that level of contention, even about your process in considering those guidelines?

**Dr Breen**—I would not say contention so much as trying to get the document as clear as possible before it goes out for wide consultation.

**Senator JACINTA COLLINS**—Are you able to provide this committee with the results of the first phase of consultation?

**Dr Breen**—I can describe it; I do not think I can accurately provide you with the result at this stage. The way the first round was advertised was to notify interested members of the public that the revision process was going to commence and that those people were welcome to make submissions on the strengths and weaknesses of the current document and to make any comments on things they would like to see incorporated in the future. So it was not a

consultation process that would be required to meet our statutory responsibilities to sign off new guidelines; it was an invitation to get some early input for the working party. I think we received some 60 submissions.

**Senator JACINTA COLLINS**—In relation to those 60 submissions, and the issue that I think is most significant to this committee, is it possible for us to be provided with a summary of the issues raised concerning how those guidelines relate to the destructive use of human embryos?

**Dr Breen**—I would have to take that on notice to find any barriers. The only one I can think of immediately is the current system, by which people make submissions as to whether they regard those as being in any way confidential. I cannot, on the run, answer that for you.

**Senator JACINTA COLLINS**—If that is the case, perhaps it could be provided on the basis that the source of the concern is not identified but the issue that is being canvassed can be identified. Dr Breen, have you had an opportunity to look at the response to the questions that I had put on notice?

**Dr Breen**—Do you mean the document that Dr Morris provided you with?

**Senator JACINTA COLLINS**—Yes.

**Dr Breen**—Yes, I have.

**Senator JACINTA COLLINS**—The way I would summarise those questions is that I asked for a summary of the state of play in relation to the destructive use of human embryos where that is in fact allowed. Correct me if, in your view, this is an unfair summary of the response: 'Even though we are reviewing our guidelines, we cannot give you that information.' How can you be conducting a review of guidelines without having an understanding of the practices that those guidelines are meant to apply to?

**Dr Breen**—I will answer that in two ways. I believe you were asking for data on numbers et cetera. We do not have that—

**Senator JACINTA COLLINS**—No, I was asking for data on how institutional ethics committees reached their decisions, what they saw as extraordinary circumstances, what types of research were regarded as perhaps extraordinary—issues such as that.

**Dr Breen**—They are valid criticisms, and we do not have access to that information.

**Senator JACINTA COLLINS**—As I understand it, you do have access to that information in relation to two funded projects from Monash University using the already established Singaporean stem cell lines. This is probably a question best directed to the NHMRC, but shouldn't the Monash institutional ethics committee be asked to provide that information in relation to those two projects that we are aware of—given that, if you are funding a project, there are certain requirements about the amount of information that should be recorded by an institutional ethics committee?

**Dr Morris**—Senator, you are aware that those two projects relate to the use of embryonic stem cell lines rather than research on embryos.

**Senator JACINTA COLLINS**—Yes. And I also understand, from earlier discussions here and from your answers to my questions, that the interim guidelines and the institutional ethics committee process do apply to such projects.

**Dr Morris**—That is right. The HREC in question would have made its decision based on the interim advice from AHEC of September last year.

**Senator JACINTA COLLINS**—Yes. Since we know that that is within that time frame, that the provisions of the NHMRC regarding record keeping would apply and that, as you are funding those projects, the NHMRC has the authority to seek that information, I am asking that that information actually be sought.

**Dr Morris**—We will take the question on notice and see whether we can get the information for you.

**Senator JACINTA COLLINS**—Given that part of the argument in the NHMRC submission is that the NHMRC has the means, in the currently regulatory system, of regulating this system, and given how you have described these two projects and the timing and circumstances of them and the requirements on record keeping, it would be very interesting and very concerning to this committee if that information is not available.

**Dr Morris**—That is fine. I am a little confused, because your questions on notice were asking about details of each exceptional circumstance in relation to both research involving embryos and the use of embryonic stem cell lines. Dr Breen may like to comment, but the interim advice from AHEC was fairly clear on which aspects of both the national statement and the 1996 ethical guidelines on ART would be relevant in the situation—

**Senator JACINTA COLLINS**—Let me rephrase my question—and you understand from my earlier questions the level of detail I am seeking. I am asking for the detail of how the interim guidelines were applied to the use of the stem cell lines in these projects. An example of a question there is: one of the provisions under the interim guidelines is that if stem cell lines have been imported, the institutional ethics committee seek to ascertain whether those imported stem cell lines had been derived ethically. I would be interested in the answer to that question as well.

**Dr Morris**—We will take that on notice and see what we can do for you.

**Senator BARNETT**—I may have missed something here about the actual copy of the guidelines from September 2001.

**Dr Morris**—It is interim advice from the Australian Health Ethics Committee.

**Senator JACINTA COLLINS**—Perhaps I should explain.

**Senator BARNETT**—I was wondering where that is.

**Senator JACINTA COLLINS**—If you have a look at my questions on notice, you will see that a deficit in the original NHMRC submission was identified in that it did not specify the latest interim guidelines. They have now been provided and attached to the answers to my questions on notice.

**Senator BARNETT**—Do we have a copy of those?

**Senator JACINTA COLLINS**—Yes. It is called 'Information for Human Research Ethics Committees. Sheet No. 5—Stem Cell Research.' Apparently it is the interim guidelines referred to by previous witnesses when they said it is on the web site. My response to that was that I took the NHMRC submission to be the current state of play and did not go searching further on the web site. But it was an unintended oversight in the NHMRC submission.

**Senator BARNETT**—But it is now here?

**Dr Morris**—Yes.

**Senator JACINTA COLLINS**—They have now rectified it, yes.

**Dr Morris**—On page 26 of our original submission we referred to AHEC recently issuing an information sheet to HRECs, and we summarised the information sheet, but we did not refer to the information sheet or say where it was available.

**Senator JACINTA COLLINS**—And the information sheet does, in part, contradict the earlier point at the top of that page which says that no legislation or proscription relates to established stem cell lines. This information sheet, to the extent that the procedures of the NHMRC operate, is regarded as proscribing the circumstances in which established stem cell lines can be used. Is that a reasonable summary?

**Dr Breen**—Yes, I agree.

**Senator JACINTA COLLINS**—Could I go further in relation to a couple of issues—firstly with respect to AHEC. You would be aware, I am sure, from the debate in the House of Representatives that Mr Andrews indicated that he had not been satisfied with the provisions regarding diagnostic investigations being exempted. It was indicated that this matter had been a matter of concern of AHEC. Has the process that Dr Morris alluded to before, where he said some adjustment had been made, satisfied the concerns of AHEC, as it is obvious from the House of Representatives debate that it has not satisfied the minister?

**Dr Breen**—That aspect of the legislation has not been discussed by a full meeting of AHEC. It was an issue that arose during what I described in my opening remarks as the informal consultations that our executive was asked to have with the people drafting the legislation. The notes of the AHEC meeting—I was overseas at the time the two telephone hook-ups took place—show that two members on two occasions expressed concern that the diagnostic aspects of the use of embryos might have been an opening for people to misuse the legislation and that that be conveyed to the minister. I believe that happened. Beyond that, AHEC has not taken it further.

**Senator JACINTA COLLINS**—Has there been a full meeting of AHEC since that time?

**Dr Breen**—Yes, there has been one full meeting.

**Senator JACINTA COLLINS**—And this issue was not on the agenda?

**Dr Breen**—No, it was not.

**Senator JACINTA COLLINS**—Essentially, the answer to my question is: you do not know.

**Dr Breen**—No, I do not know. I have just told you that a full meeting of AHEC has not discussed—

**Senator JACINTA COLLINS**—No, my question is about the concerns that have been raised in AHEC by two or more members on one occasion. As I understand it, other members followed those two members in expressing similar concerns, so it is actually more than just two members on two occasions. Have those concerns been satisfied by the adjustments that were made to the draft? I think a fair summary of your answer is that you do not know.

**Dr Breen**—That is correct.

**Senator JACINTA COLLINS**—Is there a means for this committee to receive an informed response to that question?

**Dr Breen**—Yes, I could do that, in terms of calling a full meeting of AHEC by teleconference, or the executive, and discussing it again.

**Senator JACINTA COLLINS**—The difficulty for this committee is that we have had this canvassed as an issue that was a concern to AHEC, we have had the minister indicate that he

has not been satisfied of there being a potential loophole and we do not have an informed position from AHEC on that issue. If you could take that on notice, it would be appreciated. Further to that question, were there other areas of concern with the bill arriving from the process you described?

**Dr Breen**—I would have to refer to the notes of those meetings; they were a while ago. Dr Morris might remind me of things that we discussed.

**Dr Morris**—We did provide in our supplementary submission the notes from the meetings with the members of the AHEC executive, which discussed various issues.

**CHAIR**—Is that in confidence?

**Dr Morris**—Yes, that was provided in confidence.

**Senator JACINTA COLLINS**—That is in the earlier in-confidence notes. Dr Breen, are you aware of a concern—similar to the one that I raised earlier, about the cart being before the horse, so to speak—that the parameters of 'significant gain in knowledge' and other similarly grey areas of the draft bill were being discussed within AHEC?

**Dr Breen**—Yes. We intend to put out to public consultation an attachment to the revised guidelines, which will expand on how to interpret the idea of exceptional circumstances and significant advance in knowledge. That is still being drafted as well.

**Senator JACINTA COLLINS**—Within what time frame do you anticipate that draft would be prepared?

**Dr Breen**—We have not set a date for completion of the draft. We had originally hoped to conduct our public consultation and complete this by the end of the year. As we have made the decision to wait for parliament to complete the legislation, it may be later than that.

**Senator JACINTA COLLINS**—As I understand it, the concern within AHEC was that the bill itself should further describe these parameters; is that not the case?

**Dr Breen**—I honestly cannot remember that.

**Dr Morris**—I do not recall that being among their concerns.

**Senator JACINTA COLLINS**—Let me characterise for you my understanding of the way those concerns have been described. AHEC raised the concern that, without further describing the parameters of significant gain in knowledge or other similarly grey areas of the draft bill—for instance, those terms open to interpretation such as 'proper consent'—the proposed regulatory system will not deliver the strict regulatory regime required by the COAG decision.

**Dr Morris**—I am at a loss. I do not know where that has come from.

**Dr Breen**—It is in our notes from 16 May.

**Dr Morris**—These are the notes we provided in confidence to the committee.

**CHAIR**—I am somewhat concerned that in-confidence material is now being read into the public record.

**Senator HARRADINE**—Why does it have to be in confidence?

**Senator JACINTA COLLINS**—I have actually received this from other sources, not from there, so if it happens to be in that as well then—

**Dr Morris**—If you have received those from other sources, it may be a breach of AHEC's committee-in-confidence procedures.

**Senator JACINTA COLLINS**—It may be.

**Dr Morris**—It is a difficult situation.

**CHAIR**—That becomes a very serious problem for this committee.

**Senator MARK BISHOP**—As Senator Collins said, the source she has received the material from is not the same source referred to by Dr Morris—that is all she said.

**CHAIR**—If that is the case, I am not disputing that. The fact remains that there is an in-confidence document—

**Senator JACINTA COLLINS**—All I am saying is that I have not referred to that in-confidence document, and I have not indicated that my understanding of this situation is directly sourced from AHEC either.

**CHAIR**—I thought you had just read a section of that document.

**Senator JACINTA COLLINS**—No.

**CHAIR**—I think we just need to proceed with caution because we are dealing with—

**Senator JACINTA COLLINS**—I do not even know if this is an issue that confidentiality concerns relate to either. I would be concerned if it did because I cannot see the possible reasons that confidentiality would need to relate to such a matter.

**CHAIR**—Dr Morris, can I just clarify your previous comment? I understood you to say that you believed the quote that Senator Collins had used was in fact from that confidential document.

**Dr Morris**—Dr Breen has pointed out to me where it occurs in the document we gave to you in confidence.

**Dr Breen**—I thought the words that Senator Collins was using seemed to be very similar to the words of the notes of a meeting we had. That was why I drew it to Dr Morris's attention.

**CHAIR**—I think we just need to proceed with great caution.

**Dr Morris**—These notes were from early in the process of developing the legislation. This was a consultation during the earlier stages of developing both the legislation and the explanatory notes—

**Senator JACINTA COLLINS**—Which is why I am asking these questions.

**Dr Morris**—which may bear no relation to the final documents. These are internal notes of consultations which we were having with members of the AHEC executive. You are taking them out of context. It seems that you are applying them to—

**Senator JACINTA COLLINS**—No, I am not taking anything out of context. I am asking a question about them. I am saying: did AHEC express a concern characterised this way and, if so, does that concern remain?

**Dr Breen**—Could I attempt to answer that? Obviously in this process there is iteration and discussion. I and the chair of the revision working party both attended a meeting quite late in the piece that the CEO of NHMRC and Dr Morris held—and Andrea Matthews as well—to present pretty much close to the final briefing on the bill and we had an opportunity in a full-day meeting to raise any residual concerns we might have had. I believe the notes of that meeting will show that we left that meeting quite satisfied. In the give and take of trying to develop legislation, when you are being consulted you do not expect to win every argument. But we left that day being reasonably satisfied.

**CHAIR**—Senator Collins, I draw your attention to the fact that we are now 10 minutes overdue for completion and other honourable senators are wanting to ask questions, I presume.

**Senator JACINTA COLLINS**—I could perhaps deal with the rest of my questions on notice.

**CHAIR**—As long as they are not too numerous, otherwise it will simply potentially delay the return of—

**Senator JACINTA COLLINS**—I am simply responding to Dr Morris's offer earlier that he is happy to facilitate whatever information the committee think is appropriate for us to determine these matters.

**Senator BOSWELL**—I address my question to Dr Clive Morris. Dr Morris, at your first appearance before the committee you refused to be drawn into discussing the merits of embryo research because you said your job was to prepare legislation according to the COAG agreement. That is correct, I believe. Have you approached any witness group with a view to helping them with their evidence to this committee?

**Dr Morris**—Can you give me more information, please?

**Senator BOSWELL**—Has anyone approached a group of people from your department and asked them to put in a submission?

**Dr Morris**—Has somebody approached a group from my department?

**Senator BOSWELL**—Yes. Have you got a person in your office called Ben Battisson?

**Dr Morris**—Yes.

**Senator BOSWELL**—What is his position?

**Dr Morris**—Mr Battisson is a project officer working for us.

**Senator BOSWELL**—Is he working on this particular—

**Dr Morris**—Yes, he is working with us.

**Senator BOSWELL**—He is working on the stem cell—

**Dr Morris**—Not on stem cells; he is working with us in the COAG implementation task force of the NHMRC.

**Senator BOSWELL**—Are you well aware that Mr Ben Battisson sent a fax, following up a phone call and asking questions about witnesses who appeared before this committee, and the fax was 17 pages?

**Dr Morris**—Can I take the question on notice? Do you have a copy of the fax?

**Senator BOSWELL**—No, I am asking a question. Are you aware of it?

**Dr Morris**—Can you tell me whom the fax went to? That might help me.

**Senator BOSWELL**—The fax went to Miriam Dixon, CEO of Parkinson's New South Wales.

**CHAIR**—Senator Boswell, do you have a copy of the letter from Miriam Dixon?

**Senator BOSWELL**—Yes, I do.

**CHAIR**—She is not implying in this in any way—

**Senator BOSWELL**—I have the copy of the fax.

**CHAIR**—that there has been any interference in anything that has been done. She has simply said that they had been asked for confirmation that Parkinson's Australia support the statement as reported in *Hansard* by Dr Peter Silburn to the Senate Community Affairs Legislation Committee. She has not in any way suggested that there has been any interference or pressure placed on her or on her association.

**Senator BOSWELL**—Ben Battisson has sent her a facsimile, a 17-page letter or fax—and I wondered whether you knew anything about it, Dr Morris.

**CHAIR**—Seeking clarification, I understand.

**Dr Morris**—Is there a problem? I did ask for clarification of whether—

**Senator JACINTA COLLINS**—Can we understand exactly what the facsimile says?

**Senator BOSWELL**—I will table the fax, but I just want to refer to it before I table it. This is the fax sheet by Ben Battisson of your department urging that a letter be forwarded from New South Wales Parkinson's to the chair of the committee by 4.30 p.m. that day.

**CHAIR**—What are you alleging, Senator Boswell? I am unsure what you are alleging.

**Senator BOSWELL**—Madam Chair, we have a project officer working with the NHMRC who has approached a group of people asking to clarify a position in opposition to a witness, so seeking a different view to a witness who gave evidence in this committee.

**CHAIR**—Senator Boswell, I just want to clarify this because I think we are talking about different things.

**Senator BOSWELL**—No, we are talking exactly—

**CHAIR**—Senator, when I speak, can I just finish my sentence. I let you finish your sentence. I am seeking to clarify whether we are both talking about the same thing. The letter that Miriam Dixon sent today does not have any contradiction contained in it between the evidence that was given by a witness—Dr Peter Silburn in this case—and the position taken by Parkinson's NSW Inc. That is what I thought you were referring to, but now you are saying that someone in the NHMRC contacted Miriam Dixon to get her to take a contrary view to the witness and the evidence that was given. Are we talking about the same witness and the same event? That is what I am trying to clarify.

**Senator BOSWELL**—I am talking about a Mr Ben Battisson and the department of the NHMRC who wrote to Miriam Davis, Parkinson's Australia—

**CHAIR**—Miriam Dixon or a different person?

**Senator BOSWELL**—Sorry, Miriam Dixon. You are quite right, and it was actually Parkinson's NSW. This person sent her a 17-page fax. I consider it absolutely deplorable when someone working from a department seeks to get another group of people to put in a submission that virtually overrides or qualifies a submission.

**CHAIR**—But it does not override anything. That is what I am trying to establish, Senator Boswell: are we talking about the same thing? Miriam Dixon's answer does not override Dr Silburn's evidence. I just want to clarify: are we talking about the same thing?

**Senator BOSWELL**—Miriam Dixon's letter does not contradict. It says that not all people share that view. That was sought by an officer, Mr Ben Battisson, of your department. Is it normal for your people to interfere in the Senate, Dr Morris, seeking information or seeking to put another view? You were not prepared to give a view on the bill when we asked you. Now you are actively getting in the game. Your role is to keep the score and we will play the game.

**CHAIR**—Senator Boswell, I am sorry, I cannot allow you to make such allegations against officers of the NHMRC. It is quite unparliamentary. You are alleging interference and, if what I am reading from Miriam Dixon is what you are referring to, there is absolutely no interference. It is quite improper to suggest that there has been interference. If you have evidence of interference—

**Senator BOSWELL**—I have the fax; he sent a 17-page letter.

**CHAIR**—What did the 17 pages contain? Was it 17 pages of *Hansard*?

**Senator BOSWELL**—I do not know what it was.

**CHAIR**—Nor do I. That is what I am trying to clarify.

**Senator BOSWELL**—I think it is quite improper that an officer of a department would seek out——

**Senator McLUCAS**—Madam Chair, on a point of order: these are allegations that Senator Boswell is making—table the document and let us have a look at it. You do not know what the 17 pages are. It is very hard for us to be sitting around here and making any judgment about what is happening. You are making very serious allegations, Senator Boswell.

**Senator BOSWELL**—I certainly am, and I am going to refer it to the Privileges Committee and this guy will be very—

**Senator McLUCAS**—It is very unfair to other members when we have no idea what you are talking about.

**Senator BOSWELL**—I will table it and print it out.

**Senator JACINTA COLLINS**—Chair, can I suggest that we move on to the senator's questioning and that a copy of this be circulated to us? We can then revisit this matter later, if necessary.

**CHAIR**—Senator Boswell, you might have other questions that you want to move on to.

**Senator BOSWELL**—No. I want to ask this question. I want everyone to have the copy of the fax sheet and then I would like to come back to it with your—

**CHAIR**—I am prepared to adopt Senator Collins's suggestion because Senator McLucas has a very valid point of order. At this stage, you have not been able to clarify for us exactly what your allegation is. We now have before us the fax to which you were referring, but I understand it is only one page, not 17 pages.

**Senator BOSWELL**—It is the fax sheet.

**CHAIR**—No, what I just glanced at then is a cover sheet. You have referred to 17 pages—I do not know what the 17 pages contain. I do not know whether you do, but if you would provide that to the committee we would be happy to look at it. There are some very serious allegations being made in this, and I think we should all have a look at it. I will adopt Senator Collins's suggestion: we will move on to other questions to give us all time to have a look at this.

**Senator HARRADINE**—Dr Morris, I asked last time on what basis—on what evidence, on what documentation—the states had decided on this legislation. You have not provided that information.

**Dr Morris**—I think we clarified at the time that the request had gone to the Prime Minister's office and that they were COAG documents—documents that were provided to COAG for consideration by COAG.

**Senator HARRADINE**—But you did not come into the business after the COAG process. You came in well before, so I am asking you on what basis—on the basis of what documents—the states came to their determination to pursue the particular proposals in these bills.

**Dr Morris**—The NHMRC was involved in developing the legislation after the COAG meeting. Before the COAG meeting on 5 April, the process of developing reports or whatever for COAG was handled by a different agency.

**Senator HARRADINE**—But you were involved. You wrote to the various state health ministers, did you not?

**Dr Morris**—You are referring to the process started through the Australian Health Ministers Conference in July 2000, where the NHMRC was asked to facilitate a process to develop nationally consistent legislation to ban the cloning of humans. This process ended up being subsumed by the subsequent process of developing a report to COAG.

**Senator HARRADINE**—Quite so, but you were involved up to that stage, weren't you?

**Dr Morris**—I was involved in facilitating the development of the report with a Commonwealth-state working party prior to the issue coming to COAG in, I think, June 2001.

**Senator HARRADINE**—That is right, and that is what I am asking you to provide: the relevant documentation that was presented to the health ministers which was the basis for their decision—a recommendatory decision, but nevertheless a decision.

**Dr Morris**—That report did not go to health ministers. My understanding is that it was used to inform the deliberations of developing the report to COAG.

**Senator HARRADINE**—That is what I am asking for—that information. How can we make up our minds about what the states are insisting on until we have all the documentation? That is what I am asking.

**Dr Morris**—I will have to take the question on notice to find out what information, if any, went to health ministers in relation to this.

**Senator HARRADINE**—I would like all of the information and documentation—including the material which went to the health ministers—that was used by those responsible leading up to the decision of COAG. In other words, what convinced the states that they should have the legislation that we have got?

**Dr Morris**—Senator, that goes back to my previous answer in that it is probably with the Prime Minister's office; it is probably part of COAG documentation that is with the Prime Minister's office. I can take it on notice to find out if, and what, information went to health ministers.

**Senator HARRADINE**—And to the other ministers leading up to the COAG?

**Dr Morris**—In relation to COAG, I am unable to provide you with information but I may be able to find out if information went to health ministers. Does that help you, Senator?

**Senator HARRADINE**—That would be part of it yes, but I think that we should pursue the other matter. Are we pursuing the matter?

**CHAIR**—Do you want to go back to Senator Boswell's issue now?

**Senator HARRADINE**—No, are we pursuing the matter with the COAG material?

**CHAIR**—Yes, we are continuing to pursue that.

**Senator HARRADINE**—If you cannot provide that, Dr Morris, then I would appreciate the material that was provided for the health ministers. Last time you appeared before this committee we were trying to get from you the information as to how many embryos are likely to be accessed as a result of this legislation going through parliament—if it went through the parliament.

**Dr Morris**—Is that your question: how many embryos are likely to become excess?

**Senator HARRADINE**—No, how many embryos will be accessed? It is getting late. We are told that it will be 70,000 embryos and we are also told that it may be less than 100—there have been various numbers mentioned: 20, 50 or whatever—embryos will be used for basic research on stem cells. You were going to do an examination of the material to provide us with a response to that.

**Dr Morris**—Yes, Senator, we did provide a supplementary response on 13 September in relation to your questions. We went through the submissions—

**Senator HARRADINE**—What page are you looking at?

**Dr Morris**—It is 2b; we did not have page numbers in our supplementary submission. It is about eight pages into the document.

**Senator HARRADINE**—It is not page 8 in my document, or page 7. Is it after 'Importation of Stem Cells'?

**Dr Morris**—Two more pages after that.

**Senator HARRADINE**—Can you tell me, in respect to the other areas of research, how many embryos are expected to be accessed for examining the effectiveness of new culture media used in ART practice, for example?

**Dr Morris**—Senator, we cannot say more than we have said in our supplementary submission in relation to numbers. So although the number of 70-odd thousand has been quoted numerous times, we feel that probably it is far fewer than 70,000 that would be available for research or other uses.

**Senator HARRADINE**—So that we can get it clear, do the types of research that the legislation will permit include examining the effectiveness of new culture media used in ART practice?

**Dr Morris**—Sorry, can you please repeat the question? I did not hear the whole question.

**Senator HARRADINE**—If the bill goes through, will it permit this type of research?

**Dr Morris**—Yes.

**Senator HARRADINE**—It will permit examining the effect of a new culture media used in the assisted reproductive technology practice?

**Dr Morris**—That is right.

**Senator HARRADINE**—Will it permit understanding embryonic development and fertilisation?

**Dr Morris**—Are you reading from our explanatory guide on this?

**Senator HARRADINE**—I suppose that it has been helpful.

**Dr Morris**—The answer is yes.

**Senator HARRADINE**—Will it permit training clinicians in microsurgical ART techniques?

**Dr Morris**—All of these things will be permitted, subject to gaining a licence from the NHMRC Licensing Committee.

**Senator HARRADINE**—It will permit anything to do with improving ART techniques?

**Dr Morris**—Yes, subject to a licence.

**Senator HARRADINE**—What about transportation and observation?

**Dr Morris**—Transportation, observation and storage would not require a licence; they would be permitted if they are exempt uses.

**Senator HARRADINE**—What about micromanipulation, lasering, cutting and dissecting?

**Dr Morris**—It would depend on the opinion of the licensing committee. There are a whole range of potential uses, but each use would first need to get the approval of the local human research ethics committee in relation to the criteria that it uses. Then it would need to get approval from the NHMRC Licensing Committee and would be subject to whatever conditions the licence requires.

**Senator HARRADINE**—What about studies in genetic make-up and expression?

**Dr Morris**—They are subject to the same cavaets.

**Senator HARRADINE**—What about quality assurance testing to ensure that pre-implantation diagnostic tests give accurate results?

**Dr Morris**—It is subject to the same caveats.

**Senator HARRADINE**—What about drug testing, including toxicology studies on human embryos?

**Dr Morris**—It would be up to whether or not the institutional human research ethics committee thought it was viable research, based on criteria provided by AHEC.

**Senator HARRADINE**—I do not want to enter into an argument with you about the research committees. There was a question about their openness and the information that is largely kept secret. Regarding commercialisation, can embryonic stem cells be sold under the legislation?

**Dr Morris**—As I said in my opening statement, the legislation maintains faith with the COAG communique which, in relation to stem cells, says that they should continue to be subject to the regulatory regime that they are under now. The legislation does not extend to the use of stem cell lines.

**Senator HARRADINE**—Can you sell them overseas once you have the decision?

**Dr Morris**—It does not extend to—

**Senator HARRADINE**—So there is nothing to prevent a commercial operation from taking stem cells from some of the frozen embryos and selling them for profit overseas, for example, to a pharmaceutical company to use in drug testing?

**Dr Morris**—Senator, I think we covered a lot of this ground when we appeared before.

**Senator HARRADINE**—Is it yes or no? Could you have an organisation or a scientist who, having received or obtained the embryonic stem cells, proceeds to sell them overseas to a pharmaceutical company for drug testing?

**Dr Morris**—As I said, the legislation does not extend to the issue of stem cells.

**Senator HARRADINE**—I just want a yes or a no.

**Dr Morris**—The use of cells derived from any tissue would be permitted to be sent overseas.

**Senator HARRADINE**—I will ask you again and I want a yes or a no answer. Does this bill allow and permit the sale of embryonic stem cells derived from frozen embryos, to their destruction, to pharmaceutical companies for drug testing or toxicology studies?

**Dr Morris**—The use of embryonic stem cell lines is not covered by this legislation.

**Senator HARRADINE**—Is it yes or no? Why will you not answer yes or no?

**Dr Morris**—It does not prohibit it. It is in different language that is all. This legislation does not prohibit the uses of embryonic stem cell lines.

**Senator BOSWELL**—Being sent overseas?

**Senator HARRADINE**—Does it allow for their commercialisation?

**Dr Morris**—It does not prohibit any uses of embryonic stem cells.

**Senator HARRADINE**—Just yes or no, please. Does it allow for their commercialisation or not?

**Dr Morris**—It does not prohibit any uses of embryonic stem cell lines.

**Senator HARRADINE**—Does it allow for their commercialisation or not? This is a very important question.

**Dr Morris**—Madam Chair, I have answered the question I believe.

**CHAIR**—How many times does Dr Morris have to answer the same question the same way?

**Senator HARRADINE**—I wish he would answer the question with a yes or a no.

**CHAIR**—He has answered the question as best he can. I cannot direct a witness to answer a question in any specific way, just as no senator can be asked to answer a question in any specific way in the chamber.

**Senator HARRADINE**—I will ask you again: does the legislation allow for the sale of human embryonic stem cells, derived from frozen embryos, to pharmaceutical companies for the purpose of testing drugs?

**Dr Morris**—The bill does not expressly allow it but it does not prohibit it either. The bill does not regulate that.

**CHAIR**—It is now 11.08 p.m. I plan to go back to Senator Boswell's question.

**Senator HARRADINE**—I have a number of questions and this is the problem with this type of rushed committee work.

**CHAIR**—I can hardly say that this has been rushed, with the equivalent of four days of hearings.

**Senator HARRADINE**—I am sorry: it has been rushed, and there are a lot of people who need to be heard who have not been heard.

**CHAIR**—That is a view of some and not of others. That is a subjective view. I want to return to Senator Boswell's position. I have now looked at the facsimile cover sheet, which Senator Boswell provided, as have other senators. I understand that the other remaining pages that were sent with the header sheet were copies of *Hansard*. Reading from that facsimile header sheet, the officer has simply asked Miriam Dixon whether the views expressed by Dr Silburn are the views of Parkinson's Australia. Ms Dixon replied, in part:

Financial constraints and short notice prevented Parkinson's Australia from being directly represented by one of its Office Bearers at the Committee's hearing on Tuesday 17 September. We accordingly suggested—

I emphasise 'suggested'—

that Dr Peter Silburn speak on our behalf as he was already attending the committee.

Dr Silburn mentioned in his evidence and his introduction that he was the spokesperson for Scientific Committee Parkinson's Australia, Princess Alexandra Hospital and Parkinson's Australia. He went on in his evidence to refer on a number of occasions to the fact that he was expressing views of Parkinson's Australia. So, Senator Boswell, I now ask you, in light of our having had time to look at all those relevant documents, what it is that you are now alleging is improper about someone being forced or coerced in any way to provide evidence.

**Senator BOSWELL**—Can I rephrase that question and ask: Dr Morris, would you condone one of your officers—I think he was a project officer—approaching Parkinson's New South Wales and asking them, 'I would be interested to hear from you as to whether the views expressed by Dr Silburn are the views of Parkinson's Australia'? Do you think that is a reasonable thing for a project officer to ask—whether these people agree or disagree with Dr Silburn—bearing in mind you did tell us that you were absolutely neutral in this?

**Dr Morris**—I would like to go back a step to our consultation process in developing the legislation. We spoke to a range of groups throughout Australia, one of which was Parkinson's New South Wales, headed by Miriam Dixon. When I looked through *Hansard*, seeing the way Dr Silburn was presented as a spokesperson for Parkinson's Australia, I asked my project officer if this was the case, because we had heard different views during our consultations. So, as to what happens next, I cannot say but I can find out. The fax that we see relate to a discussion which I am not privy to. The fax to me are fairly innocuous in that the project officer is asking for the views of the person.

**Senator BOSWELL**—But, with due respect, sir, you told us you were neutral. Your job was to implement the COAG agreement. That was your only role in this.

**Senator HARRADINE**—And doing it for two years.

**CHAIR**—Are you alleging bias? If you are alleging bias, Senator Boswell, you are beholden to state—

**Senator BOSWELL**—I am alleging impropriety. I will let it go on the record.

**CHAIR**—No, it is very important that you actually state the cause of the impropriety and what you believe to be improper.

**Senator BOSWELL**—I believe that an organisation that claims to be absolutely neutral and only there to implement the COAG agreement then writes a letter to Parkinson's Australia and says, 'Do you agree with the witness?' That is a leading question. In fact, I am going to present it to the Privileges Committee. It will be going to the Privileges Committee.

**CHAIR**—I would welcome that.

**Senator BOSWELL**—I ask Dr Morris: you are taking it on your head that you were the one who asked for it to be done?

**Dr Morris**—I asked my project officer whether this was the case. We will take it on notice as to what happened next. I agree there may have been other ways to find out the information that I was asking for. In terms of due procedure, there may have been other ways for me to find out whether or not Dr Silburn was representing the views of Parkinson's Australia.

**Senator BOSWELL**—Dr Morris, did you ask anyone else? Did you ask your project officer to approach any other people?

**Dr Morris**—No, Senator.

**CHAIR**—Dr Morris, I want to clarify this for my own benefit. Do I understand what you are saying to be thus: during your consultations with many groups, Parkinson's New South Wales being one of them, you thought that different views had been expressed. Dr Silburn came before this committee and expressed opinions purporting to be those of Parkinson's Australia. You had a concern that those did not reflect the views that had been expressed to you in the consultation process by Parkinson's New South Wales.

**Dr Morris**—That is correct.

**CHAIR**—You were afraid that the evidence that was being given might not be truly reflecting the views of Parkinson's New South Wales?

**Dr Morris**—Or vice versa.

**CHAIR**—Or vice versa.

**Dr Morris**—We have consulted a range of people in terms of getting the legislation into parliament.

**CHAIR**—Therefore, so as not to misrepresent either party—

**Senator BOSWELL**—Madam Chair, I suggest you are leading the witness.

**CHAIR**—I am sorry, I have to clarify this for my own benefit.

**Senator BOSWELL**—You are supposed to be the chair. You are not supposed to be putting words in the witness's mouth.

**CHAIR**—I am not putting any words in the witness's mouth. I am clarifying, Senator Boswell, what has been said by the witness. You are alleging impropriety. You are saying to me that you are going to go through this committee in an attempt to send this matter to the Privileges Committee?

**Senator BOSWELL**—Yes. I do not know what avenue I will take.

**CHAIR**—You have to abide by standing orders.

**Senator BOSWELL**—Granted, but I would have thought that I could make the charge in the Senate.

**CHAIR**—There are standing orders that have to be abided by. Given the seriousness of the allegations that you are making at a public hearing I think it is exceptionally important to this committee that we establish the veracity and the motive behind the witness's evidence. I was unsure as to what the witness had finally said. You are saying that I am now leading the witness when I am repeating what I understood the witness to say. The witness can quite clearly say, 'Sorry, Senator Knowles, you are barking mad; you are wrong.'

**Senator JACINTA COLLINS**—I would like to indicate that I agree with you. It is important for us to establish the facts of this matter, and I for one saw you as doing no further than that. In fact, there are a couple of things that I think also need to be clarified. I have been the instigator of a matter that did go to the Privileges Committee about a government department soliciting evidence on behalf of the Senate. I do not think the circumstances quite relate to this but it is important that we get the detail of the matter clear as far as it is possible to do so this evening.

**CHAIR**—I want to make sure that if there is an allegation then the witnesses have an opportunity to respond to that allegation while they are here.

**Senator EGGLESTON**—As I understand it, Dr Morris has said that Parkinson's Australia gave information to the National Health and Medical Research Council which formed the basis of their considerations in recommending the format of this legislation. The information that was given on the 17th appeared to be different from the information they were given previously and they sought clarification of the position of Parkinson's Australia. Is that correct?

**Senator JACINTA COLLINS**—Was it Parkinson's Australia or Parkinson's New South Wales?

**Dr Morris**—Parkinson's New South Wales.

**Senator EGGLESTON**—Is that what you were saying?

**Dr Morris**—That is basically correct. In doing so I do not believe we were promoting either side of the debate. We were just noticing an inconsistency.

**Senator EGGLESTON**—You were simply seeking clarification?

**Dr Morris**—Yes.

**Senator JACINTA COLLINS**—Was it suggested to Miriam Dixon that she actually canvass members of Parkinson's Australia.

**Dr Morris**—As I have said, I would have to take that on notice. I was seeking clarification. I had not discussed exactly how that happened or—

**Senator JACINTA COLLINS**—The other important issue is that the outcome of that process appears to be this letter to Senator Sue Knowles. We do not understand whether that was something solicited or whether that was something instigated by Ms Dixon at her own behest.

**CHAIR**—To clarify, that appeared on my screen this afternoon.

**Senator JACINTA COLLINS**—I understand that, but my concern, from past incidents, is that government agencies dealing with the bill not be soliciting witnesses on behalf of the Senate committee. To the extent that it is possible on the facts of this matter, I think it is important that the NHMRC clarify that point.

**CHAIR**—I will just read the covering note that Ms Dixon sent to me today. It states, 'Dear Senator Knowles. Please find attached a letter clarifying Parkinson's Australia's position re the Research Involving Embryos and Prohibition of Human Cloning Bill 2002. Regards, Miriam Dixon, CEO Parkinson's NSW.' That was included with the letter.

**Senator BOSWELL**—With reference to that letter, I will just put down a few facts. The letter was not ratified by the President of Parkinson's Australia. It does not represent the views of the Scientific Committee Parkinson's, which Dr Silburn does. The writer is not a medical practitioner but a layperson. Can I just ask one other question?

**Senator McLUCAS**—Can I make a point about that too?

**CHAIR**—I do not understand the relevance of what you are saying.

**Senator BOSWELL**—I am just saying that that letter that was put down was not signed by Parkinson's Australia. It does not represent them.

**CHAIR**—So that is not the letter to which you are referring?

**Senator BOSWELL**—Yes, it is.

**Senator BARNETT**—It is from Parkinson's New South Wales.

**Senator BOSWELL**—It is from Parkinson's New South Wales. That is what I am saying.

**Senator McLUCAS**—The relevant sentence is:

I have contacted the delegates to Parkinson's Australia and a clear majority supports the draft legislation in its—

**Senator JACINTA COLLINS**—But from this letter we do not know if they are the New South Wales delegates or the Australian delegates.

**CHAIR**—Presumably they are the New South Wales delegates, because she is only talking on behalf of New South Wales.

**Senator JACINTA COLLINS**—We are not sure of that. She might have canvassed other states' delegates to Parkinson's Australia, for all we know.

**CHAIR**—I am more worried about the allegation of impropriety. If that is to be established, it has to be established and the witnesses have to be given an opportunity to respond. If there is nothing further that you wish to add, Dr Morris or Senator Boswell, I propose to move on.

**Senator BOSWELL**—There is one other question. Is Professor Nick Saunders head of the NHMRC?

**Dr Morris**—Professor Saunders is the chair of the NHMRC.

**Senator BOSWELL**—He is also Alan Trounson's boss at Monash, isn't he?

**Dr Morris**—I would have to confirm that. Professor Saunders is a dean of medicine. I am not sure if that means he is Alan Trounson's boss, I am afraid.

**Senator BOSWELL**—Are you aware that Professor Saunders was recently a fellow director, with Alan Trounson, of Biocom International Ltd? How did you stay neutral in that situation?

**CHAIR**—Are there any further questions?

**Senator McLUCAS**—I will put mine on notice.

**Senator JACINTA COLLINS**—There is just one further issue, arising from your earlier answers. You have mentioned to me—it was on page 2 of the response—that, in the last round of the compliance survey, questions were asked that might yield some useful information. That survey is described as the 2001-02 survey. When was it actually conducted?

**Dr Breen**—I think that was mailed out to ethics committees in June or July. We go on the financial year. It would have been to collect data up to the middle of 2002. I think the responses were due in some time towards the end of August. We only gave them about two months grace.

**Senator JACINTA COLLINS**—How far off might you be from processing the data to yield something useful to us in relation to destructive embryonic research?

**Dr Breen**—I cannot give you a date, but I can take that on notice.

**Senator JACINTA COLLINS**—If you could take that on notice and see if there is any way to yield, from that process, information that might be useful in terms of the field to date, I would appreciate that.

**Dr Morris**—That survey will provide us with an idea of which HRECs are considering research involving ART technologies. It may not provide us with much evidence about research involving the destruction of embryos.

**Senator JACINTA COLLINS**—Are you saying that the specific description of the research may not be detailed enough to identify whether it involves the destruction of embryos?

**Dr Morris**—That is right. The question would have been, I imagine—and Dr Breen could confirm it—a box which HRECs would have ticked to say, 'Yes, we have considered research involving ART technologies.'

**Senator JACINTA COLLINS**—But there would be no further description of what they are looking at?

**Dr Morris**—No. Is that correct?

**Dr Breen**—I believe that is correct.

**Senator JACINTA COLLINS**—Could you take that on notice? I would be interested if it can yield anything of any use to us.

**Dr Morris**—We will provide you with the information.

**Senator BARNETT**—On a totally different tack, I have a question in regard to something that we touched on at the previous hearing with the NHMRC, and that is the constitutionality of the bill. I think Ms Andrea Matthews was responding. Since that time, we have had confirmation of the tabling of the Australian Government Solicitor's advice of 13 February and further advice on 30 April 2002. The February advice reads:

Under the Constitution, the Commonwealth parliament has reasonably extensive legislative powers in this area. However, these powers would not support comprehensive legislation to regulate human cloning, regulated assisted reproductive technology or the proposed unacceptable practices listed above.

On page 3, at the bottom, it says:

As a result of the Commonwealth's lack of comprehensive legislative power in relation to this subject it would, for example, be difficult for the Commonwealth to prohibit or control human cloning and related unacceptable practices carried on within a state by a natural person or persons alone or in partnership.

Does that sound consistent with the previous advice that was provided?

**Dr Morris**—I believe so, Senator.

**Senator BARNETT**—Since our last hearing, have you requested or received any further legal advice on the constitutionality of the bill?

**Dr Morris**—Not since our last hearing, no.

**Senator BARNETT**—Let me express it another way: since February and April this year, have you received any further legal advice?

**Dr Morris**—I will have to take that on notice. During the development of the legislation we would have received a variety of legal advice. I am not sure whether or not we have received any additional legal advice on the constitutionality issue.

**Senator BARNETT**—So you will get back to us?

**Dr Morris**—We will take that on notice.

**Senator BARNETT**—Will it take long for you to respond? We have a short time frame.

**Dr Morris**—We will do our best.

**Ms Matthews**—We should be able to find that out relatively quickly.

**Senator BARNETT**—I thought it would just be a matter of flicking through the files and forwarding it. I do not have the previous document that you tabled with us at the last hearing—that is back in my office—but that document said that total and comprehensive backing for the federal legislation would require state legislation. Can you confirm that again tonight for the committee?

**Ms Matthews**—That is right. Our understanding, on the basis of the advice that we have received from the Australian Government Solicitor—as it says there—is that there is a lack of comprehensive power, and as such there is a need for it to be supported by nationally consistent, complementary state and territory legislation.

**Senator BARNETT**—Yes, I am just getting it on the record. To make it watertight, backing by each state and territory government would be required?

**Ms Matthews**—That is my understanding on the basis of that advice.

**Senator BARNETT**—Dr Breen, you are nodding; is that in affirmation of that view?

**Dr Breen**—That is my understanding, yes.

**Senator BARNETT**—On a different subject: a witness who spoke earlier tonight, Professor Illingworth, on IVF, commented that there were 71,000-odd surplus embryos in Australia, and he made a comment regarding the number of non-viable human embryos each year. He said there were some non-viable human embryos that were surplus—in storage—and then there were some on which research is being undertaken. I asked how many and, as an expert, he responded that there were an estimated 40,000-odd per annum. Does that sound consistent to you? Is that an appropriate number?

**Dr Morris**—We would have no way of confirming or denying that number. I do not believe statistics are kept on that. Most of that information would come from the Australian Institute of Health and Welfare, which does collect some statistics from IVF clinics, but I do not know if they collect statistics on the number of non-viable embryos.

**Senator BARNETT**—Dr Breen, do you have a view on the number of non-viable embryos that may exist each year?

**Dr Breen**—I have no view, except to say that I know of Dr Peter Illingworth and I respect him as a conscientious citizen.

**Senator BARNETT**—He also made the comment—it leads to the next question—that the AHEC guidelines were currently being revised, and I understand that he was referring to these guidelines, the *Ethical guidelines on assisted reproductive technology*. Do you have them?

**Dr Breen**—Yes, that is the bound copy.

**Senator BARNETT**—I just have the Internet version. He said, 'Those guidelines are currently being revised and I think they are dated 1996.'

**Dr Breen**—That is correct.

**Senator BARNETT**—He also said, 'They are loose in places and it is under public review.' Does that sound consistent to you?

**Dr Breen**—They are certainly not particularly detailed. The draft that AHEC is working on will contain much more detail, so in that way I would agree with him, yes.

**Senator BARNETT**—Going back to the definition of the 'human embryo' in the bill, does it cover both a viable and a non-viable human embryo?

**Dr Breen**—I am not the right person to answer that. I am sorry, Senator.

**Senator BARNETT**—Because if it did, it would obviously cover the 70,000 embryos in storage. It depends on the 5 April deadline as well, so it depends on what happens to that in years ahead. But if there are 40,000 extra non-viable embryos that they can do research on every year, that obviously increases the numbers very substantially. Do you want to respond to that? You do not have to respond.

**Dr Morris**—The definition in the legislation states: 'human embryo means a live embryo that has a human genome' et cetera. So a non-viable embryo is presumably alive.

**Senator BARNETT**—I want to get your views and confirmation of the import and export prohibitions in the bill. Can you confirm your understanding of what is prohibited and what is not?

**Dr Morris**—In our supplementary submission, we did give some more information on what is and what is not prohibited.

**Senator BARNETT**—Your supplementary submission has only just been distributed tonight, so can you provide us verbally with that information?

**Dr Morris**—It was distributed a couple of weeks ago—but that is beside the point, Senator. Firstly, there are prohibited embryos. There would be a prohibition on the import or export of prohibited embryos under the legislation. In relation to the import of embryos which are not prohibited embryos—that is, embryos which are part of an IVF program or embryos which were part of an IVF program and which perhaps have been declared to be excess—if they are part of an IVF program then the import or export would be for the purposes of the IVF program. If they were embryos which were declared to be excess to an IVF program, to import them for other purposes—for example, research—under the Quarantine Act you would, firstly, need to get an import permit from the Director of Quarantine. You would also need to get a licence from the NHMRC Licensing Committee.

**Senator BARNETT**—That is not a problem, but what about with respect to the import and export of human embryo stem cell lines?

**Dr Morris**—In relation to the import and export of embryonic stem cell lines, there is general legislation relating to the import and export of tissue. But beyond that, I believe that there is not very much.

**Ms Matthews**—The legislation before you does not propose to regulate the import or export of embryonic stem cell lines.

**Senator BARNETT**—That is my understanding.

**Ms Matthews**—That is my understanding, but the existing Customs regulations do regulate the export of embryonic stem cell lines and other human tissue to the extent that it meets the criteria in the Customs regulations.

**Senator BARNETT**—That is another matter.

**Senator HARRADINE**—That does not prevent, does it, an institution here from selling embryonic stem cells to pharmaceutical companies overseas at a profit?

**Ms Matthews**—The legislation before you does not prevent that.

**Senator HARRADINE**—The Customs regulation does not either, does it?

**Ms Matthews**—The Custom regulation provides that approval must be sought in certain circumstances for the export of tissue. But in terms of, I guess, the philosophical position of it

being sold to a foreign company or externally, no, it does not address that directly in the Customs legislation.

**Senator HARRADINE**—This is rather important. Are you suggesting that the Customs legislation would prevent export of human embryo stem cells?

**Ms Matthews**—It would not prevent it; it just provides that a permit is required for the export under certain circumstances. For example, the Customs regulations in respect of prohibited exports provide that a permit is required for the export of human body fluids, organs and other tissue, including parts or constituent parts of material of that kind, if the internal volume of the immediate container in which the material is packed exceeds 50 millilitres. And that is something that we are currently working with Customs and Quarantine on to better understand how that works.

**Senator HARRADINE**—That is not working.

**Senator BARNETT**—Senator Harradine is just making the point that it does not prevent it.

**Ms Matthews**—That is right. It does not prevent it.

**Senator BARNETT**—You just have a permit in fact and that is obtainable.

**Ms Matthews**—That is my understanding.

**Senator BARNETT**—Have you finished, Senator Harradine?

**Senator HARRADINE**—Yes, I just wanted to clarify that.

**Senator BARNETT**—That was a very good point. Some witnesses have talked about handling fees and the money that is required for the transportation, distribution or sale of these embryonic stem cells. I wish to confirm your understanding that the bill allows for handling fees or some other sort of fees to be paid.

**Ms Matthews**—No, it would not allow that. As for the intention when we drafted the legislation—and we have not received formal AGS advice on it but we have certainly been discussing it with states, territories and OPC—we have expressly tried to draft it so that it does catch brokers and people trying to get handling fees, so that any valuable consideration, whether it be an inducement, a priority, a discount or any money, is caught regardless—

**Senator BARNETT**—Where does the bill say that? I ask that because we have received advice to say that it is open to that. Can you point to the clauses that are relevant?

**Ms Matthews**—Clause 22 says:

(1) A person commits an offence if the person intentionally gives or offers valuable consideration to another person for the supply of—

an embryo. It does not have to be the donation. For example, a person who is a broker may have got a donated embryo from someone—

**Senator BARNETT**—Sorry, this is clause?

**Ms Matthews**—Clause 22. Say, for example, I am a broker and they have got an embryo donated from someone who has given it to me. If I try to sell it on to a third person and charge any sort of handling fee, brokerage or any additional money, then I am caught.

**Senator BARNETT**—Do you believe that is watertight?

**Ms Matthews**—Like I have said, we have not received formal Australian Government Solicitor advice on it.

**Senator BARNETT**—As a committee, we have received advice—and you can look at the evidence in the *Hansard*—to say that it is possible.

**Dr Morris**—Is that legal advice?

**Senator BARNETT**—No, we have received evidence; I did not say legal advice. Bearing in mind that you scrutinise *Hansard* so carefully, would you follow that up and obtain legal advice? Otherwise, can you confirm for the committee that that will not happen? Can you come back to us on that? Would you put that on notice and respond to confirm that that is watertight? That is of great interest to me and, I think, other members of the committee.

**Dr Morris**—Sure, Senator.

**Senator BARNETT**—I wish to confirm your opening comments, Dr Morris, because Dr Juttner clearly stated on the record that, in his view, the NHMRC supported two of the amendments that he put. Is the letter that you have forwarded to the committee secretariat your response to his comments?

**Dr Morris**—Dr Juttner has written to the secretariat of the committee because neither I nor Professor Pettigrew could remember having a conversation with him about that issue.

**Senator BARNETT**—Do you or do you not support his amendments, the ones referred to in *Hansard*?

**Dr Morris**—Would it matter if we supported them or not? It would be up to parliament to decide on amendments.

**Senator BARNETT**—That is what he said the other day, and I was seeking your views on it.

**Dr Morris**—I am not actually aware of what the amendments are. So if you think—

**Senator BARNETT**—Well, if you are not aware then that seems to deal with that matter. As for the consent provisions, we heard earlier tonight from Professor Jansen regarding the three or four levels of consent that were required for using an embryo for research purposes. Can you explain how the three or four levels of consent that he was talking about would work?

**Dr Breen**—I did not hear his evidence, so I would have to look at that and comment on notice. I would have to know whether he was talking about consent for developing embryos or consent for research. If we are talking about consent for research, there have to be at least two sets of guidelines supporting the legislation. One is the existing *National statement on ethical conduct in research involving humans*, which makes it clear that one of the things that ethics committees must look at is the type of information given so that people do give consent appropriately. The new guidelines that our committee will be developing will also be very detailed on information giving and the way in which consent has to be obtained.

**Senator BARNETT**—It was my view that he was talking about the latter, which you are responding to. Is this the first set of guidelines?

**Dr Breen**—They are the 1996 guidelines, which we are in the process of revising.

**Senator BARNETT**—But we have been advised that that revision process is now on hold.

**Dr Breen**—That is correct. We are reluctant to put it out for consultation until the parliament has decided the legislation.

**Senator BARNETT**—So we are signing up to legislation—as I think Senator Collins pointed out earlier—not knowing exactly what guidelines apply?

**Dr Breen**—That is true.

**Senator BARNETT**—The second set of guidelines, which have not yet been drafted, will also apply?

**Dr Breen**—There is no second set. I am talking about the preliminary content of the revision of those guidelines, which will be much more detailed about what will be required for consent.

**Senator BARNETT**—I think I follow you. Clauses 36 and 39 of the bill talk about consent provisions and the protocols that apply to the provision of consent. Does that ring true to you?

**Dr Breen**—That is the same language, yes.

**Senator BARNETT**—And these are the appropriate protocols. Clause 3.2.5 of the 1996 guidelines—the current guidelines—talks about the specified research that is possible once you have signed that consent and says, 'See guideline 6.4 and the glossary.' At 6.4 you find that approval requires

... a likelihood of significant advance in knowledge or improvement in technologies for treatment ...

Then 6.5 talks about seeking to:

... avoid the likelihood of production of embryos in excess of the needs of the couple. Techniques and procedures which create embryos surplus to the needs of the infertility treatment should be discouraged.

The way I read it, 'should be discouraged' does not say that it is prohibited. Can you shed light on that for us?

**Dr Breen**—Only in the sense that, when these were written, the fact that stem cells even existed was unknown. These were written in the context of research on embryos for the betterment of the embryo.

**Senator BARNETT**—But we have a bill that says that it is required for embryos in storage prior to 5 April this year and we have guidelines which refer to:

Techniques and procedures which create embryos surplus to the needs of the infertility treatment should be discouraged.

Not prohibited.

**Dr Breen**—That is true.

**Senator BARNETT**—That is surely a conflict. They do not say the same thing, do they?

**Dr Breen**—No, they do not.

**CHAIR**—Senator Barnett, how much longer do you anticipate going?

**Senator BARNETT**—This is an important point. This consent provision concerns a number of us, and I am trying to get to the bottom of how it is going to work. We have a bill and then it is left wide open. All it says is that you must have consent and appropriate protocols, and Dr Breen is telling us that we do not know what the protocol is and that it is going to be revised at some stage in the future. I am concerned and I understand others are as well.

**Dr Morris**—If I can just clarify the word 'protocol' in relation to the bill. It is not referring to guidelines by the NHMRC or AHEC; it is referring to protocols developed by the people proposing to do the research for obtaining consent. When people are getting approval to do research from a human research ethics committee they need to have a protocol for that particular research in order to get the consent of the people donating the tissue, for example,

so that they can get informed consent. Certainly the HREC needs to see the protocols the researcher is going to use.

**Senator BARNETT**—I understand that, but this was in 1996. It is under revision and it is on hold. I will go to my last question because it is getting late and everybody wants to go. I think these are important issues and that is why I am asking the question. I would like to ask Dr Breen a question about clause 25(2)(d)(ii). Dr Breen, can you tell us your views on clause 25(2)(d)(ii) and the views of AHEC? Since others may not have the bill in front of them, regarding the use of the excess ART embryo, it talks about the uses carried out by an accredited ART centre and it goes on to state:

... the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created ...

Can you advise the views of AHEC in regard to that clause?

**Dr Breen**—Senator Barnett, this is the question that Senator Collins put to me and that I said that I would take back to AHEC on notice. My personal views are not relevant because it is a matter for AHEC.

**Senator BARNETT**—So you have to go back to AHEC and ask their views? You cannot recall what the views of AHEC were at the time when you were discussing it with AHEC and the NHMRC?

**Dr Breen**—No. As I said earlier, the dialogue over the evolution of this bill, when we were asked to give assistance and guidance if we could help in framing a bill that was going to be accurate and faithful to COAG, took place with the AHEC executive. There were several of those meetings and the two at which this was raised I was not present at and I am therefore aware of the notes.

**Senator BARNETT**—Thank you for getting back to us. Can you advise your views on the definition of 'diagnostic investigations' and as to what that means?

**Dr Breen**—That would normally be a reference to the testing of an embryo that was not research—it had become routine. In any medical practice and health research et cetera there are often tests that, at a point in time, are research and either by some official declaration or gradual evolution they become accepted diagnostic procedures.

**Senator BARNETT**—I can understand what you are saying—that is, that it is the usual procedure—but there is no definition in the bill of 'diagnostic investigations'. For a layperson, if you just have a look at the bill, it is pretty broad and ambiguous. Is that your view? It could include a whole a range of techniques and investigations. What is an investigation?

**Dr Breen**—'An investigation' is jargon for an actual laboratory test.

**Senator BARNETT**—So it could include all sorts of laboratory tests that could be described as an investigation?

**Dr Breen**—I guess what you are looking at there is the point that was made by at least two members of AHEC as to whether people would behave unethically and use that part of the bill to do research that was not under the licence. There is always the possibility that renegade researchers or clinicians could do that. But you cannot frame legislation presuming that you are going to cover one renegade.

**Senator BARNETT**—This is what we are trying to do: we are trying, for the good of Australia, to draft good legislation which is tight but is appropriate to the public good. That is

where we are coming from. But the concern is the scope. You have talked about the renegade practitioners. These are the sorts of people that we do not want in practice.

**Dr Breen**—I agree.

**Senator BARNETT**—I have no further questions. Thanks very much for your time.

**Senator BOSWELL**—Madam Chair, as Dr Morris has admitted instructing a project officer to approach a witness group, I am happy for the matter not to go before the Privileges Committee but I look forward to his answer regarding the activity of his staff in this matter, including whether they urged a new witness to send a letter to this committee late this afternoon.

**Senator HARRADINE**—The bill states:

> the use is carried out by an accredited ART centre, and:
>
> … … …
>
> the use forms part of diagnostic investigations ...

On the question of diagnostic investigations, is it proposed that such investigations are undertaken in order to weed out, as it were, an embryo with genetic defects?

**Dr Morris**—Senator, if I can paraphrase your question, clause 25(2)(d)(ii) says:

> the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the ... embryo was created ...

You are asking if that diagnostic investigation could be used to weed out, did you say?

**Senator HARRADINE**—Yes, that is right, to do diagnostic tests on the embryo for, say, some genetic abnormality.

**Dr Morris**—The first criterion is 25(2)(d)(i) which says:

> the excess ART embryo is not suitable to be placed in the body of the woman ...

So that type of testing may have already been done on the embryo.

**Senator HARRADINE**—What does that mean—'not suitable to be placed'? Does that mean that with, say, down syndrome, if you could do a test—I do not know whether that test could be done at this particular stage—it is unsuitable for it to be placed in the body of a woman? Where do you draw the line? Do you say, having established a diagnostic test, that an embryo will be born with dwarfism?

**Dr Morris**—Senator, this is not seeking to regulate ART clinical practice. The diagnostic investigation would need to be for the purposes of improving the treatment of that particular woman. If it has already been decided that the embryo is not suitable for whatever reason, it is unlikely that you would be doing a further test for something like down syndrome. The test would have to be for the benefit of that woman's treatment.

**Senator HARRADINE**—The bill states:

> (d) the use is carried out by ...
>
> (i) the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created; and
>
> (ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom ...

It is circular. Is it by definition that, for example, an embryo that has been tested for down syndrome is unsuitable to be placed in the uterus of a woman?

**Dr Morris**—This is relating to excess ART embryos as a first criterion. This is only regulating the use of what are defined as excess ART embryos; it is not defining a screening test for use with embryos. It is defining an exemption for the use of an embryo which has already been deemed to be excess. In the case of paragraph (d)(ii), it is a diagnostic investigation which forms part of the ART treatment of the woman for whom the embryo was created.

**CHAIR**—Can I draw your attention to the time? It is now approaching midnight. If there are further issues relating to the bill precisely, I am happy to go until exactly midnight, then we will be drawing down the curtain.

**Senator HARRADINE**—I am raising this question because I do not understand how this is an 'exempt use'. If we go through the bill, it states:

> (2) A use of an excess ART embryo by a person is an ***exempt use*** for the purposes of subsection (1) if:
>
> … … …
>
> (d) the use is carried out by an accredited ART centre, and:
>
> (i) the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created ...

What does 'is not suitable' mean? It presumably would not be suitable if it is an excess ART embryo.

**Dr Morris**—An excess ART embryo is not, by necessity, unsuitable for implantation. An ART embryo may be declared to be excess for a variety of reasons. In the case of this exemption, it must first be not suitable for implantation, because that would be the reason why there would be a diagnostic investigation.

**Senator HARRADINE**—So diagnostic investigations are undertaken on that embryo, presumably for determination of whether genetic defects can be identified.

**Dr Morris**—I will give you an example that I am aware of in relation to an excess ART embryo. In some circumstances, the cell membrane of an egg is thick when, following fertilisation, the cell division does not occur normally. The IVF technicians have a way of finding that that is the case and that is by rupturing the membrane and stimulating the embryo to divide. In order to determine that—following an instance of treatment where this has occurred and the embryos are not suitable—they analyse the embryo to determine the thickness of the cell wall in order to ensure that the embryos are viable in the next treatment.

**Senator HARRADINE**—Why should that not be part of a reference to the committee?

**Dr Morris**—Sorry?

**Senator HARRADINE**—Why should that be exempt?

**Dr Morris**—During consultation, there was a range of reasons. Primarily—where we are using an embryo which is not viable in order to determine why it is not viable—if these diagnostic investigations were not exempt, then they would be subject to the same restrictions that the licensing regime puts in place, including the restriction of 5 April. This may disadvantage couples having treatments now, as opposed to couples who had treatment before 5 April, in terms of limiting their access to such diagnostic investigations.

**Senator HARRADINE**—Isn't it the case that, in this whole area—which is a very sensitive area—it is not appropriate to have commercial-in-confidence provisions there?

Interested people will not know anything about certain programs or projects that are passed by the licensing committee if there is a commercial-in-confidence claim by the applicant.

**Dr Morris**—Firstly, the bill makes a lot of information publicly available in relation to the determinations of the licensing committee. Secondly, in relation to what would be deemed commercial-in-confidence information, that sort of information may not be relevant to the determination of the committee. There is always an obligation to maintain the privacy of the people putting in applications. There has to be a balance between making a decision, having a transparent process and protecting confidentiality. I think the bill seeks to make that balance.

**Senator McLUCAS**—Madam Chair, I draw your attention to the time. We are an hour and a half over time. I acknowledge that we have done a lot of work in that time. I know the witnesses have suggested that they will accept questions on notice and I would encourage us to do that. I think it is appropriate that the committee do now adjourn.

**CHAIR**—Thank you. I agree with that entirely. We are in fact two minutes beyond what I said would be the end. I thank the witnesses and apologise for the lateness of the hour. In concluding the hearing, I thank the secretariat for the volume of work that they have had to contend with and Hansard for their patience.

**Committee adjourned at 12.02 p.m.**