COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

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

TUESDAY, 17 SEPTEMBER 2002

CANBERRA

BY AUTHORITY OF THE SENATE

INTERNET

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

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

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

WITNESSES

SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Tuesday, 17 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: Senators Barnett, Bishop, Boswell, Collins, Denman, Harradine, Harris, Heffernan, Hutchins, Knowles, Lees, Mason, McLucas and Stott Despoja

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 3.36 p.m.

ILYINE, Mr Hugh Alexander, General Manager, Stem Cell Sciences Ltd

JUTTNER, Dr Christopher Aylwin, Senior Vice President, Medical Director, Executive Director, BresaGen Ltd

TUCH, Professor Bernie, Director, Diabetes Transplant Unit, Prince of Wales Hospital, University of New South Wales

CHAIR—The Senate Community Affairs Legislation Committee is continuing its inquiry into the Research Involving Embryos and Prohibition of Human Cloning Bill 2002. As I stated at the previous hearing, the committee has been asked to inquire into the bill to inform the Senate in its deliberations on the bill. I would ask my colleagues that their questioning remain focused on the issues that are relevant to the bill.

I welcome Professor Bernie Tuch and representatives from BresaGen Ltd and Stem Cell Sciences Ltd. 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. The committee will approach this as a panel type session, and if I could also ask committee members, as the rules of the Senate apply in committee meetings, if their staff are to deliver any notes to them, if those notes could be given to the secretariat staff, who in turn would deliver them to honourable senators, it would make for a more orderly running of the meeting.

Gentlemen, the committee has before it your submissions. Are there any alterations you wish to make to those submissions before you are invited to speak to them?

Dr Juttner—No.

CHAIR—I now invite each group to make an opening presentation, and of course this will be responded to by honourable senators.

Mr Ilyine—I shall try to be brief. First of all, thank you for your interest in this subject area and for the invitation to come here today, which we as a company appreciate. We hope we will be able to contribute something worthwhile to all of you as we go forward.

In summary, the view of the company is that we very much support the concept and idea of unified legislation to cover this area. The second part that I would make as a presentation is that we genuinely believe that having public debate on the issues is very much the right way of going about it, so again we are very supportive of the efforts that have been made here at the parliamentary level towards having full debate on all the issues that relate to stem cells.

As a company we are active in our investment in Australia and overseas at the moment in the field of stem cells, so clearly we have a very intense interest in what takes place in the development of the legislation, and we certainly hope that the community and the parliament will support the passage of the legislation that allows the use of the excess IVF embryos for use in stem cell research.

Dr Juttner—We appreciate the opportunity to appear before this committee. BresaGen is a South Australian biotechnology company which is among the acknowledged world leaders in the field of embryonic stem cell or ES research. We have four human ES lines which were derived in the United States of America in May 2001, and they are included in the 78 lines approved by President Bush on 9 August last year.

At BresaGen we are serious about developing therapies from ES cells and in the foreseeable future. We have developed a very practical and focused approach to neurodegenerative diseases. We have established the relevant animal models, we have had two preliminary meetings with the FDA and we have already had a central nervous system cell delivery catheter approved for marketing by the FDA.

I think it is relevant that I describe my scientific background and credentials in the context of this committee and this debate. Until 1995 I was head of haematology and bone marrow transplantation at the Royal Adelaide Hospital. From 1976 onwards I was extensively involved in the most established and best understood form of adult stem cell research—that is, bone marrow and blood stem cell research and transplantation. My group in Adelaide made clinically important discoveries which have influenced worldwide medical practice in this field, and I established a research group of 45 people in Adelaide, so I believe I am fully qualified to speak about adult and embryonic stem cell research and have no scientific bias for or against either. Indeed, I have interacted extensively with Catherine Verfaillie in Minnesota for many years, and two of my advanced trainees in haematology bone marrow transplantation were sent there by me to do post-doctoral research with her in the 1990s.

In 1995 I moved into the biotechnology industry working in California with a cell and gene therapy company called SyStemix. I was responsible for clinical product development in these fields in concert with the FDA, and later this included the Maryland based gene therapy company, Genetic Therapy Inc., which merged with us.

During the years between 1995 and 2000 I interacted regularly with the FDA and with many US and European experts in bone marrow transplantation and gene therapy and worked closely with other academic and biotechnology experts in the broad adult stem cell and gene therapy fields, including David Baltimore, Nobel Prize winner, Irv Weismann, Richard O'Reilly, Richard Mulligan—and there were many others.

The key points I want to emphasise in addition to our submission are that we, too, strongly support moves to introduce a nationally uniform legislative framework allowing human embryonic stem cell derivation and research. Opinion polls in Australia have shown that 70 per cent of Australians consistently support ES cell research using surplus embryos, as long as there is appropriate regulatory oversight and informed consent.

Adult stem cells are very promising, but they have not been demonstrated yet to meet all the potential needs for cell therapy, and our position is that research on both adult stem cells and ES cells should continue. Indeed, experts in adult stem cell research like Catherine Verfaillie and Irv Weismann urged that research should continue in both ES and AS cells. Most of those urging that all ES cell research should stop in order to concentrate only on AS cell research are either, with respect, politicians or religious leaders without strong science backgrounds or are scientists who are mostly not acknowledged leaders within either ES or AS cell research fields.

While we believe that there are currently enough ES cell lines for research, new lines—which we call therapeutic ES lines, having been isolated under current good manufacturing practice conditions to ensure safety and on human feeder layers or on no feeder layers at all, also to ensure safety—will be required for use in human clinical trials and to produce safe therapies to treat disease. Previously frozen embryos—those before 5 April 2002—are unlikely to satisfy these CGMP requirements, and it is critical therefore, in our view, that the 5 April 2002 deadline be reviewed early with the intention to consider its removal in April 2003, which is when we think a number of organisations will be ready to start to isolate potential therapeutic lines.

There are some states with no legislation on ES research. That means that work could proceed in those states if facilitating state legislation were passed, irrespective of what happens to the federal bill as we understand it. But we think that from a scientific and ethical and, indeed, from a business point of view it would be much better if there were uniform Australia—wide legislation.

Our commercial activities will actually not be inhibited if this bill does not pass and derivation is banned here, but unfortunately we will be forced to carry out more of our work, both research and product development, in the US, where there is no inhibition to the derivation of new ES cell lines meeting CGMP standards and under appropriate local, ethical and legal requirements. Such an exodus, we believe, would represent a significant scientific and commercial disadvantage for Australia, and it is clearly against the recommendations of the Wills report. I look forward to answering your questions.

CHAIR—Thank you. Professor Tuch.

Prof. Tuch—The Diabetes Transplant Unit is a unit devoted to the treatment of people with type I diabetes, of whom there are 100,000 people in Australia. I am a clinician and I treat people with the therapy that we have available today, which is insulin, two, three or four times a day. We are a cutting edge research group. There are 20 of us, and we are looking at a variety of possibilities of which stem cells are a potential future treatment. Currently, for example, we are trying to utilise insulin producing cells obtained from donor people who die and from pigs. Stem cells that we have been looking at include both embryonic and non-embryonic stem cells, in the belief that by exploring all these options we will eventually come up with a particular strategy which will be of benefit to people in this country with type I diabetes. We are focused in relation to that and we work with, collaborate and cooperate with others who can potentially help us in achieving our particular goal.

CHAIR—Thank you.

Senator McLUCAS—Professor Tuch, in your submission you talk about 'requiring stringent and tightly enforced government regulation' and then you go on to list three requirements that should be included in the legislation. Is it your view that the legislation accommodates those needs?

Prof. Tuch—Sorry, I am not quite sure I follow which part of the document—

Senator McLUCAS—I am sorry; I am in the wrong submission. We are in a different order here. Do you understand the question or should I ask it again?

Mr Ilyine—I think I understand the question you are asking. If I can just make reference to the submission, I can probably give an answer that is a little more clear.

The first one was in relation to the consistency of application of the regulations pertaining to this law, such that all IVF clinics would in fact undergo what you would call a standard approach on how they would behave and perform in this regard. That was felt to be important, given that the IVF clinics are generally private organisations. They are strung around Australia in general where the bigger populations are. We felt that that was an important aspect that should come through, that there would be a very consistent approach on how things would be done. That was the first point.

The second point related to the concept of donation. From here we saw that there should be no inducement made of the donor couples. It is very important that the donor couple understand what they are doing, first and foremost, in terms of the donation. Secondly, that there would be no inducement—clearly financially under the law but, just as important as well, that there should be no attempt to induce people so that they would come forward armed with knowledge and able to understand what they were going to do. That was the second part we felt in some way should be encapsulated as guidance as to how one would go forward with people who are actually donating material that comes from them. That is part of that respect for the donor couples.

The third point was a concept of introducing a cooling-off period, because at times people will make impulsive decisions which they believe are good and then maybe on reflection they may decide they would like to withdraw. So we felt it was also important that within the regulation of how one goes about this business that a donor couple should also have the right to withdraw within a certain period of time.

Senator STOTT DESPOJA—Picking up that point, perhaps if I start by asking Dr Juttner: in your submission you talk about the prohibition of financial incentives to donors. That is something, as you would be aware, we agree with and the bill provides for, but I notice that you have suggested strengthening the bill by incorporating two provisions from the US National Institutes of Health. I wonder if you have sought any NHMRC briefing or advice or consultation on these, and if so could you provide for the committee's benefit an outline of their response?

Dr Juttner—Yes, I have discussed the position paper with Alan Pettigrew and Clive Morris, and I think they are in essential agreement. While the bill is strong in preventing that sort of financial incentive, I think that the way the NIH guidelines are written is a little clearer and a little more certain, and it lasts for longer by being quite specific about the potential use for therapeutic outcome and that there might be commercial benefit to someone from that.

Senator BARNETT—Specifically what did the NHMRC agree to? Did they agree to your two amendments?

Dr Juttner—We discussed it casually. They were largely responsible for drafting the bill, as I understand it; is that right?

Senator BARNETT—Yes.

Dr Juttner—I did not ask them specifically to put that in, so I guess you would have to check with them.

Senator BARNETT—But they agreed with the thrust of your two amendments?

Dr Juttner—That is my understanding, yes.

Senator HARRADINE—I understand you use the term 'therapeutic cloning' in your submission.

Dr Juttner—Yes.

Senator HARRADINE—Do you regret having used that?

Dr Juttner—I think that, if you look at my submission, what I did was to talk about the concept of reprogramming or de-differentiation versus therapeutic cloning, and the point that I was trying—

Senator HARRADINE—Sorry, I just asked you about the question of 'therapeutic cloning' itself. You used that term. Did you know that that term was used by Dr Clive Morris and he was taken to task by the Australian Health Ethics Committee of the National Health and Medical Research Council?

Dr Juttner—Senator Harradine, in the submission the title of the heading to which I think you are referring says 'Reprogramming or de-differentiation versus therapeutic cloning', and what I have set out to do, I thought clearly, was to explain that we do not support therapeutic cloning in terms of transferring an adult nucleus into a human oocyte. We have always felt that that is absolutely unacceptable ethically, scientifically and practically. But there are alternate possibilities, and we have done a little work on that in mice, where one might transfer a nucleus into an embryonic stem cell line, which means then you do not have to collect lots of eggs to do that and you are much further from the risk that it could be used to produce a baby. That is not possible.

Senator HARRADINE—You qualified that heavily, I noticed.

Dr Juttner—You asked me if I regret using the term 'therapeutic cloning' in the context—

Senator HARRADINE—No, you qualified that process in your submission.

Dr Juttner—Absolutely, in order to make it, I hope, clear. We do not support therapeutic cloning, but we believe that considering reprogramming or de-differentiation using different techniques that do not produce embryos is something that should be considered. in fact, from the advice we have had, the technique I am talking about here is not prohibited by the bill as it stands.

Senator HARRADINE—The stem cell scientists next to you, though, do support therapeutic cloning, so-called.

Senator STOTT DESPOJA—It is a different submission.

CHAIR—Senator Harradine, Senator Stott Despoja has questions. Could I come back to Senator Stott Despoja and then you can pursue your line of questioning?

Senator HARRADINE—So long as we can get this clear about 'therapeutic cloning' from the start, that that is a misleading statement. According to the Australian Health Ethics Committee of the National Health and Medical Research Council, the term 'therapeutic cloning' is misleading and should not be used. So long as from the start we can get that very clear.

Dr Juttner—Well, Senator Harradine, what we set out to do was to try and not use that term, but since it is so commonly and widely used, we felt it was important to draw the differentiation between reprogramming not using human eggs as the recipients and so-called therapeutic cloning. So to use those words in order to add clarity, hopefully for the benefit of this committee, is not something that I regret.

Senator HARRADINE—Thank you.

Senator STOTT DESPOJA—Pursuing that point, it is pointing out for the record that Senator Harradine has sought to differentiate between the submissions but, in respect of BresaGen in the submission, you actually do not advocate somatic cell nuclear transfer. You actually put forward an alternative in your section 5—I have got it here—which talks about using established embryonic stem cell lines as opposed to unfertilised eggs. Do you want to perhaps elaborate for the committee on that alternate view and also explain if there are any impediments within the legislation for your alternate view?

Dr Juttner—When we set out to look at solving the problem of rejection and finding a way of having cell transplant products that were identical, we felt from the beginning that therapeutic cloning using human eggs as the recipients of an adult nucleus was never going to be possible because the success rates are so low that you would have to hyperovulate 10 women to get enough cells—say 100 eggs—to have a chance of getting one matching cell line. So that was practically impossible. We felt it was ethically unacceptable because these would be egg donors and it would not be reasonable to ask anyone to do that. Indeed, there is also the risk that those cells, those therapeutic clones, could form embryos and then babies. So it was totally unacceptable.

We developed the hypothesis that maybe you could do that by putting adult cells into an embryonic stem cell that had had its nucleus removed. It is not easy. We have worked on that for three years in mice. We have had the beginnings of some success, and we have had advice from NHMRC and the people drafting the legislation that these do not constitute embryos because they cannot produce babies. They would be cloned embryonic stem cell lines but not cloned embryos. So we believe at present that the bill does not inhibit that line of science, and it is likely, I think, that the Biotechnology Centre of Excellence will take up and expand this if it does indeed go ahead.

Senator STOTT DESPOJA—Thank you for that. In your updated position paper you refer to your belief that the capacity of adult stem cells to convert to many different types of cells is being seriously questioned on scientific grounds. Now, something I intend to ask all witnesses, including the scientists, is to provide evidence or citations in relation to your references. I am happy for you to take that on notice, and if you would provide to the committee some examples as to what makes you reach that conclusion—

Dr Juttner—Certainly.

Senator STOTT DESPOJA—Perhaps at that point it might be appropriate, Professor Tuch, to ask you a similar question. I note in your submission the research that is being conducted in Spain on the work being done on diabetic mice and also the work that is being conducted in that group in Israel. Would you be prepared to provide further evidence or citations to the committee in relation to those examples?

Prof. Tuch—Absolutely, Senator. Perhaps I could just summarise that information. We could give you chapter and verse after the event, after this.

Senator STOTT DESPOJA—It would be useful now.

Prof. Tuch—Basically, in relation to the embryonic stem cell side of things, there have been three seminal papers that have been produced. The first one was produced in the year 2000 by a person by the name of Soria, in Spain, who demonstrated that you could turn mouse embryonic stem cells into insulin-producing cells and that when you transplanted those cells into diabetic mice you would normalise the blood sugar levels. They have produced data as late as a month ago now to demonstrate they are up to a year out with the animals still having normal sugar levels.

The second paper came out of Washington from the McKay group. Lumelsky was the first author. Effectively, instead of using what is called gene trapping—in other words, changing the genes of the relevant cells or selecting the cells by means of gene trapping—that group changed the culture conditions of growing the cells in the laboratory and demonstrated also that you could produce insulin-producing cells which, when transplanted, remained that way in mice. Both of those papers are in *Mouse*.

That was followed some six months later by an article that appeared in *Diabetes*. Skorecki is the last author. It comes out of the group in Haifa in Israel which demonstrated that you could turn human embryonic stem cells into insulin-producing cells. That work is not as advanced as with the mouse embryonic stem cells. No-one has yet transplanted those to the best of my knowledge, but the direction of the work is pretty straightforward.

In relation to the non-embryonic stem cells, some work has been done in that field, and perhaps we could deal with that. There are several sources of such cells. One is the pancreas itself, which is the source of insulin-producing cells—and you will forgive me if I do not remember the author's name, but we could provide you with the material, which was published some two years ago now, to demonstrate that if you take the precursor cells—the cells that would normally develop into insulin-producing or other pancreatic cells—out of mice, grow them up in a laboratory and transplant them, you can also reduce diabetes. Remember, the source is the pancreas.

To do the same theoretically in humans you are going to require pancreases. Let me remind you and this committee that the number of people who donate organs in this country is very small. Last year it was 185. There are 100,000 people in this country with type I diabetes. Even if you could achieve your end point, even with two out of one pancreas, you would be nowhere near meeting the demands of the particular group.

There are other potential sources of non-embryonic stem cells—cord blood, bone marrow—all of which can be explored. Our group in Sydney has certainly looked at doing that and has been working for the last two to three years now with our haematology colleagues to try and achieve that goal, and we have not been successful. I am unaware of anyone so far being successful in that particular direction. That is not to say we should not keep working on it. I clearly think that we have got to explore both avenues to come up with what is the best option. But at the moment we are able to produce insulin-producing cells with mouse embryonic stem cells exactly as the Washington group have and gone one step further. So in terms of our own experience, quite simply, it has been easier to pursue the embryonic stem cell than the non-embryonic and that is not because of time, it is because it has worked out much more easily. And for that reason we will continue to explore both avenues.

Senator STOTT DESPOJA—Can I just pursue that line a little further? In your submission you refer to it being easier for a couple of reasons, but also you say that adult stem cells cannot hope to match the potential of ES cells, partly because of the shortage—

Prof. Tuch—Supply is the major reason.

Senator STOTT DESPOJA—Do you agree with BresaGen, for example, in its submission that the problem is that there is just a lack of them, or is it something to do with adult stem cells and their pluripotency?

Prof. Tuch—Based upon the knowledge of how these insulin-producing cells develop—and we still do not fully understand how that occurs right from the word go—it would be best to say that supply is the major issue at this point. I think the mysteries of how to turn an adult stem cell into an insulin-producing cell will eventually be discovered, given enough research into that particular area, but I think supply will always be the issue. We just do not have enough sources of cells.

Senator STOTT DESPOJA—Thank you for that. Just in relation to Stem Cell Sciences—

Senator BARNETT—Professor Tuch, you said that you are not aware of any adult stem cell research that is benefiting type I diabetes. Is that what you said?

Prof. Tuch—I am happy to be corrected, but I think I said that, based upon mouse experiments, non-embryonic—and I prefer to use the word 'non-embryonic'—which includes adult because there are lots of sources, has certainly reversed diabetes in mice. I did say that and I did, however, say that there would be a number of potential sources. The pancreas is one, and that has demonstrated efficacy. Non-pancreatic sources such as bone marrow and blood have not demonstrated efficacy to the best of my knowledge.

Senator STOTT DESPOJA—I am curious: in your submission you talk about a national stem cell bank. Could you elaborate for the benefit of the committee why you talk about that? I am just wondering, is there a particular reason based on, for example, the UK experience, that you have advocated this bank?

Mr Ilyine—I am very happy to explain, Senator Stott Despoja. We have a close experience with what is happening in Europe and in the UK, in particular, where we have our own facilities and we have a collaboration arrangement with the Centre for Genome Research at the University of Edinburgh, so we are very in tune with what is happening in Europe and the UK.

In the UK they have taken a decision which was announced only on 9 September—very recently—through the MRC, the Medical Research Council, to establish a national stem cell bank which will be managed independently of academic research institutes and commercial companies. It will have, if you like, an as pure as possible point of independence and management of stem cell lines. If in fact researchers continue to produce stem cell lines coming from excess embryos—or in the case of the UK where it is possible under research to create embryos for the purpose of such things, under their law—what you will have is a profusion of stem cell lines. In trying to manage that, to minimise the number of embryos destroyed for that purpose, the UK government saw that it would make sense to hold all of the stem cell lines in a central point where there would be free and unencumbered access to those stem cell lines to qualified researchers.

The condition for participation was that those who wished to gain access to the broad set of stem cell lines would also have to offer up their own stem cell line created to the stem cell bank—in other words, if you are going to have access to the range you will have to contribute your own line. From a company perspective we felt that this has a lot of merit in terms of providing the best opportunities in research for researchers who are qualified to take and make use of the best range possible of stem cell lines. So that is part of our submission.

Senator STOTT DESPOJA—So you are suggesting a public good argument.

Mr Ilyine—Yes.

Senator STOTT DESPOJA—I am just wondering whether the recent decision in the UK came about as a consequence of any specific problem. Was there any particular reason in relation to the issue of distribution of embryos to researchers?

Mr Ilyine—There has been a lot of difficulty with researchers getting access to the stem cell lines, I believe, for one reason or another. The second part is that the European approach is probably different from the US approach in the general philosophy of how things are done. There are of course recent recommendations to the European Union from the European Union ethics council, which has really come out to say that there should be no patenting of human stem cell lines. At the moment there is a patent which relates to stem cell coming out of the Wisconsin university under Professor Jamie Thompson. So the European position is looking to be different from that taken in the US. Then the question is: where does Stem Cell Sciences, as a company, wish to position itself? Our position is that we support the position in Europe as distinct from the position that is taken in the US.

I add another piece for transparency: at this stage the company, Stem Cell Sciences, has no human stem cell lines and has not worked with human stem cells, so you could argue that it is easier for us to take this position relative to those who have actually invested, such as BresaGen, in the development of stem cell lines, and I grant you that.

Senator STOTT DESPOJA—I will ask the professor and Dr Juttner for their views in relation to the issue of patents. It is slightly removed from this debate but, as someone who believes strongly that you do not patent genes or gene sequences, I speak with a bias, but I am curious. For the record would you be prepared to tell the committee your views on patenting of the cell lines?

Dr Juttner—My view used to be like yours until I worked in the US and started to understand the difficulty. I mean, I have always been interested in turning new discoveries into new therapeutics. That is what I did in academia for 30 years. I went to the US because it seemed the opportunities there were greater. I had your view, but as I saw and learnt just how much it cost to do stuff, to get a product into a therapeutic, I became convinced that patenting was necessary. There needed to be protection to allow a period of time for an inventor to gain some recompense for the hundreds of millions of dollars they invest in development.

Having said that, our own position about our embryonic stem cell lines is that within the US for any NIH-funded researcher we make those cells available for a transfer fee of $5,000, and we do not even get, because of the way NIH negotiated this, a right of first refusal to inventions that come from our lines. That was not our preferred position. Our preferred position is to make cells available for a small training fee of $5,000 and then to have a right of first refusal to negotiate on new IP, but with no guarantee or ownership built into that. We take that view because this is such a vast field. We are a small company. We are focused on one area. We cannot encompass everything. It is much better for us to have cells widely available. We are enthusiastic, indeed, to see comparative studies done between our cells and other people's cells. If they are not as good as other people's cells, the sooner we find out the better.

Senator STOTT DESPOJA—Thank you.

Dr Juttner—I don't know whether that answers your question.

Senator STOTT DESPOJA—No, it does.

CHAIR—Senator, have you—

Senator STOTT DESPOJA—I was going to ask the professor for his views, if that is acceptable.

Prof. Tuch—The Diabetes Transplant Unit is an end user of the cells. It is not our aim to create embryonic stem cell lines but to work with others who would do so. We do not have IVF access directly, which is why we will work with those who have that particular capacity, whether it is BresaGen, Stem Cell Sciences, ESI, Sydney IVF or any other particular organisation. We would be prepared to work with them to obtain the cell lines and see what we can achieve.

In terms of patents, what we can do with those particular cell lines is use our own particular manipulations and culture conditions and a variety of other things that we learned. That we would certainly wish to have patented but we clearly would have to refer back to the people who provided us with the embryonic stem cell lines, to involve them in some manner equally as well since material transfer agreements will have to be signed before we can get the cells.

Senator STOTT DESPOJA—Thank you.

Senator DENMAN—I have a very quick question, Professor Tuch. Have you any idea how many embryonic stem cells would be required to advance your research? You probably cannot answer that.

Prof. Tuch—Sufficient to answer our particular questions. How many that happens to be, I can guess as well as you can, but I can tell you that we currently are using two human embryonic stem cell lines provided through the services of ES. Effectively they behave in different manners when we grow them. I cannot answer how many are particularly required; it could be six, it could be 12. I think once you get to that sort of number you should have a few but two is certainly not enough.

Senator JACINTA COLLINS—Are the two lines that you are using subject to the problems that BresaGen has been raising, about the tissue that they have been grown in or about meeting the standards?

Prof. Tuch—What we are using them for at the moment is simply to see whether we can convert them into insulin-producing cells and not for the purposes of therapeutic use, but to understand how to develop them. Once we understand what we can do in our laboratory, then we will be in a position that BresaGen has put forward which basically says, if I can quote accurately:

The new embryonic stem cell lines will need to be created in a manner and grown on human tissue as opposed to mouse tissue.

Which is the current position.

Senator JACINTA COLLINS—The current ones are mouse tissue?

Prof. Tuch—We are happy where we are at the moment, but we are obviously exploring putting our cells on to human tissue but not currently for therapeutic use—that has got to be years away.

Senator BARNETT—I want to pick up on a point that Senator Stott Despoja was making with Mr Ilyine. In your submission from Stem Cell Sciences you support unencumbered access to human embryo stem cells for basic and applied research, and you indicated that you had no trademarks—patents, I should say—of embryo stem cell lines at this time. Do you have other patents in other regards?

Mr Ilyine—Absolutely. The company has at this stage 14 patents to my knowledge which are either granted or applied for which really relate to technologies. It is a type of toolbox for how to grow, propagate, differentiate and select for the cell types that are derived from the stem cells.

Senator BARNETT—Is another way of saying that that it is a form of cloning?

Mr Ilyine—No. If you have stem cells growing, which you learn how to grow properly and well, and you allow them to differentiate, essentially they tend to differentiate randomly. The knowledge is not there on how to guide them to become a neuronal cell, if you like. In order to provide assay material for drug discovery, in order to provide material that would go into cell therapy, you need to be able to provide pure populations of the desired cell type, and the company's technology is actually involved in making that propagation and selection of the designed cell type.

Senator BARNETT—You mentioned your company structure in your submission. Is it a for-profit company?

Mr Ilyine—Yes.

Senator BARNETT—I noticed you said in your submission there was a link there with Professor Trounson's department until 1999. Does he have an interest in your—

Mr Ilyine—No. There is no financial or commercial connection at this time with the Monash Institute of Reproduction and Development, but that notwithstanding, it is fair to say the founder and CEO of Stem Cell Sciences was the person who started the stem cell unit, Dr Peter Mountford, in the Monash Institute of Reproduction and Development, and he worked there from 1995 to 1999, and after that he went out to take over his current role as the CEO.

Senator BARNETT—Are you the recipient of any of the federal government grant recently provided, the $46.5 million—are you involved in that?

Mr Ilyine—No. We hope to find a place where we can contribute to that centre, but in the initial work, we were not invited to participate in that centre of excellence.

Senator BARNETT—I have two questions I would like to ask each of the witnesses, if I could, and I realise that other senators would also like to ask questions. In the report *Human Cloning*, of August 2001, it notes on page 120:

> They noted the evidence from Professor Trounson and Mr Klupacs that existing stem cell lines are sufficient for both research and the development of stem cell banks. Professor Trounson asserted there is no need to use any more embryos to create embryonic stem cells.

And they have put a footnote for that. It then it says:

> This was supported by Mr Robert Klupacs, the general manager and CEO of ES Cell International. We have now grown six cell lines within our research laboratories. The commercial reality is that it is very unlikely we will ever have to go back to another embryo source again to grow a new line … our position is that we do not think we will ever have to go back to derive another embryonic stem cell line.

And, Dr Juttner, you are quoted in today's *Canberra Times*. It says that:

> BresaGen said, 'Although those embryos would be satisfactory for basic research they would almost certainly not meet more stringent safety requirements for therapies'.

I am just wondering what the difference is between those two, and you are quoted as saying:

> There were already enough stem cell lines available for research, but no fully compliant stem cell lines had yet been created for therapies.

So, my question is specifically, how many human embryos are required for human embryo stem cell research?

Dr Juttner—For research, we believe there is probably not a need to derive any more research mouse-derived embryonic stem cell lines. Twenty years of very productive research with mouse embryonic stem cells was done with only four lines. At present there are

somewhere between 15 and 78 Bush-approved lines in existence around the world. Ten of those are based with Australian companies. The proviso is that, as Professor Tuch has said, we expect that different cell lines are going to behave differently and, indeed, when we move towards the therapeutic lines that are derived on human feeder layers, then because of the way they are derived—because what those feeder layers do is to give signals to the cells to allow them to change from inner cell mass cells to cell lines—it is likely that those cell lines will behave differently so that the research that is done with mouse-derived cells is going to have to be repeated with human-derived cells. Then, when it looks as if you have moved to a stage where you can reasonably consider on the grounds of animal models, safety and efficacy that you are ready to move into human trials, then you need to introduce the GMP element, but probably not before. It is a staged process. I cannot give you an answer—

Senator BARNETT—Yes, but, with respect, Dr Juttner, other scientists have in recent times specifically indicated a figure of 50, a figure of 100 and a figure of 200 human embryos that would be required—maximum—to do the human embryo stem cell research. I am just asking you; you are a professional, you are an expert in the area. How many are required?

Dr Juttner—My view is no more at present. In a year's time, when we know more about what exists at present, there may be need for more.

Senator BARNETT—How many? Just the maximum number?

CHAIR—It is a hypothetical question.

Senator BARNETT—Roughly. I am asking the question—

Dr Juttner—It is a difficult question to answer because if you are trying to produce cells for diabetes or cells for neural disease or cells for cardiac disease, they may behave differently. We know enough from the mouse lines and our initial experience with human lines that different lines have different propensity and capacity to be directed in the directions—

Senator BARNETT—I am aware of that. Other scientists have put a figure on it, but you're not prepared to put a figure on it?

Dr Juttner—I would rather not.

Senator BARNETT—Okay, thank you. Would you be able to respond to that question before we —

Senator JACINTA COLLINS—Can I just clarify a point from the submission. In the executive summary, the last dot point refers to 600 to 1,000. Is there a different concept we are referring to there?

Dr Juttner—That is a totally different concept. If you are producing therapeutically effective cell lines, there are multiple potential ways of dealing with the issue of rejection and compatibility, from producing identical self embryonic stem cell lines to using immunosuppression and then in between there are approaches of partial matching. The 600 to 1,000 cell lines is based on work that I did with John Hanson in the Fred Hutchinson Cancer Research Centre in the US when we looked at how many bone marrow cell lines, if one could achieve them, and no-one has yet, you would need to be able to achieve a high degree of tissue matching such that those cells might be suitable for the majority of mankind.

Hanson, who is probably the most knowledgable individual in the field of tissue matching in the world, did some complicated research and came back with the advice that, by choosing carefully the right tissue compatibility antigens or markers, six cell lines bearing carefully chosen markers are likely to provide satisfactory matching for 90 to 95 per cent of any given

racial ethnic group. Our estimate from that goes on to say that if you have successful therapies which work with partial matching, then something like 600 to 1,000 therapeutic cell lines will be necessary to provide therapies for a wide range of humanity. But that is a long way down the track. So it is not to do with this basic stage of research at all.

Senator BARNETT—Okay. Professor Tuch?

Prof. Tuch—I do not really have much to add. I have already addressed it as much as I can with Senator Denman's question, unless there is something extra.

Senator BARNETT—You cannot put a figure on how many human embryos are required for human embryo stem cell research like other experts have?

Prof. Tuch—Let me just perhaps expand upon the answer I gave to Senator Denman to see if that addresses your concern. First, if we are provided with a dozen embryonic stem cell lines, in terms of being able to turn them into insulin-producing cells, that would seem to be enough in terms of research purposes. How many fertilised eggs would one require to produce those? If they are already available to us, then the answer would be exactly what Dr Juttner has said.

Senator BARNETT—In your submission you say more human embryo stem cell lines need to be created to overcome this limitation. This is on page 2 of your submission. Can you justify that statement?

Prof. Tuch—Perhaps I can draw a distinction. I think the distinction has been made by Dr Juttner, but just to clarify it: I am drawing a distinction between therapeutic and research purposes. We are not at the stage of therapeutic purposes. We do need to create more embryonic stem cell lines to be able to grow them in a manner which potentially could be used for therapeutic purposes.

Senator BARNETT—So there is a difference is there, between research and therapeutic? Is that what you were meaning, Dr Juttner, in your comments in the newspaper today when you said that BresaGen said that although those embryos would be satisfactory for basic research, they would almost certainly not meet more stringent safety requirements for therapies?

Dr Juttner—That sounds very much like my submission to this committee, which I certainly have not released to the press and I have not been interviewed by the *Canberra Times*, but yes, that is the point I was trying to make. In this submission, we make a clear differentiation, I hope, at point 3 between—

Senator HARRADINE—I think it was online.

Dr Juttner—That is interesting, because there were strict rules about not making it public.

Prof. Tuch—I received a letter which indicated that all material is public information and is available online.

CHAIR—It is not some miracle!

Dr Juttner—Point 3 sets out the differences as we see it between research and therapeutic lines.

Senator BARNETT—Mr Ilyine, would you like to respond to that question?

Mr Ilyine—I know that by your comment you suggested that there are a number of people who provided evidence that said that there were no further cell lines needed more or less for ever. I think experience in time has shown that that is not really the correct position, which is that there are in fact additional cell lines needed for all sorts of reasons. We already have

made some progress from mouse feeder cell systems to human feeder systems, but I would argue that perhaps that is not far enough either, and that actually the cells in time, to be fully GMP compliant, would have to be able to be grown in a fully defined medium where all the components of the medium were known and understood to be safe in their own right.

Senator BOSWELL—The question asked was how many.

Mr Ilyine—I believe there will be a need for quite a number of cell lines to be developed for all sorts of purposes. I could not put a number on how many, but I think the number will be more than counting on our hands and so on. There will be a need for a good number of cell lines to be available. If in fact the cell lines that currently exist are encumbered, where researchers cannot have free access to those cell lines, where companies like us may not have free access to those cell lines, clearly we would wish to make our own. If those were available in a national cell bank where we could draw upon them for specific projects, then of course the number of cell lines would be able to go down.

Senator BARNETT—Would you need any more on that basis, from the national cell bank?

Mr Ilyine—I believe, given the likely diversity that one would find within those cell lines, that we should look to have an increased number over what is currently available.

Senator BARNETT—My second question—if you could just make your answers as brief as possible—relates to the definition of 'research'. The bill talks about research on human embryos, stem cells. In respect of the definition of research, can you define for this committee your definition of research? Does it include, for example, drug testing, facial moisturisers and whatever else—a whole range of different types of research? It can be a broad definition or it can be a narrowly defined definition for therapeutic purposes. Can you help us and advise us of your definition of research?

Dr Juttner—I am not long out of academia. For me, research is a scientific endeavour aimed at answering questions and moving ahead and improving the way one does things, and my interest is therapeutic, so I am interested in new therapies. For me, research involves everything from where we are now to having products that are being used to treat patients, in the case of cellular transplants. It also includes the possibility of using embryonic stem cell lines for things like drug testing, which I think is actually a proper activity if it saves patients from being exposed to testing of new drugs, but I am not talking about, and absolutely reject, the concept of using embryos as such for that testing. It is embryonic stem cell lines or the products of them, and actually it is more likely that cell lines that have differentiated into liver cells, kidney cells or heart cells would be wanted for things like drug testing.

Senator BARNETT—Thank you.

Prof. Tuch—My definition of research would include the development of therapies which could be of benefit to humans and the modifications thereof until we have reached the point where we accept them or reject them.

Senator BARNETT—Benefit to humans?

Prof. Tuch—Yes. For example, if I could focus on my specific area of diabetes to give you an illustration —

Senator HARRADINE—Are you using humans?

Senator BARNETT—No, benefit to humans Professor Tuch said.

Senator HARRADINE—Are you using humans? I am just wondering.

Prof. Tuch—Human embryos.

Senator HARRADINE—Human foetuses to what age?

Prof. Tuch—If I could just clarify the question through you, Madam Chair. The question I think we have been asked is the definition of research as it relates to human embryonic stem cells. Is that correct?

CHAIR—That is correct.

Prof. Tuch—That relates to the use or development of embryonic stem cells which may be of help to people who have a number of conditions which we currently cannot treat. That will be in its infancy and also would require some years of development to achieve a particular point where it will or will not be of help. It will include understanding how diseases occur and how particularly the genes are involved in terms of the formation of cells whereby for example we have specific conditions which are of a genetic nature. And yes, I would include drug testing in association with that. I think they are pretty broad definitions in terms of—

Senator BARNETT—Facial creams?

Prof. Tuch—I am not qualified to comment on that particular area.

Senator BARNETT—Mr Ilyine?

Mr Ilyine—I am probably the least qualified to answer on such matters, not coming out of research, but my own view is that research represents scientific endeavour that leads to new knowledge and discovery. Clearly what we would like out of that is that it is conducted ethically and correctly.

Senator HARRADINE—Does that include human cloning experiments involving implanting a cell containing human DNA in a pig?

Mr Ilyine—In terms of a definition of research, yes.

Senator HARRADINE—Dr Mountford has undertaken those experiments over recent years?

Mr Ilyine—I am not sure if that is a question, with great respect.

Senator HARRADINE—Yes, it is a question. Would you include that as ethical?

Mr Ilyine—The work that is being done by the company has been done correctly and properly.

CHAIR—Senator Harris has a question before he is called back to the chamber.

Senator HARRIS—Thank you, Chair. It is primarily directed to Professor Tuch. You mentioned there were approximately 100,000 patients in Australia with type I diabetes. Are you aware of any research that has been directed towards taking adult stem cells or stem cells from an adolescent from the pancreas of a donor that is such a close relation who would have a similar blood grouping? Has any research been done? You mentioned earlier the incidence of rejection. Has any research been done in that manner to be able to grow out or multiply cells that would provide insulin?

Prof. Tuch—It is a good question and one that we are attempting to pursue in animal models at present. There are two difficulties, and perhaps I could clarify them for you. The idea of taking a cell from the pancreas in people with diabetes or relatives—

Senator HARRIS—I apologise, Professor. My question was not related to the person who has the type I diabetes, it would be towards a close relative who does not have type I diabetes.

I just preface that by also saying I do know of tests that have been done by taking very small tissue samples from donors for other research.

Prof. Tuch—I was going to address this in two ways, but now I will expand it to three if I may.

Senator HARRIS—Yes.

Prof. Tuch—One is biopsy, which is what you are referring to, where you take a small amount of tissue.

Senator HARRIS—Yes.

Prof. Tuch—There is only one country that I am aware of in the world at the moment that is currently doing biopsies of pancreas and that is Japan. The reason behind that is that 99 per cent of your pancreas produces enzymes which are used to digest food. If you disturb that, you release those enzymes, and it will digest its own tissue.

Senator HARRIS—Right.

Prof. Tuch—So taking a sample of a biopsy of a pancreas creates a medical condition or could create a medical condition, and most countries—with the exception of Japan, for reasons I do not understand—will not go down that path. You could take a biopsy of liver and other organs much more readily. Secondly, there is a study that has been carried out in Minneapolis—it was carried out in the mid-1980s—involving twins. One person had diabetes, the other one did not. This is not stem cell work, but perhaps it can be used to explain. They did take half a pancreas from the twin that did not have diabetes and transplanted it into the person with diabetes. And of course the person with diabetes was no longer diabetic for two weeks, and then their diabetes recurred because of the self-destruct mechanism which causes type I diabetes. I have to say that for long-term follow-up studies of people of that nature, of the people who donate half a pancreas, some of them go on to develop diabetes, so much so that now virtually, with the exception of Minneapolis, I know of no place in the world that is prepared to take out part of the pancreas because of the potential problem that can arise in the donor.

The third situation is in relation to this: let us assume we could overcome all of those obstacles and take out part of the pancreas. The problem is we cannot readily isolate your precursor cells, the so-called stem cells which will develop into the insulin-producing and other forms of cells present. So I think the approach that needs to be taken is not taking out cells, but to put in genes or other agents which will try and turn those non-insulin-producing pancreatic cells into insulin-producing cells. Since they both come from the same source, the theory is good; the practice of course is yet to be realised, but it is a path that we and others are moving down.

Senator BOSWELL—Can I ask a series of questions of Dr Christopher Juttner from BresaGen? Doctor Juttner, we are trying to understand where BresaGen fits into the picture of embryo stem research and where the funding is going and so forth. Can you tell me what related projects you received government funding for?

Dr Juttner—Certainly, and I would be happy to do that. There are a series of written replies that I have previously given to Senator Harradine on questions related to our start grant which I would be happy to forward to you if you would like them.

Senator BOSWELL—Can't you just give us a couple, just tell us now.

Dr Juttner—Certainly. You are talking about funding we have received from—

Senator BOSWELL—From the federal government, or the state governments for that matter.

Dr Juttner—We have funding only from the federal government under the start grant scheme. We received funding in June 2000 for work in embryonic stem cell research based in the University of Adelaide aimed at both mouse and human embryonic stem cell research. That work has continued and is continuing, and the grant is meant to complete in December 2003.

Senator BOSWELL—And that is the only grant that you have received?

Dr Juttner—From the Australian government?

Senator BOSWELL—Yes.

Dr Juttner—Yes, that is correct. I should say we are part of the National Centre for Advanced Cellular Engineering, which was under the Major National Research Facility Award. That grant was received in August of last year. That also involves Monash, IRD and Alan Trounson, but under that grant there was no intention that we would receive any funding. We were there as contributors to the centre, contributing cells background, intellectual property and hopefully expertise, but we were to receive no funding under that.

Senator BOSWELL—So you have worked with Alan Trounson and Monash University and some of those spin-off companies?

Dr Juttner—Well, not really. We have talked about working together, but no actual collaborative work has happened yet.

Senator BOSWELL—What was the nature of your relationship? Just talking or have you got any intellectual property agreements or funding agreements?

Dr Juttner—No. What we have is an agreement to cooperate in the MNRF, which began in June 2001 when we first started talking to the Monash group, and we have an agreement to be involved in providing background intellectual property and cell lines and contributing our expertise where it is contributory.

Senator BOSWELL—I have a fair few questions to ask and I will just run through them fairly quickly. In the estimates earlier this year we were told that you were negotiating to be a commercial partner in the National Centre for Advanced Cell Engineering. That received $5.5 million funding from the Department of Industry, Tourism and Resources. ES Cell International was involved. What was the outcome of those negotiations?

Dr Juttner—They are not complete yet. The heads of agreement and the business plan have yet to be signed off, so that the—

Senator BOSWELL—But how can you receive $5.5 million if the heads of agreement have not been signed off? I cannot quite understand that.

Dr Juttner—Those are the rules established by the Department of Industry, Tourism and Resources, and indeed little money has been forwarded. You should also understand that MNRF funding is specifically limited to providing infrastructure support. It is for infrastructure support; it is not to fund research.

Senator BOSWELL—But it still seems hard to understand that someone gives you $5.5 million. I am not being disrespectful, but just generally speaking it seems to be very difficult to understand how someone can give $5.5 million without an agreement being signed. It beats me, anyhow, but you have answered the question. BresaGen is described as a key commercial partner in the Biotechnology Centre of Excellence which received $46.5 million from the

Commonwealth government. Can you explain how that structure works and how you commercialise the results of several research establishments around Australia? You are a research establishment; ES Cell is a research establishment. How does it fit together?

Dr Juttner—Originally the planned arrangement was that there would be 15 academic centres who would be the recipients of the funding and ESCI and ourselves would be the commercial partners who would provide human embryonic stem cells for work to be done in those centres and who would help with commercialisation and management of intellectual property and we would seek a relationship whereby we would have first right of refusal for inventions that came out of the academic centres. Now it is being discussed that there would be an intervening commercialisation company called Cellcom which might take that role, and we do not have a complete resolution of that situation either.

Senator BOSWELL—Has the centre started to disburse these grant funds and is BresaGen a direct recipient of those funds?

Dr Juttner—No, BresaGen will not be a recipient of those funds. We have no intention of applying for them, and in fact I think it is not appropriate in the way we discussed this arrangement. None of those funds have been disbursed yet to any of the academic centres.

Senator BOSWELL—Have you signed agreements with the government and the centre itself?

Dr Juttner—We signed an agreement in late March-April whereby we accepted the general structure, with the proviso that we reserved a right to negotiate further on the business and commercialisation structure. I am talking about the Cellcom entity. We were dissatisfied with that arrangement.

Senator BOSWELL—When will you be receiving some of that $46.5 million? When will those funds be disbursed?

Dr Juttner—We do not expect to receive any of those funds. The funds are likely to be disbursed for research in the second year of existence of this centre of excellence, so that in the first year the only funds that are being disbursed are to hire key people like the chief operating officer and CEO. That is my understanding.

Senator BOSWELL—Last meeting we had the NHMRC confirmed that nothing in this bill regulates the exports of embryo stem cell lines. Can you tell us what your ambitions are with regard to exports? Where are going to send them, to whom, for what reason and what kind of financial arrangements would be involved?

Dr Juttner—We are in the situation not of exporting embryonic stem cell lines, we are importing them at present from the United States.

Senator BOSWELL—But do you intend to as the research develops? You are an overseas company, I believe.

Dr Juttner—No, we are an Australian company.

Senator BOSWELL—Is BresaGen also an overseas company?

Dr Juttner—We have a wholly owned subsidiary called BresaGen Inc. which is in the US.

Senator BOSWELL—Would you guarantee that? Where is the majority of shares?

Dr Juttner—In Australia.

Senator HARRADINE—I thought the majority of, not shareholders, but the majority of money, is overseas.

Dr Juttner—No, the majority of the money is in Australia. There are some overseas shareholders, but they are a minority, both of holders and of actual shares.

Senator BOSWELL—We were told that once stem cell lines are developed in laboratories around Australia they can go out, and that once they go out we have no end user certificates on them. Would BresaGen guarantee not to export embryo products to countries or researchers that act outside Australia's ethical guidelines on, say, cloning? Would you guarantee not to?

Dr Juttner—We have no interest in cloning.

Senator BOSWELL—No, but would you send any of these products outside of Australia, to countries that act outside Australia's ethical guidelines?

Dr Juttner—We work always within the ethical guidelines of both organisations. So, in the case of bringing embryonic stem cells from the US to Australia, we meet both the US and the Australian guidelines, laws and import ethical requirements. That would be our policy for any cells that we sought to export to other countries.

Senator BOSWELL—Do you use monkeys in research or for any other activities?

Dr Juttner—No, we do not use monkeys in research.

Senator BOSWELL—You will soon know that John Smeaton has just recently relocated to Athens in Georgia, US, where you have got labs on the University of Georgia Athens campus. Would you be exporting embryo products there? You mentioned in your submission that unless you get the kind of legislative arrangements you need here, I think you even said it today, you may go overseas. Really, you are already there if your CEO is over there.

Dr Juttner—We have a small operation, we have 10 employees in the US and the vast majority of our people are in Australia.

Senator BOSWELL—How many employees do you have in Australia?

Dr Juttner—In Australia, 64.

Senator BOSWELL—Your CEO, John Smeaton, told genetic engineering users that the COAG proposal was okay for research but has not addressed the issues on the horizon as we move into therapeutic development. He then went on to say:

> Frozen embryos won't meet their needs because they are mostly four to six cell embryos that would need to be cultured onto … at this stage to harvest themselves.

He then went on to say:

> That is not what we want to waste our time on … frozen embryos will not provide genetically diverse tissue banks.

What I want to ask you is, what is in the bill as it exists now, if you have got enough embryonic stem cell lines for research, as you say in your submission, that will do anything to help you further with some business? How do you get a bang for your buck out of this bill?

Dr Juttner—As I said before, it is a staged process. We have to take the research further until we get to a stage where we believe we have developed cell—transplant products that can be taken to the next step. That will involve testing donors in relevant animal models to show they are effective and safe. Having achieved that we will then need to derive therapeutic cell lines.

Those therapeutic cell lines could be derived perfectly legally in the US now but there are reasons, such as the fact that we are an Australian company, reasons to do with the quality of

IVF, its management and regulation which is much higher here in Australia than it is in the US, and reasons to do with the genetic variability of the human population of Australia that say that Australia would be a very good place to do this kind of work.

On balance we would prefer to move into the commercial phase doing the work in Australia. If it becomes a successful business, then shipping therapeutic cell lines around the world is technically feasible, but it depends on what the laws allow us to do.

Senator BOSWELL—There are some countries that just do not have any rules or regulations at all on embryo stem cells, I would imagine, like China. Would you be prepared to send Australian stem cell lines to a country that had no ethical way to stop the misuse of them?

CHAIR—Senator, that has nothing to do with the bill. I am sorry, you must keep to the parameters of the bill.

Dr Juttner—I am happy to say no.

CHAIR—A question from Senator Collins, please.

Senator JACINTA COLLINS—I will start with Mr Ilyine in relation to his submission. It has been put to us in discussions on this bill that it proposes a fairly stringent or tight regulatory regime. I am interested in your submission about the need to control the commercial processes. I go to point 7 in your submission:

SCS strongly opposes any commercial control and exploitation of such a fundamental biological resource as human stem cells ...

That is essentially the argument for prohibiting patenting in the EU and is also your argument—correct me if I am taking steps beyond your submission in trying to paraphrase it—for why there should be a national stem cell bank. In that sense, do you see the model that you would propose, with a national stem cell bank, as creating greater controls in relation to destructive embryonic work than this bill would do?

Mr Ilyine—I think there are two parts, one of which is the legislation, of course. The second part is how one manages and goes forward in a way that is productive, ethical and correct. I do not know—I am not a lawyer—whether one includes all these things in law or whether one puts them outside into regulations, or how in fact one goes forward on that.

What we were saying is that there needs to be great clarity in how these things are undertaken and are prescribed. That is a good basis for the start, but the reality is that in ensuring an independence for that management there is the opportunity to have fairness for the entire research community, whether it is academic or commercial.

Senator JACINTA COLLINS—Is there anywhere in this bill where you see that independence being provided?

Mr Ilyine—I have tried to read through the bill, and I am not sure that there are a lot of specifics which cover that particular area.

Senator JACINTA COLLINS—That is in part one of my concerns about how this bill is currently framed in dealing with some of those issues and the potential commercial exploitation issues in relation to such matters.

I noted from your earlier comments that you referred to one of the advantages of having the bank as being that it assisted in minimising the number of embryos that would be destroyed. Presumably it takes the commercial competition aspect out—

Mr Ilyine—That is right.

Senator JACINTA COLLINS—and enables that minimisation. Going back to our regime: we had the NHMRC-AHEC guidelines, which in states other than Victoria, South Australia and Western Australia enabled, through a process or through these guidelines, destructive embryonic work, but they also indicated that one of the factors to be taken into account would be restricting the number of embryos destroyed.

Mr Ilyine—Yes.

Senator JACINTA COLLINS—One of my concerns is that that limitation concept has been removed from this bill. The bill refers now to the licensing process taking account of the number, but the notion that there should be an objective to limit the number is not in this bill. Given that, and given also that there is no prescribed process which might enable such limiting, can you assist the committee with this from your experience in Europe to that effect?

Mr Ilyine—The interesting thing from the European environment, and particularly if we look at the UK, is that they anticipate that it will take quite some time before everything is operational. It is really because they are going to have to go away and think about all the practical ramifications of going forward with this new stem cell bank. It is not something that would be hurried even in the UK.

What I have seen is that they estimate it could take one year from the time of the notification of this intent to the actualising of that stem cell bank. It is about 12 months of time that would be needed to develop the protocols and procedures that would go with that.

Senator JACINTA COLLINS—And who is managing that process of the protocols and procedures? At what level of the legislative regulatory regime is that occurring?

Mr Ilyine—First of all, it has come through the law. Secondly, it has come through the authorising of an institute, a government institution, to then proceed to make it happen. I am not quite sure of the name, but it is a national institute of standards in the UK, in this case.

Senator JACINTA COLLINS—One of the difficulties we face is that we have the NHMRC-AHEC guidelines that have been in place in some states. They are currently under review but the parliament does not have the benefit of that review. We are told that that review will underpin what is prescribed in the legislation in terms of factors that the licensing body should take into account, such as how one would assess the likelihood of a significant advance in knowledge, how one should take into account the number of embryos that might be used and a number of those factors. But they are not available for this committee or for the parliament to learn from what has been occurring under similar guidelines that the NHMRC and AHEC have been operating since 1996, as I understand it. So at this point in time there seems to be a void of information in terms of how we are considering these issues. I am interested in how that process occurred in Europe.

Mr Ilyine—It is quite a lengthy process and we should not underestimate that, because it has been the subject of public debate for a number of years, which led to the legislation in the UK which enabled an expansion of what was current legislation relating to the use of embryos. The basic legislation was there, and then from there was the expansion to how to make use of that expansion on the legislation to incorporate issues relating to human embryonic stem cells. It was worked off the back of what you would call existing legislation.

Senator JACINTA COLLINS—I have one final point to ask of you in relation to your submission. The prohibition of patenting unmodified human stem cells: can you explain for us the distinction between modified and unmodified and exactly what is meant there?

Mr Ilyine—Yes, I am very happy to. The unmodified human stem cell line in Europe, it would be argued, comes from nature and therefore should never be patented because a patent

granted in this domain would be so broad as to be hugely inhibiting to discovery, because any discovery made on the back of that would have to relate to the original patent holder. So the European position is to say that discoveries made when using such cell lines are indeed patentable when they have novelty and all of the factors that go into making a patent. However, the unique biological material itself should not be patented because it is of human nature.

Senator JACINTA COLLINS—So it is a 'for the public good, for knowledge' type of argument?

Mr Ilyine—So there could be no encumbrance of research being conducted on the human stem cell lines, no patents were granted for their isolation or their development. But for discoveries made when using those cells which are beneficial for one matter or another—drug discovery, toxicology testing, gene validations and cell therapies—those discoveries would indeed become patentable.

Senator JACINTA COLLINS—Dr Juttner and Professor Tuch, there are a few issues I would like to explore with you in relation to what is currently occurring with embryonic stem cell lines in Australia. Professor Tuch firstly, in your submission you refer to the work that is currently being done and approved by the ethics committee of New South Wales. They were the two embryonic stem cell lines you were referring to earlier?

Prof. Tuch—Correct.

Senator JACINTA COLLINS—Where did those stem cell lines come from?

Prof. Tuch—They came from Embryonic Stem Cells International and were provided to us with training by the group in Monash. The original source of those of course is Singapore and they were derived by a technique which required the consent of the donors, as consistent with the interim guidelines of the NHMRC.

Senator JACINTA COLLINS—But even under the guidelines in the New South Wales arrangements you could have derived such cells yourselves, in New South Wales? Were the stem cell lines purchased?

Prof. Tuch—The cells were provided, as I think I mentioned previously, under a material transfer agreement readily provided in the spirit of cooperation—the same thing that BresaGen and Chris were talking about previously in terms of making things available to allow things to occur.

Could we have made them ourselves? We are not set up to do so; we do not have access. That is why we formed a collaboration with Sydney IVF with a view to do so, and it would be consistent certainly with the interim guidelines of the NHMRC. It is my understanding that there is no prohibitive legislation in New South Wales to stop that.

Senator JACINTA COLLINS—It is interesting that you give the example of your work. If it was the stem cell lines from Singapore that you got through Monash, then on my understanding of the interim guidelines there is no need for you to get approval from an ethics committee because the embryos have already been destroyed through the Monash process or through the Singapore process. Why did you need the ethics committee approval to do that work when your work had already established stem cell lines?

Prof. Tuch—That is a good question. In the spirit of closing ranks—not closing ranks but closing circles—we approached the ethics committee of the university last year—at least, I did—and asked them, 'Do we need permission?' They wrote back to say absolutely we do.

Based on NHMRC guidelines, if you are working in a public institution, certainly a hospital or university, if they say you need it, you have to get it.

Senator JACINTA COLLINS—Yes. But my understanding of the guidelines is that you need approval if you are going to establish embryonic stem cell lines involving the destruction of an embryo. Now that had already occurred. You were not actually doing that; you were working with those already established lines. But you were playing it safe, in a sense, in terms of their interpretation of the guidelines—is that right?

Prof. Tuch—My understanding is that the guidelines specifically require that, certainly by the NHMRC. I stand to be corrected, but that was my understanding. I did approach the chairman of the AHEC and asked him the specific requirements, and the advice I received was to proceed in the direction we were proceeding.

Senator JACINTA COLLINS—You describe them in your submission as interim guidelines. Are we referring to the same thing? Are we referring to the NHMRC-AHEC ethical guidelines on ART? Your submission refers to interim guidelines of the NHMRC.

Prof. Tuch—Perhaps I have the terminology incorrect, but certainly they are interim guidelines in the sense that they were produced, as I understand it, in September or October of last year and put out specifically in relation to this. They are readily available on the web through the NHMRC site.

Senator JACINTA COLLINS—September or October?

Dr Juttner—There were NHMRC guidelines before that. We initially imported some human embryonic stem cells from Wisconsin late in 2000 and gained approval from the human research ethics committee of the University of Adelaide. We read the NHMRC guidelines that existed before September 2001 when the add-on came out as requiring approval for any work with human cells. So we gained that approval before importing them. I would agree with Professor Tuch. It has been the case for some time that, for any work involving even existing human embryonic stem cell lines, you require the approval of a properly constituted human research ethics committee.

Senator JACINTA COLLINS—Okay. When you look at what a properly constituted ethics committee is, you go to such organisations as Sydney IVF, for instance. I know my original assumption when I was looking at that was that, as in your case, you would be looking at something like a university or a public hospital ethics committee, but as I understand it Sydney IVF has its own ethics committee.

Prof. Tuch—I can clarify that situation. It is my understanding, having worked with Sydney IVF, that in fact the constitution of the ethics committee of Sydney IVF—not that I am part of it—basically has been constituted as per NHMRC guidelines, which requires there to be a member of the clergy, a solicitor, a layman or laywoman, a scientist—all those are in black and white. It is my understanding that that is the case.

Senator JACINTA COLLINS—The issue there is whether we regard the NHMRC guidelines about how one should establish an ethics committee as being adequate. I personally question whether a private commercial organisation can establish their own ethics committee, regardless of how you deal with the composition.

There is a question that I am putting on notice to the NHMRC about what the practice has been to date under their guidelines. You yourself might receive a question from them about the cases when you have had ethics committee authorisation for work that you are doing. Given that we will not have the result of their review of the guidelines that have been in place since about 1996, I have asked that question about the practice to date. As I understand it,

they are likely to write to any organisation that has been working with embryonic stem cell lines involving the destruction of embryos, to provide us with that material.

What I also wanted to understand further from the BresaGen submission is: of the overall number of embryonic stem cell lines, are there any that—going back to the words in the BresaGen submission—'would meet current good manufacturing practice conditions'?

Dr Juttner—No. There is one cell line that has been reported recently which was derived in Singapore and was derived on human cells—it caused something of a furore because they were foetal cells—but that cell line, as I understand it, was not derived according to good manufacturing practice. It was derived according to good laboratory practice, but that does not have the documentation—I will not go into it; it is very boring and detailed. Basically, it does not have GMP requirements.

Senator JACINTA COLLINS—Are there any stored disaggregated embryos that have not been cultured or put in mouse tissue?

Dr Juttner—I believe it is rumoured that amongst the 78 lines that Bush approved in August last year, which was worldwide, there are a number of embryos that are disaggregated embryos—frozen. They have not started to attempt to derive them. So it may be that there are lines that—

Senator JACINTA COLLINS—Could potentially meet these guidelines?

Dr Juttner—They are unlikely to meet the GMP guidelines. They might be able to get away from the mouse xenotransplant issue. Without knowing anything about the standards associated with IVF in Scandinavia, India and South Korea—because that is where most of those lines actually come from; few were derived in the US—I cannot answer your question, but I think it is unlikely. I know a fair bit about IVF practice in the US, and it is essentially unregulated, so it is very unlikely that that will meet GMP requirements.

Senator HARRADINE—I want to ask a couple of questions of Professor Tuch. They go to this question of utilising animal models prior to experiments on human subjects. Have you undertaken extensive preclinical experimentation in animal research before undertaking human studies? Isn't this necessary to get adequate proof of concept? Isn't this the normal scientific process?

Prof. Tuch—I am not quite sure I understand the question, Senator Harradine.

Senator HARRADINE—I am talking about the experimentation that you are undertaking now on embryonic stem cell lines. I am asking you: have you undertaken extensive preclinical experimentation in animal research before undertaking this on humans?

Prof. Tuch—Perhaps I could answer that in several ways. Firstly, let me state very clearly that the use of human embryonic stem cells in whatever form is not ready, by any stretch of the imagination, for clinical trials. Let me be very clear about that. It is my view that it will take years—three, four, five-plus years—before we are in that position.

Senator HARRADINE—So at the present moment you are experimenting only on animal models?

Prof. Tuch—Perhaps I could clarify that. We are certainly carrying out research as I have defined it. We are using both a mouse embryonic stem cell line and human embryonic stem cell lines in attempts to convert them into insulin-producing cells. We have been able to achieve the conversion of a mouse embryonic stem cell line into a mouse insulin-producing cell. We have not achieved that as yet with the human embryonic stem cell lines.

Senator HARRADINE—I note that you said that in your submission, but your unit has a history of actually using foetal tissue from aborted foetuses.

Prof. Tuch—I certainly have used human foetal tissue obtained from therapeutic terminations of pregnancy, but it is my understanding that that has no connection whatsoever with this bill.

Senator HARRADINE—I am sorry, it is a question of what the ethical arrangements are and the effect that this might have on persons who are employed in that particular area. This is very relevant to the bill, because we are talking about having access to frozen embryos. This will have to be performed by people, and the effect of that on people is clearly relevant to the bill. What was the effect on the employees in your unit in respect of their obtaining or utilising material from aborted foetuses?

Prof. Tuch—Perhaps, in answering your question, I could allude to the study you are basing it on. I guess its relevance to this particular bill would be, if I could paraphrase: what is the effect of using human embryonic stem cell lines on the researchers who are using them? Perhaps that might be an extrapolation, and let me address that issue. I address that issue by inviting each and every member of this committee to come and look for themselves at what human embryonic stem cell lines look like. Could I be so bold as to ask whether anyone in this committee has actually seen a human embryonic stem cell?

Senator BOSWELL—Adult stem cells?

Senator HARRADINE—I am asking you a question, Professor Tuch.

Prof. Tuch—Sorry, I was not trying to be irreverent.

Senator HARRADINE—I am asking you a question: do you believe, frankly, that human status is determined by size?

Prof. Tuch—No, Senator Harradine, but what I am trying to get at—

Senator HARRADINE—What about the aborted foetuses? For example, how old were these aborted foetuses that you used for the same purpose that you are proposing to use the embryonic stem cells for?

CHAIR—Senator, could you allow Professor Tuch to answer each question that you raise, please.

Senator HARRADINE—Sure. Sorry.

Prof. Tuch—Perhaps I could address the first concern, which is: what is the effect it has on researchers? You are alluding to a publication we put out in 1993 where we looked at the effect of the use of human foetal tissue—which is not part of this bill—on the researchers. But, as I said, I wish to extrapolate that to the current bill and invite you, Senator Boswell and any member of this committee to see for themselves what a human embryonic stem cell looks like. The point I am trying to get at is that, when you look under a microscope at the embryonic stem cell lines—remember, we do not create them; we have lines—I would defy anyone to tell me that they can separate that from a mouse embryonic stem cell or any form of cell of whatever nature. I accept the argument ethically, and I accept the views quite genuinely, that people have ethical objections to the creation of them. That is their right, and I accept that entirely But what I am suggesting to you is that what you see with your eyes is very different from what one thinks about, quite correctly, on an ethical basis. I would humbly suggest that it is the combination of the two of those which will allow us a greater understanding of what we are talking about. Without seeing it with your own eyes, we can all have an ethical debate and we will choose to disagree with each other; but seeing with your

own eyes what we are talking about adds and allows some more communication to occur to allow us to come together to some extent and decide where we agree and where we disagree. That is the point I am trying to get at.

Senator HARRADINE—I am trying to go to the question of the ethics conducted by your unit. The only thing I can go on, of course, is the fact that your unit has been, for quite a number of years, utilising material from aborted foetuses for the purposes for which you are now seeking to use embryonic stem cells. The question that I am asking is: what protocols were used? For example, did you get the consent of the mothers to undertake experimentation using foetal tissue?

Prof. Tuch—I will answer that in two parts, Senator Harradine. One is to give you a little more background about me in terms of my relation to ethics, because we are on the ethics issue; and then I will address your second question. I need for you to be aware that just because I am a clinician or a scientist does not mean to say that I am not an ethicist. I sat for 10 years on the ethics committees of the South Eastern Sydney Area Health Service and the University of New South Wales. I am no longer a member of either of those, nor was I at the time when decisions were reached to support growing, or to give agreement for us to grow, our human embryonic stem cell lines.

I am a member of the ethics committee of the Jewish Medical Doctors Association. We think long and hard about these decisions in terms of the use of them and on both a personal basis and a religious basis. I think it would be fair to say that the members of our unit, certainly if they have particular objections to the use of human embryonic stem cells or the use of human foetal tissue, are not obliged to do so and are given that particular separation.

In answer to your second question, on the issue of human foetal issue, I emphasise yet again that this is not part of the bill, but since you have raised it on numerous occasions let me address it again. I refer you yet again to articles which came out in 1992 or 1993 in the *Medical Journal of Australia* which detail in chapter and verse exactly how human foetal tissue is obtained under NHMRC guidelines, which were created in 1993—with the consent of the mother and the agreement of the ethics committees of the institutions I work under. The people who obtain that tissue obtain the same degree of agreement from their ethics committees. Those are the conditions, and they are out in chapter and verse; and that was 10 years ago. Nothing has changed, with the exception of the consent form. That has been modified recently by agreement between the University of New South Wales and the University of Sydney.

Senator HARRADINE—Finally, in the *Journal of Clinical Ethics*—that was the matter referred to—you said:

> ... almost all (87 per cent) of the people who had handled the foetal tissue reported that they had experienced some reaction, ranging from curiosity to tears and nightmares.

Could I ask you to comment, if you wish, on the fact that in a review of your article by bioethicist Professor Stuart Younger, published in the same journal, Professor Younger stated:

> ... the study by Tuch and his colleagues sows more confusion than it sheds light.

Younger said:

> The authors' conclusions about this data are unjustified and, in my judgement, demonstrate the bias that permeates their entire article.

Prof. Tuch—Senator, once again I emphasise that this is not part of the bill, but since it seems that I am required to answer the question—I am not shirking from it; I am happy to have a private discussion with you in relation to this exercise—let me just say that not

everyone agrees, as you know, in relation to the outcome of research studies. My unit undertook to have a look at what effect human foetal tissue would have on its researchers, in a genuine belief that we should understand what we are doing and what effect it has. If our study, in the comment you quoted—and I am not familiar with it—caused more confusion than light, clearly that is the view of that particular person. But the people who made the decision to accept the article into the *Journal of Clinical Ethics* clearly could not have agreed with that, otherwise it would never have been accepted. Most journals, I would suggest, make decisions about acceptance or rejection on the basis of whether they believe the data is accurately carried out and whether there is a message that people wish to get across. On that particular point, I am not sure what more I can add, except to make the point that human foetal tissue is absolutely not the same as human embryonic stem cells.

Senator MARK BISHOP—I have just one issue to explore with the witnesses. It goes to the issue of the frozen embryos, the thawing process and then what is to be done if they are thawed—the issue of whether they can be used for research purposes. The particular issue I want to get your comment on is the necessity to thaw. Couples create the embryos. One or more may be fertilised and come to be born as a child in due course, and there are the surplus embryos that are frozen. One of the latest submissions comes from Dr Peter McCullagh from New South Wales, who says:

> The basis for the requirement that frozen embryos be removed from storage and allowed to thaw after certain specified periods is also of some interest.

He also says, and this is the critical part:

> There is no biological reason for a "use by" date. An adequately frozen and stored embryo should have a very long shelf life.

I will ask him questions about that in due course, but would you care to comment on that and either dispute his conclusion—that there is no biological reason for a use-by date—or confirm it?

Dr Juttner—I may be the best person to answer that because of my experience with freezing bone marrow for many years. A lot of studies have been done showing that frozen bone marrow appears to remain fully effective up to at least 10 years, as long as the freezing is okay. There are transplants which have been done with marrow frozen for as long as that. So from a scientific point of view I suspect he is probably right, but I do not know of any studies that have been done looking specifically at embryos for true viability beyond about seven years; certainly embryos frozen for seven years have been used to produce babies. It is very hard to tell whether that freezing procedure causes any harm because, as I am sure you know, one in 50 babies born, whether they are IVF babies or normal babies, have something significantly wrong with them and you do not know whether that was going to happen anyway or whether it is a result of freezing. But it seems that it is scientifically probably correct.

Senator MARK BISHOP—So, apart from the cost angle involved in maintaining embryos once thawed, perhaps ad infinitum, being retained as thawed, the argument for de-thawing is essentially a purely research based argument?

Dr Juttner—As I am sure you know, in Western Australia, South Australia and Victoria there are laws saying that they shall not be stored for longer than a certain period of time. I know John Fleming, with whom I have spoken about these matters a lot, has a view that actually keeping an embryo in suspended animation forever is as much against the dignity of human life as destruction. It is an interesting moral and ethical question, I think, as much as it is a scientific question.

Senator BARNETT—The NHMRC, just this afternoon have provided a response to the inquiries that we made a week or two ago of them. In that response they advised, in response to a question I asked about how many human embryos would be required, that they had made some investigations and they said that you had in your submission to the NHMRC during the consultation process used a number. You indicated earlier that you were not quite sure of the number. I do not have a copy of that submission. Can you help us on that?

Dr Juttner—I think the only number I used is 600 to 1,000 for therapeutic cell lines that Senator Collins asked me about. But you are asking me specifically about research lines. I would say that probably to carry out the research that is required with therapeutic lines that are derived on human cells that are not GMP, somewhere in the range of 100 to 200 cell lines ought to be plenty. I must say I have not thought about it very fully.

Senator BARNETT—The other thing the NHMRC said is that there were two projects that were funded for embryo stem cell research. Have you received funding from the NHMRC?

Dr Juttner—We have not.

Senator BARNETT—Or anyone at the table?

Mr Ilyine—No.

Senator STOTT DESPOJA—Dr Juttner, this is obviously very important to the committee. You have pointed out the distinction between the therapeutic and the research cell lines. You have explained that the lines are not to cGMP standards, but you also indicate that introducing those standards retrospectively is a problem. How important is it that this bill seeks the repeal of the sunset clause? How strongly do you feel about the date to which a number of people have referred in their submissions—5 April? How does that impact on the establishment of those cell lines that are cGMP standard?

Dr Juttner—I suggested a year from the COAG meeting because my estimate of the rate of progress that is being made incorporates the fact that the group in Singapore now appears to have derived a human ES cell line on human cells, which suggests that in 12 months it may be legitimate to be doing that. My estimate from my past experience is that it will take about three months to establish cGMP standards in any cooperating IVF clinic. That is the reason I make the statement of a year.

Senator STOTT DESPOJA—Thank you very much.

Senator BOSWELL—I am being encouraged to ask one last question

CHAIR—I had not indicated that anyone could have one last question because we are now running over time.

Senator BOSWELL—I will be very brief.

CHAIR—If you are brief, you may go ahead.

Senator BOSWELL—Thank you, Madam Chair. On referring to the person from Stem Cell Sciences, you will see that Peter Mountford told the journal *Genetic Engineering News*, 'We are hoping to change the ban on therapeutic cloning to a moratorium', and it went on. Is it true, as stated by the journal, that your company, Stem Cell Sciences, claims to have a strong patent position for the technique of therapeutic cloning?

Mr Ilyine—The answer is we do have a patent position which relates to therapeutic cloning.

Senator BARNETT—Chair, I asked that question earlier today and he said no.

Senator BOSWELL—That is a totally different answer from what you said, actually.

Senator BARNETT—I am totally puzzled.

Mr Ilyine—Perhaps I did not appreciate the question that you were asking.

CHAIR—Would you like to clarify that?

Mr Ilyine—Certainly. We have, as I say, a range of patents. I commented on the essence of the patent range. There is in fact also a patent which relates to a particular process relating to nuclear transfer. That is a fair statement.

Senator BOSWELL—How do you hope to benefit from this bill if you are claiming specialist?

Mr Ilyine—We are not claiming specialist. I think that is the first point. We are a company that saw benefits for drug discovery when using certain techniques that would be able to find solutions for what are currently complex genetic diseases that do not have any cures. We saw that as an opportunity.

Senator BOSWELL—Why did you take out a patent on it? Isn't that for the general benefit of mankind?

Mr Ilyine—Discovery has the opportunities for patent.

Senator BOSWELL—But you are commercialising your discoveries.

Mr Ilyine—In order to be able to commercialise the discovery through investment, you do require patents.

Senator BOSWELL—Yes, I know. That is the answer.

CHAIR—I thank all three gentlemen for appearing before the Senate inquiry this afternoon. Thank you for your time.

[5.41 p.m.]

PIKE, Dr Gregory Kym, Deputy Director, Southern Cross Bioethics Institute

SILBURN, Professor Peter, Spokesperson, Scientific Committee Parkinson's Australia, Princess Alexandra Hospital, and Parkinson's Australia

CHAIR—Colleagues will notice that Ms Margaret Tighe is also listed to appear with this group. She has, I understand from Senator Barnett, requested that she be heard separately, and I therefore propose we hear from the two gentlemen before us, followed by Mrs Tighe at probably about 6.50 p.m. We will have about 70 minutes for the gentlemen now before us. Dr McCullagh is not available. He rang in today that he is not able to join us today. I welcome Professor Peter Silburn and Dr Greg Pike as witnesses before the committee.

Witnesses are reminded that the giving of evidence to the committee is protected by parliamentary privilege. However, giving of false or misleading evidence may constitute a contempt of the Senate. The committee will approach this as a panel type arrangement. It has before it your submissions, and I invite each of you to make a brief comment or anything additional to your submissions that you care to make, at the conclusion of which senators will ask you questions. Professor Silburn, would you like to lead off?

Prof. Silburn—I am here as a clinical neurologist but also to express some views from Parkinson's Australia, which is the support group for people with Parkinson's disease in this country. I have provided just an outline of what I would like to speak to today, and I would be more than happy to provide this in greater detail if so requested. Essentially I would like to address the committee on the basis that I am here as a clinician, therefore I would like to talk about patients and not patents. I would also like to talk about some of the scientific evidence in my capacity as a scientist involved in research into diseases of the brain as well as looking after those patients. I would also like to express some concern about how I feel science has be handled thus far.

I think it is also important that I am here in the capacity of representing some of the views of Parkinson's Australia, which is the support and care group for people with Parkinson's disease. Why Parkinson's? Well, it is often one of the diseases that have been targeted for stem cell therapy. Essentially I feel that the scientific evidence has not been well handled. I think that in discussing the bill we need really to stick to the point, and the point is the use of the availability of extra embryos from what is available now. I feel that the point of the evidence is that we should really stick to that. I think that in the submissions you can see we all agree that there are adequate embryos to develop cell lines for research, and this is across the board: we have this. What is the evidence that we need to increase the amount of embryos and embryo cell lines now? It falls from the nexus to therapeutics, the commercialisation and how this affects public health.

I feel that the point of the bill should stick to how many embryos we need. I think that we have enough embryos for research. This has been expounded by previous speakers here, and therefore the issue comes down to, do we need these extra ones for therapeutics? I think we have put the cart before the horse because the mere fact that we still require research means that we are not in the position and do not have adequate evidence to go on to human studies—human experimentation. Therefore, if we do not have the therapeutics, if we do not have the evidence to do therapeutics, where do we stand? We need more research, so we have a circular argument.

I think the commercialisation unfortunately is having a big impact on this. In the past we had the opportunity to be in the joint party room when some of these issues were discussed

and it is a very difficult area; it is obviously a difficult area. The argument has been diverted away from why we need extra embryos.

CHAIR—Just a moment, Professor Silburn. Something has been put on the table. I do not know from whom or by whom. Is it the agreement of the committee that the *Australian* newspaper take a recording of evidence given here, other than the recording taken directly off the network?

Senator BOSWELL—It is a public hearing.

CHAIR—I am not asking for a brawl, Senator Boswell; I am asking a procedural question.

Senator BOSWELL—You certainly will not get a brawl from me. I cannot see any reason—

CHAIR—This is the trouble I get for letting you ask that last question.

Senator JACINTA COLLINS—What about other recordings being taken when they are recording?

CHAIR—I do not know. Any further reporting of it should be of course checked against the full *Hansard* record, but it would be helpful if media outlets in future could seek the approval of the committee before just walking up to the committee. Is it the agreement of the committee that we proceed and that the *Australian* be allowed to record? There being no objection, it is so ordered.

Prof. Silburn—We come back to the point I was making, which is that in this bill the whole question comes down to how many embryos we need. Do we need more embryos? The previous people have agreed that we do not need more embryos for research. So what do we actually need them for? That of course is a very difficult question.

I think in the past we have been diverted away from the issue and people have actually talked about the value of stem cell research. We have just gone off, and it is much easier to prove points about stem cell research because everybody needs stem cell research. We want this. So it is not really saying anything, and I think that diversion away from the point of the bill is the crux of the problem.

I think there is universal agreement regarding the necessity for research, animal research, in terms of embryonic stem cells before we go on to human experimentation. I think, as well, and I reiterate the point, that we have the adequate lines. This has been pointed out before. I am very disappointed in how the handling of scientific evidence has been used in the support of this bill. I think the science has been poorly done by. If we come to the point about how many embryos do we need, at various points in the party room, when this is discussed—

CHAIR—Professor Silburn, I have to say here that this committee is made up of senators of all persuasions. This is not just coalition senators and members.

Prof. Silburn—What happened was that we had the discussion, and Professor Trounson and another colleague were talking about how many embryos were needed. If we were given $46 million of the public money, that is a big, big outlay. When you are planning research it is only proper that you work out how many subjects you need before it. It is called intention to treat or working out how many people you need to look at to work out the power of the study. When it started out there was mention of 10; halfway through the discussion it went to 20; and at the end it was 50. Clearly if the point of the bill is how many we need and nobody can agree on how many we need and in fact that changes as the discussion follows, we are lacking some science here. I see that the submission from BresaGen mentioned something like 600 to

1,000. We have a vast array of estimates of what we need, but we have no real scientific evidence to back up that number. I think that is not a good thing at all.

I think in that submission or the discussion there is also from the people from Monash the use of the now ill-fated rat. Why was that used? It is surprising that that sort of thing was used. The issue was used, and it was portrayed that this was an embryonic stem cell line from a human that was used to treat and cure—the word 'cure' was used—an animal with motor neurone disease. We have subsequently learnt that when you actually look at that evidence, look at that statement, indeed they were not human embryonic stem cell lines. We also found out that these in fact were not published, so much so that it generated a response from the editor of *Nature* to say that it was erroneous.

We also found out that in fact it was not motor neurone disease and that the animal was not cured. In doing so, by saying they were embryonic stem cell lines, it put into great difficulty the fellows who actually did the research, because in the US, if that were a human embryonic stem cell line, they risked going to jail and Johns Hopkins University risked its funding. Why did this happen? Why was this particular example used? It was said that this was a naive attempt and all that. Professor Trounson is very well regarded, and I do not see how it could be naivety that did that.

If that is the sort of evidence that is being used to support the bill, where is the real evidence? In fact, is there any real evidence? That is what science is about. In science you have to provide hypotheses and observations, collect the knowledge and test your hypotheses, find out the implications of those hypotheses and test them and then use supporting evidence. Unfortunately, I felt that was a very poor example, and it represented science badly because it is very important that people, parliamentarians and the community, understand this. You a very dependent on what is being given to you. Certainly nobody would expect you to be cellular and molecular biologists, so you are dependent on the quality of information and I felt that was not good information.

I wondered, therefore, if that is not good information, where is the real evidence to support this, to support the numbers, to support why you need more? We know we don't need it for research—there is universal agreement on that. I think it came down, unfortunately, to lobbying, and it was an eye-opener for me as a doctor who looks after patients and as a scientist who is very committed to keeping public research in the public domain. I am not interested in commercialisation or patents. That is not the issue of what true science is about. But we are not here to debate that.

I felt that the lobbying was obvious to me and that it was very one-sided over many years. There was an argument and statements without support, and the statements were these: that embryonic stem cells are going to cure diseases; that stem cell research is important; and that if this bill does not get through, stem cell research will stop and there will be no cure of disease. That is what was relayed to people at that meeting.

It is also the impression that you see in the media and it is the impression of people whom I deal with. Patients come to me and say, 'Gee, how can this bill not go through? We won't have cures for diseases.' I can tell you right now that clinicians who deal with people with diseases of the brain or the spinal cord, when anybody mentions that you are going to cure a whole host of diseases, should immediately look at these things with suspicion and look hard at the evidence. That is what it is about.

Where is the evidence? The evidence is certainly not in a rat that did not have the condition. It was not published work. It generated a response from the editor of *Nature*. When it was looked at it, it sent the people who did the work ducking for cover because they had not

published it. That is not true scientific evidence and that should not be the quality of work that we present to you people to make decisions. Therefore, it came down to lobbying.

Our community is very dependent on you, and our community should demand cures from medical people. Our people should demand new treatments, and medical people should demand from people in science ways of doing that. What has happened is that it has gone the other way round. The scientists are telling everybody what they should do. Fortunately, in this field—the science field of providing information—people in science have given us ways of doing this. They have admitted today that there are enough cell lines in this to continue the research.

I think the research should go ahead—absolutely—and it will go ahead whether or not the bill fails, but then people started talking about therapeutics and commercialisation. If there is no evidence for human embryonic stem cells in treating disease where is the therapeutic application for that? Where does that relate to public health? Goodness me, there are a number of public health issues out there at the moment. The research will continue, and if you do it in the proper spirit of scientific research that goes out to the public domain, people pick it up and there is none of these secrecy agreements or anything like that, you just get on with it. I was very disappointed to see how it was handled and the influence of lobbying, I must say. I apologise in many ways for the way science has been handled and presented to you.

I would also like to talk about the view of Parkinson's Australia. Why Parkinson's disease? Look at all the business about stem cell research—people claim that it will cure Parkinson's disease. That is nonsense. The reason it is nonsense is this: we have information that placing dopamine neurgic cells in the brain can help the motor symptoms of Parkinson's disease. There is evidence for that. There is no evidence that embryonic stem cells will do that. In fact, one in five turned into teratocarcinoma, a form of cancer.

So if it is not going to cure Parkinson's, what is it going to do? It is going to help the motor symptoms. But Parkinson's is not just one cell type. There are many other different cells and many other areas of the brain that are affected: in the frontal lobe, deep in the brain, further down—in fact throughout the body cells can be affected. Placing cells in the specific area in the brain to produce dopamine is not the solution; it may be a help, but it certainly is not a cure. I think it is inappropriate for people to talk about a cure.

I spend every second Wednesday placing things in the middle of people's brains, and then we do the surgery. We do these things. Years ago, when we first started doing it, everybody thought it was a cure. It is not a cure, and even when you said to people it was not going to cure it people still thought they were going to be cured. What you are dealing with is susceptible individuals—people who will have a go at anything. If you say, 'You have got a bad disease,' and someone says, 'Look, I am going to be able to cure this,' they will grab at it. I think creating false hope is poor. It is a poor effort; it is a very poor show. Creating real hope is a different thing. Parkinson's Australia is very happy for research to continue, and I will be very pleased to report to everybody that if the bill fails that research will continue—research into embryonic stem cells as well as adult stem cells. That is appropriate, and we have got enough cell lines to do it. We certainly have the capability in our country, and we are very well placed for the research.

So where are we left? What is happening with this bill? Why do we need so many more embryos? I have not seen any compelling evidence for it—not that I am against anything, just show me the evidence. I think that in our country and with you people we should be providing the evidence—proper evidence, evidence that you can rely on and evidence that is going to be placed in the public domain that everyone else can rely on. Given the opportunity today, I

would also like to look at some of the other claims in the submissions, particularly—not singling people out—BresaGen. I note that it says:

> ES cell therapy, likely order of uses: simple single-cell therapies.

As I have just said, you cannot consider treating Parkinson's with a single cell. It does not happen like that. There are nine other neurotransmitters or chemicals in the brain that are lost. It says:

> Matching not needed.

That is nonsense as well, because the brain is a site that when you place things in it things are still rejected. When you put things in the brain they may not be rejected as rapidly and aggressively as elsewhere in the body like transplants, but they are still rejected. We know it from the work on porcine grafts and foetal tissue. This work is known.

Spinal cord injury? Of course, it is in the central nervous system as well. Cells are going to be rejected, so it is preferable to use your own cells. That work in the laboratory that I am associated with has already been under way with olfactory mucosae. You take the cells out and grow them up—in fact 70 million of them—and they have been placed already in therapeutic trials for people with spinal cord disease. There are no big claims being made that we are going to cure anything. There is none of this business. In fact, we think it is going to be some time before we will have any idea of whether or not it has been worth it. But certainly in the animal experiments you can transect—you can cut the animal's spinal cord, sever it and place cells from that animal back in there, and they grow, and the animal improves; the animal is not cured, but it improves.

Why do we do that? It is the big issue of rejection. You will hear of rejection all the time—rejection, rejection. That is immune rejection. Immune rejection is when you take something that is foreign to you and place it in you. Your body recognises it is foreign and rejects it. If we go down the adult stem cell line, that argument is deleted—finished. You do not have to worry about it; end of the story.

I also heard that the adult stem cells are no good—I saw this in the handouts and all that. In fact there is work that is rapidly evolving in adult stem cell work. There is a recent reference with 145 citations on how adult stem cells can change around, and it is a sensible one; it is not biased. It does not say it is going to be the cure-all of these things. It certainly does not say it is going to be the cure-all of a multitude of diseases. For years, with susceptible individuals who have disease conditions, people have come up and said, 'I am going to cure this, this, this and this with just this here.' That has been happening since medicine started. You have to look at that critically. Where is the evidence for that?

I see here 'stroke'. Goodness me! With true, out in the field, real life stroke, if you block off a very small artery at the start where it comes into the brain and a large area is destroyed, placing cells in there is not going to repopulate the whole of that brain. When you talk to people who are involved in stroke, they will tell you that that is not the case. They will tell you that there are some nice models and perhaps non-disabling strokes that you can help, but you are asking for some cells to then go and repopulate the architecture back to normal and the relationships back to normal—all those things that have taken years to do. I find it very hard to believe.

I see here 'simple organs' and 'complex organs'—it just goes on. I find it very hard when I read things from the Spinal Trust and the Motor Neurone Disease Association. In each of those submissions you will see that people want research to go ahead, and when we come back to the bill, research will go ahead. There are enough embryonic cell lines to do that.

Adult stem cell research will continue. It does not even have to be stem cell research, as I pointed out before with the spinal cord. You can take these cells and turn them into ensheathing cells, which are a special sort of cell. You can take cells from throughout the body. So the proof of concept is there. The big issue is not to give people false hope, and certainly not to go around mentioning cures, cures, cures.

There are many other advantages of pursuing adult stem cells, for therapeutics, and then I think we come back to the bill again. Let us not be diverted away, which is what has been happening, and diverted away in the community's mind. This is not an issue of whether or not stem cell research is good. Everybody says that. So what. And I do not think that we should be leading the community astray by saying, 'If this bill fails, there is no stem cell research and there will be no cures.' That is incorrect; that is nonsense. Students of logic in philosophy departments will take great interest in this, and someone in the future will be doing a PhD on it—so they should—to see how in goodness' name it got to this stage. You have to rely on a good philosophy department. I think that the decision here should be on reliable science.

CHAIR—Professor Silburn, can I just draw your attention to the time? The senators are wishing to have adequate time to question both —

Prof. Silburn—I would like to finish off and say that we need reliable science. We need people to look very carefully at the evidence presented, not just mere statements, to look behind the evidence and to look at those issues. I think then the quality outcome of this debate will improve. It will not be lopsided; there will be full, reliable information, and your decisions will be responsible and accountable to the nation. I think only in that setting should we proceed further. Thank you.

Dr Pike—Before going to four brief points, I wonder if I could clarify my background a little more. I spent about 15 years in medical research in neuroscience and basic medical research and then some applied, before moving to the Bioethics Institute about four years ago. It is an interesting reflection back on my years in science to realise that what I now realise to be a normative discipline, as ethics, is one that was extremely lacking in my training as a scientist. I wonder whether that may be why we get into some of these difficulties now—that in science training there has not been that grounding in ethics.

If I could move onto these separate points. One of issues which we tried to highlight in our submission was the nature of a human embryo. I note in reference to work by Belinda Bennett from the University of Sydney, when talking about the human embryo, that models of the human embryo or understandings of the human embryo which are based on property or an embryo being an object have been generally rejected by committees of inquiry both here in Australia and overseas. I will read a couple of the statements which are relevant which come from some of those committees. One is from the 1984 Victorian report on the distribution of embryos produced by IVF, where the committee does not regard the couple whose embryo is stored as owning or having dominion over that embryo; it considers that these concepts should not be imported into and have no place in a consideration of issues which focus on an individual and genetically unique human entity. A Canadian royal commission stated:

> In the commission's view reproductive material should never be characterised as property because terms such as 'ownership' and 'property' suggest that human zygotes can be treated as objects, which is contrary to principles such as respect for human life and dignity and non-commercialisation of reproduction.

I take these to be very serious comments made by committees at the highest level which are making comments about the nature of the human embryo. My view would be that any

destructive research on human embryos unfortunately does just that: it treats the human embryo as an object.

My second point is that we have tried to clarify what we see as a distinction which in one respect we hoped would never have to be made, and that is the distinction between intentional killing and allowing to die. It is a difficult one, but one recognised in ethics in several different arenas. What concerns me most about this particular application of the 'they're going to die anyway, so let's use them' approach is that that line of reasoning has been used in other arenas in the past and some of those have been quite disturbing. As often happens in ethics and philosophy, what is a consistent argument in one arena gets transferred into another arena. So it is quite possible that if this distinction is not recognised here, whereas it is at other places and times—for example, end of life, which is one of the best examples we have of that particular distinction—if we lose it here we may lose it elsewhere.

This may seem a long shot, and I am not trying to make this a direct comparison by any stretch of the imagination, but in our submission we have referred to the Tuskegee experiments, which were carried out on impoverished black men in America who had syphilis. The important part of that particular story is not only that they were untreated but that they had no prospect of treatment, and because they had no prospect of treatment they were considered to be as good as gone anyway. Because of that the argument then put forward was: 'at least let's gain something useful from them, from their predicament; they are in a predicament, therefore let's use them and their predicament to gain something useful in terms of medical knowledge'. I think there is a parallel, certainly in structural reasoning, with the use of human embryos which are destined to die. The ethicist Gilbert Meilaender, who is on the US president's bioethics committee, has said there is something inherently corrupting about the argument that says we have decided that they will die, therefore they are going to die anyway so therefore let's use them, because it is human choice from the start that has brought the predicament upon us.

The third point I would like to make, and I will try to be brief, is the argument from necessity. My scientific background tells me that—it is certainly in agreement with Professor Silburn—this is not something that has to be done. I am also concerned from an ethics perspective that arguments from necessity are a bit of a warning signal for a breach of a major principle. When it is argued that this has to be done, you can almost be sure that what will follow will be a suggestion that some major principle ought to be suspended—in this case it is the deliberate, intentional taking of human life.

The fourth point I would like to make is that this debate tends to have been, from my reading of it, framed almost entirely around stem cells and stem cell cures. On reading the research involving embryos bill, it is fairly clear that the consent provisions do allow, once the embryos are released from parental care, for those embryos to be used for all manner of purposes. In other words, the parents do not then have control over what their embryos will be used for.

We had this debate to a large extent in the 1980s, over research on human embryos, and at that point we had no knowledge or awareness of what stem cells were capable of doing—we did not even have human embryonic stem cells. The debate at that time was framed around all of the other purposes to which human embryos could be put in destructive research. Those are still with us. All of those desires and intentions are still with us. I note that in the explanatory guide to the bill there is a list of the types of other uses besides stem cell research to which human embryos would be put. It is my view that it would be extremely difficult to hold back from the pressure applied to use human embryos way beyond embryonic stem cell research.

Our institute did a bit of a research project where we looked worldwide at the work done on human embryos and to what sort of uses human embryos have been put, and we found a very broad range of uses in the published literature and we have the deep suspicion that there is a whole lot which never got to be in the published literature of what was done to human embryos.

Senator HUTCHINS—Professor Silburn, on a few occasions you said you were quite sceptical about where the scientific evidence was for this to occur et cetera, but you put it down to one reason, and that was lobbying. Could you expand on what you mean by 'lobbying'? What were these groups lobbying for; what they were against; what were they hoping to achieve; or what they were hoping to defeat or gain? Would you like to expand on what you meant by that?

Prof. Silburn—I was trying to make a distinction between two things: one is scientific evidence and the other one is lobbying. With scientific evidence you should just keep to the facts—published facts which have been peer reviewed and accepted. The lobbying that I have picked up as I have come into this debate—late—is basically generated very much I think from an embryonic stem cell group. I feel that there was a very large push to say that is important to get this bill through because it is going to lead to cures—stem cell research will lead to cures. I think that argument was strongly pushed. In fact, I was surprised to hear that a number of parliamentarians had been shown personally the video of the famous rat and all that sort of thing. I think that if you are going to look at scientific evidence and be given information, somewhere along the line somebody should have raised the alarm bells and said, 'Well, that's one story; what's the other story?' Somewhere along the line the balanced information should have been given.

The reason that there was not much lobbying from, say, people doing adult stem cell research is that there is not a great deal of commercialisation involved. People are just out there doing the work, and they are publishing it in the public arena for everyone to see. This is not a patent issue; it should never be—I do not think it should be. But if you have got commercial backing and you have got funds to travel around the country and you have got funds to get on TV, in the newspaper and the *Medical Observer*, that enables you to push your point of view. It is easy then to say, 'Oh, we want to do all sorts of research,' but as you have heard today there was not much mention of, say, adult stem cells and how we are going to patent these or commercialise these and all those sorts of things.

I think it would be very difficult to charge a person for their own cells in the first place. But certainly if you have secrecy agreements and all these patents and all that sort of thing going on, there is commercial backing. When we talk about biotechnology, we enter into the field of making companies viable. When you enter into the field of making companies viable, you enter into the field of talking dollars. When there are dollars about, other dollars seem to be attracted to them. When you read through the paper you see the financial trails that are starting to emerge in this. I find it very difficult. I do not want to go down that line; I am not interested in that.

I think the lobbying influenced people into diverting people away from the actual point of the bill. The lobbying pushed people into saying, 'We need stem cell research. If this bill fails, it'll never happen. There'll be no cures for an extraordinary range of diseases.' The point of the bill is: how many embryos do we need for research? Everybody before you earlier said, 'We've got enough embryos for research. We can establish many cell lines.' Four mouse cell lines established research for 40 years. So why do we need more embryos? We need more research. We need more research to try to prove that there is a therapeutic potential. If you use

the argument that we need more research for therapeutic potential without even proving it first, it's nonsense. It doesn't make sense and you don't want to get into commercialisation there.

Senator BOSWELL—I want to ask you some questions. We have limited time and three more witnesses.

Senator HUTCHINS—Can I ask something? I'm not a scientist and I do not have a scientific background—I got the impression from people earlier that that was one of our drawbacks—but you kept using the term 'therapeutics'. What did you mean by 'therapeutics'? I got the impression that these therapeutics were something that can be waved and the common cold would almost get solved by it. Is that what you meant by that?

Prof. Silburn—My concern with therapeutics is twofold. One is: do you need these cell lines for therapeutics to treat people? How many cell lines do you need to treat people? That is one aspect. If you ask immunologists, who are very good in our country, they say that when you look at the data you may need millions. You might need seven million to establish a 53 per cent match. That is therapeutics in terms of using embryonic stem cell lines to put into someone's brain or spinal cord.

The other thing that sometimes therapeutics is used for is to say, 'Let's establish these lines and test drugs on them.' The argument has been put forward that if you have a muscle cell lines, say, or a liver line you can put chemicals in it and basically see what happens to the liver or muscle before you use it on humans. It is very plausible. Wouldn't it be ideal to get somebody with the disease you are looking at and to establish the line from them and then see what happens to the drug? Number one, you get an idea of whether the drug is going to be toxic to the cell, whether it is a normal cell or a diseased cell, and you might see that it might improve its function.

Therapeutics is often used in a couple of ways. My impression is that you should be pursuing adult stem cell therapeutics for brain diseases for various reasons but with Parkinson's I think we should look very closely at that—and people are. You may be surprised to know, despite the previous speakers, that there have been reports of people who have had adult stem cells being used to treat a human disease, and that is Parkinson's. It improves motor function; it does not cure it. Again, we should be very careful of the word 'cure'. We should not get too carried away. People have the moral argument down at one end and you have the cure argument up this end, and the emotions generated are so strong that people start to lose the facts.

The bill is about how many embryos we need. Stick to the point—don't get diverted—and stick to the evidence. Where is the evidence that we need more embryos? We have heard today that the evidence is such that we do not need more embryos for research, so what do we need them for? Do we need them for commercialisation? I think the general public would find it very difficult to come across the concept that these embryos are going to be used for commercialisation. I think that's wrong. I think they should be used for research—I think that's right—and we have enough. We should be pursuing that. We have adequate resources in this country to do that.

CHAIR—Professor Silburn, can I just ask you to shorten your answers a little—I think that is what Senator Boswell was alluding to a moment ago—so that we can have maximum opportunity for questions.

Prof. Silburn—I get a bit passionate about this, sorry.

Senator BARNETT—I want to ask a question of Dr Pike regarding research and the definition of research. Your Southern Cross Bioethics Institute released a book a few weeks ago, *Human Embryos as a Limitless Scientific Resource*, and in it you say that the Australian company Stem Cell Sciences wants to clone human embryos to extract stem cells, although the executive director of the company, Dr Peter Mountford, indicated a broader interest in the creation of defective cloned human embryos for pharmaceutical testing. We had Stem Cell Science's representative here as a witness not long ago.

In answer to a question that I asked they advised that they did not have a patent with respect to therapeutic cloning, and that was clarified later: they did have a patent in respect of therapeutic cloning. Is that what you are getting at in this book, saying that the research is going to flow through to a whole range of other means, all the way through to cloned human embryos or for pharmaceutical testing, for face creams and that sort of thing? The cover page refers to 'a limitless scientific resource'. Can you expand on this definition of research so that we have it very clear in our minds what this bill will allow?

Dr Pike—We focused our comments in that booklet primarily on medical research. We did not go into the areas you mentioned—the cosmetic industry and so on. I suspect that even if this bill were passed it is very unlikely that embryos would end up being used for those sorts of purposes. Nevertheless it may be a fairly attractive proposition to some to use embryonic stem cell line extracted from certain embryos in the cosmetic industry, but that is not something we specifically addressed here.

We are talking primarily about medical research. We did note in that particular section that you read out that public comments had been made specifically about cloning, and in light of the UK's modifications to HFEA regulations to allow therapeutic cloning, similar calls were made here. But the particular instance there was to do with creating cloned human embryos from people with particular genetic conditions so that a cell line could be established based on that particular genetic condition, and then that presumably would be subject to pharmaceuticals testing. That is in reference to embryonic stem cells derived from the lines, but I do not see anything within the bill which would directly restrict the broader use of human embryos to direct application in pharmaceuticals testing or in toxicological testing.

Senator BARNETT—Can you expand on that a little bit? Your publication says:

> What is being been sought is a general permission for human embryos to be used destructively in experiments.

Can you set out what types of experiments you are talking about?

Dr Pike—I would have to see which categories we came up with, but we identified six, I believe, which came directly from the explanatory guide, and then we added two. The six are: one, the derivation of stem cells; second, for examining the effectiveness of new culture media use in ART practice; then for a better understanding of embryonic development and fertilisation, which would include basic research in embryology; then to train clinicians in microsurgical ART techniques; to examine gene expression patterns of developing embryos; and for improving ART techniques. To that we added toxicology studies on live human embryos and the testing of new drugs on humans rather than animals as something we saw was not specifically prohibited by the bill.

Senator BARNETT—Can you tell the committee what those last two are all about in layman's terms that we can understand or that the normal Joe Blow out there can understand? Can you expand on those last two?

Dr Pike—In terms of toxicology, the way you normally find out whether something is toxic is by giving increasing doses to a population of mice, and when 50 per cent of them die—that is the LD50—you say, 'This is the LD50 dose that will kill 50 per cent of them.' You do that on mice because that is on a living creature and it will give you a clear indication, and then you make some sort of extrapolation for humans. If you had human embryos you could be jumping the animal step and quite precisely saying, 'We can test the toxicity of this particular substance by seeing how many embryos are actually destroyed in the process.'

Senator BARNETT—What sort of substance are we talking about? Is it pretty much any substance, drugs or face creams? Where do you draw the line, or can't you draw the line? Is it very hard to draw the line?

Dr Pike—It is very difficult to draw the line because I am not aware of all the sorts of things which would happen in the cosmetic industry, but certainly in a pharmaceutical sense it is crucial to find out what dose of a substance is actually toxic. There is the therapeutic range and then you get into the toxic range.

Senator BARNETT—Are you testing new drugs on humans rather than animals? Again, where do you draw the line on that? Is that, again, a hard one to draw the line on?

Dr Pike—It is a hard one to draw the line on because it depends on the imagination of the people who come up with the ideas, but certainly one area in which I think there would be a fair bit of interest would be the development of new drugs where you cannot be sure of their impact on human development. That is one of the great concerns, of course, if a pregnant woman were to use a particular drug and you were not aware of the impact on the developing embryo or foetus. We all know the history of some problems with that in the past. In this way one could do that on developing embryos directly and see whether development is influenced in any way and actually observe the human embryos developing with these new substances.

Senator BARNETT—I have a last question for Professor Silburn. It relates to the 'how many' question: how many human embryos are actually required? We have had Professor Trounson in this parliamentary arena saying 10, 20, maximum 50. We have had Professor John Hearn at a public hearing in the library here a week or two ago saying he thought a maximum of 200 human embryos would be required for human embryo stem cell research purposes. BresaGen, in their submission today, has indicated 600 to 1,000 for a particular type of research that would affect and benefit a majority of the population. What evidence do you have that you can put to this committee to say that you think enough is enough and that what we have at the moment is adequate?

Prof. Silburn—Senator Barnett, I think it comes down to the fact that, as was pointed out by one of the speakers before, four mouse cell lines enabled an enormous amount of information to be generated in this field. Mouse cell lines are different from human cell lines, but certainly four did the job. I come back to the other point: what evidence? I have not seen any reliable evidence that you need 10, 15, 20, 45 or 1,000. I find it extraordinary that we have given $46 million to someone who cannot give an answer on that. The evidence that I would like to come back to, though, is that from the immunologist. If we are doing this stem cell research work on embryos for use in humans, their estimate is that we may need seven million to get a 53 per cent match. That is a big number—it is greater than 10, 20, 50, 600 to 1,000. It is appropriate to question the immunologists on that, and I think we should. This committee, when it gets the opportunity, should say, 'How many do you need? Why do they need that?' It comes down to that issue of rejection. When you put something foreign into you, you reject it.

Senator STOTT DESPOJA—Professor Silburn, before I question the immunologists, I am going to question you on that piece of evidence. I have asked all witnesses, and particularly the scientists before you, to provide evidence and preferably citations of any examples they are giving. Obviously that seven million figure is one on which I am sure the committee would like to see the evidence, but also I am very interested to hear your comments in relation to adult stem cells. You mentioned not the curing but the alleviation of diseases such as Parkinson's. If you would take that on notice and provide the committee with any documentation, that would be appreciated.

Prof. Silburn—Thank you for that opportunity. I would like to provide that.

Senator STOTT DESPOJA—Thank you. Doctors, you both refer to something that comes up a lot, and that is the ability—certainly Senator Hutchins has referred to this—of politicians or legislators to make decisions on scientific issues, as lay people. You have recognised that there are influences such as lobbying, and often there is misinformation and information of varying sorts provided to us.

Who should we listen to when it comes to providing advice to us, particularly on scientific matters? Would you both acknowledge that, for example, the Academy of Science is a credible and appropriate body to provide information to the Australian federal parliament? Do you have a view on that? Are they? If not, why not? Professor Silburn, would you go first?

Prof. Silburn—Sure. I find it very hard using the term 'lay people'. You look around here: everybody is smart. You would not be here if you were not smart in some fashion. You know what I mean? It means you can think logically, and often you people are much better at sorting out what those people are really on about. That is how you get here, and you should be able to use that. So 'lay people' is a difficult term. You are still logical thinkers, I would think. I think you should always question, particularly in terms of general logic; when someone comes in and says, 'I am going to cure all these diseases', you have to say straight away, 'Alarm bells!'

When it comes back to the broader issue of who you should trust it becomes difficult, because in our scientific community and in the medical community there still are influences. You need to have people who are very independent of decisions that are made. Sometimes I think it is a particularly difficult position for the NHMRC and the Academy of Science, because with issues like this you put them in a difficult position. There are often people there from the institutions that you are being asked to support the question on.

I think the parliament should say, 'Let's look at who is on this committee. Let's, for example, say, "Are there people on the NHMRC or the Academy of Science, at the top of these things, who are from Monash?"'. Take them out of it, because you put those people in an awful position. They are sitting there, and they do not want to be subjected later on to people saying, 'He was the head of the NHMRC' or 'They were the head of the Academy of Science, and they are from Monash.' You do not want that sort of thing. As parliamentarians you should get together and look at that issue. It is a very, very important issue, because the science of this country and the decisions should be based on that, not the ability of lobbyists.

Senator STOTT DESPOJA—I am going to speed you up simply because I have got a few questions.

Prof. Silburn—Is that sufficient?

Senator STOTT DESPOJA—That is more than sufficient. The word I am interested in is the use of the word 'difficult'. Dr Pike, do you agree that it might be difficult for the Academy

of Science? Obviously they will be appearing before us, but I am curious to see if they are considered an organisation that we can receive.

Dr Pike—I wonder if I could make the first comment that science is not value free.

Senator STOTT DESPOJA—Of course.

Dr Pike—And when it comes to the Australian Academy of Science, as the peak body, then certainly it ought to be absolutely trustworthy. Three years ago the academy put out a paper on therapeutic cloning recommending that therapeutic cloning go ahead. That was a decision based purely on a particular reading of scientific potentialities and possibilities. It was not one that was based on ethical considerations. I think that is part of the difficulty, that unknown and unidentified value positions within science do come to the fore. All I can endorse is that, yes, it is extremely difficult. Sorry.

Senator STOTT DESPOJA—Dr Pike, in relation to your submission there is one thing that I want to clarify. On the last page of your submission, the first paragraph, you talk about embryos being created and excess to requirements being available to researchers, so basically you are talking about it not being difficult to create an excess of embryos 'by simple changes to practices in IVF clinics'. My concern is that I do not believe this relates specifically to this bill, and I am scared that it may mislead the committee. Is it not the case that changes to IVF practices in relation to creation of embryos—excess embryos in this case—would be the states jurisdiction? Do you believe that this is actually part of this bill?

Dr Pike—This is a comment related to the slippery slope, that most unpopular phrase. I guess that what we are getting at here—I could not find the reference to the top IVF clinician who made this comment about how easy it would be. I have got the name in my head but I do not remember the actual reference. The point is that I believe it does relate to this bill because of the 5 April clause. If the 5 April clause remains, then I think this is a likely corollary of that.

Senator STOTT DESPOJA—Even though the number of eggs taken from a woman for the purposes of ART treatment is dealt with on a case-by-case basis under very stringent regulations and being state jurisdiction, you believe that that deadline, the 5 April date, impacts potentially on those state jurisdictions and those processes that currently exist?

Dr Pike—If I am correct, I think there are only three state areas of legislation which pertain. There are regulations then under NHMRC and industry bodies, but really if I could refer again to the comment made by the head of Sydney IVF, that it would not be a difficult thing to modify those practices because the clinic, certainly in New South Wales, would not be held by any state legislation.

Senator STOTT DESPOJA—I am happy for you to take that on notice, to clarify that.

Senator McLUCAS—I want to go to the issue of the motivation of the various stakeholders in this whole debate. I think that was generally the thrust of your oral contribution tonight. You said very clearly that you were very interested in assisting your patients. I agree with that; that is obvious. Then you talked a lot about lobbying, and I think you were asserting that, essentially, those people involved with embryonic stem cell work are the lobbyists. Are you saying, though, that those people associated with embryonic stem cell work are not interested in assisting their patients?

Prof. Silburn—No. I am sorry if that is the impression. I am sure that people who are involved with embryonic stem cell work are trying to improve knowledge, as they stated, in terms of learning more about human disease and learning more about ways of treating things. I think that is a given, okay?

My point about lobbying was this: if you have got people who are continually telling you one set of information, when you are there and you do not know any other information, you are going to tend to believe that. What I am saying, and my impression is, and I am clear about this, is that there was very much one—sided lobbying. I do not think there was much said about adult stem cell work at all. I do not think, in fact, in the lobbying it really put down the fact that the issue of this bill is: how many embryos do you need? And I think it is clear now that the reason they did not put down the issue of the bill, which is how many embryos, is that they do not know. People do not know how many embryos you need.

So the issue was diverted into saying that embryonic stem cells are going to lead to cures, and if the bill fails there will be no embryonic stem cell research and therefore there will be no cures. That is what is in the public's mind.

Senator McLUCAS—I agree that you are talking about perceptions as opposed to—

Prof. Silburn—Very much so. But your perceptions are guided by what information is given to you. What I am asking for is that in the broad sphere if issues like this come up again there should be some mechanism in place so people can get the broader view. When I came down here to speak at this joint party meeting, when I left the building I had a number of reporters say to me, 'Aren't you sick of lobbying for these stem cells? People are getting sick of hearing this.' I said, 'This is the first time I have been here.' And it was. I looked around to see where the troops were, and there weren't any! Then I learnt that there were a lot of people who had been lobbying over a number of years. I certainly did not have access to a room to invite people in to sit down and let me go through this for them.

Senator McLUCAS—I am sorry I was not part of that group. Who was sending out the invitations?

Prof. Silburn—But that is the situation. I do not think that should arise.

Senator McLUCAS—Don't you agree though that there is a sense of unanimity amongst those people who are proposing that we do need, first of all, legislation to manage the use of embryonic stem cells—that there is agreement amongst that group of people, whilst they may differ on the number, that there is a need.

Prof. Silburn—But with all due respect, everybody in medical research should be thinking that. That is not really saying anything.

Senator McLUCAS—No, don't you agree that they agree that there is a need, however qualified.

Prof. Silburn—Of course.

Senator McLUCAS—Right. So there is a need. So the next question is —

Prof. Silburn—There is a need for research.

Senator McLUCAS—Does the whole process of the use of embryonic stems cells need to be monitored and managed?

Prof. Silburn—Yes, I think so, very much so.

Senator McLUCAS—Then isn't this legislation a better and more regulatory approach than what we have now?

Prof. Silburn—I think that if you go along the line in the amendments and you put in all the places, that is what should be done. I am in full agreement. I think that we need a much closer view of this whole process.

Senator McLUCAS—So we do need a form of legislation? To leave things as they are is not appropriate?

Prof. Silburn—I would not think it would be appropriate to leave the things open. Certainly not.

Senator McLUCAS—Okay.

Prof. Silburn—But with this bill, the whole bill is about how many embryos you need, and there are enough embryos for research.

Senator McLUCAS—Well, that is your view, but it is not shared.

Prof. Silburn—No, this is a view that was shared amongst all the submissions, and the people before me all said there are enough embryos there for research. That is the view that was expressed. That is the commercial view. That is the view from the support groups. That is the view from the scientists. There are enough embryos for research. So then you ask yourself: okay, if that is the situation what is driving the other information? That is what I was trying to get to before. Is it therapeutics? Well, there is no evidence that there is any therapeutic advantage. Is it commercialisation? I do not know about that. I just get on with it. And what I publish goes out into the public arena, as it should.

Senator McLUCAS—Dr Pike, can you give me some background of your organisation, the Southern Cross Bioethics Institute.

Dr Pike—Yes, the Southern Cross Bioethics Institute was started in 1987, funded in large part by Southern Cross Care, the largest provider of aged care in South Australia, as an independent academic institute to pursue basic bioethics research in all of these sorts of issues ranging from start-of-life, end-of-life, doctor-patient relationships—all of those bioethical issues. There are three academic staff and two others, and we gain some other funding from various work we do. We received some from the federal government a while ago.

Senator McLUCAS—How much did you get from the federal government?

Dr Pike—Sorry?

Senator McLUCAS—How much did you receive from the federal government?

Dr Pike—I do not remember the exact figure. It was to develop a code of ethics in aged care.

Senator McLUCAS—Southern Cross Care is your sponsoring organisation?

Dr Pike—Parent body, really.

Senator McLUCAS—Can you give me some background about that organisation?

Dr Pike—I do not know a lot about them, except that they were started I think back in the 1930s—

Senator McLUCAS—Started by?

Dr Pike—Started by a group called the Knights of the Southern Cross and grew to be one of the largest providers. I believe Southern Cross Care is Southern Cross Homes in other states.

Senator MARK BISHOP—Professor Silburn, I just want to go back to your earlier comments. You said there were enough embryos available for research and you needed extra embryos for therapeutics. I just want to go back to first principles. It follows on from the comments made by Senator Barnett as to the purpose of research—it is almost a kind of good research/bad research argument. If human embryos have no particular value until perhaps they

develop into a foetus or are born as human beings, if they are just a bunch of cells, as they are sometimes referred to in the discussions, and perhaps later develop life or the potential for life, but at this early age are just a bunch of cells no different from cells that comprise your hair, what does it matter what nature of research is engaged upon them? If they have no value at that stage but might have value later when they are born as a human being or develop into a foetus, how does it matter what nature of research we can do? Women's face care products or, at the other extreme, Parkinson's disease: it is all research; what does it matter?

Prof. Silburn—That is an ethical issue, and I think Dr Pike would be much more in a position—

Senator MARK BISHOP—Sorry, I am happy to have Dr Pike comment but you have raised this distinction between therapeutic and research and you have said there are enough embryos around for therapeutic, and you have suggested—

Prof. Silburn—No, enough embryos around for research.

Senator MARK BISHOP—For research, sorry. That's right, yes. Then you have drawn the distinction between research and therapeutic and you have made some suggestions that it might be lobbyists or commercialisation or other interests generating the debate. I want to cut to the quick and find out what the difference is between the different types of research—some we should allow and some we should not.

Prof. Silburn—There are all sorts of research. At the core of any research is that you put together your observations with your knowledge, you generate a hypothesis and you test the implications. I do not think there is good and bad in science; there is just logic. Good and bad become value judgments, and then value judgments are a community generated thing. I do not think you can divorce science from community attitudes. So if the community decides these embryos are not going to be useful for anything—they have no future, no hope, we may as well use them—so be it. That is not my point in being here. My point in being here is to say: please look at the evidence and improve the quality of your decision. Then make a decision. Then let the community open it out for debate.

If you decide here, as the law-makers in our country or whatever, that those embryos have no future so you may as well use them, so be it. What I came down for originally was to say: do not base your decision on half the information, because you are going to be responsible for the decisions, you are going to be accountable for what our community thinks.

Senator MARK BISHOP—Dr Pike, do you have a response?

Dr Pike—On the question of the nature of the embryo, who is a moral subject is a question for ethics but strongly informed by the science. The science quite clearly says that we are not dealing simply with a clump of cells. There is good scientific evidence—and we have highlighted some of that in the submission—to show that the early embryo has characteristics which identify it as a new entity without doubt, one which specialises from the earliest moments. This is a very interesting new area of research, discovering what early specialisation beyond perhaps microscopic sight occurs within the early embryo. We are quickly discovering that, just as you would expect, I suppose, that it is highly purposeful, highly directed, highly conserving of energy and a continuum of process. But what makes you and me a moral subject has a sense of continuity back in time to the first point at which that entity came into place, came into being. So yes, it is an ethical question, but one that equally holds for adults as moral subjects too.

Senator HARRADINE—On that particular question, in the bill it says that experimentation can take place up to 14 days. What is so special about 14 days with an in vitro—

Dr Pike—Some of the issues that have been used to inform the decision based on 14 days, which had its origins in the Warnock committee in the UK, we have attempted to address in our submission. The Warnock committee also acknowledged that it was dealing with a continuum of development and that 14 days was indeed an arbitrary time and that it had to choose for extrinsic rather than intrinsic reasons on a time—'to allay public anxiety' was the wording used by the Warnock committee, yet it is a scientific fact that it is a continuity of development. We are talking about quite an arbitrary point of time. Arguments based on twinning or the appearance of the primitive streak are in my view quite thin.

Senator BOSWELL—Professor Silburn, you have talked today a lot about research. How would your research on stem cells differ from the research done by Professor Trounson? What is the difference in the research?

Prof. Silburn—Again, at the heart of the research is that you have a situation, you define a problem, you put the observations with the knowledge—

Senator BOSWELL—How do you do it?

Prof. Silburn—That is basically how we approach it and we have taken the issue that anything that we have gets published in the public arena. That is my stance.

Senator BOSWELL—You work it out through animal—

Prof. Silburn—Yes, I mean you don't basically jump into humans without doing animal work. And that is basically the approach that you take. You work these proof of concepts up in animals, you make sure that you are on track and then you start to apply it in terms of human conditions, and you get the information out there. As soon as you get that information out there everybody else can use it. If you have intellectual property agreements, as soon as you start to enter secrecy things or even though cells might be provided free and there are other issues that come back to you, as soon as you start to do things like that I think it slows it up somewhat. I think it slows the knowledge up. I'm not into commercialisation.

Senator BOSWELL—Have you seen what Dr Trounson has done in animal research or getting his peers to review his work?

Prof. Silburn—I think Professor Trounson has an established reputation. He has attracted funds and accolades, and he has presented information for many years in the scientific sphere. I really can't comment too much more on how he functions or how that functions. I must say that I was, however, very disappointed to see the examples used to support this bill. I found that disappointing from a scientist, from a clinician, particularly from a scientist presenting it to you people as it was presented to your colleagues. You are reliant on the information being provided. I would prefer not to talk about it.

Senator BOSWELL—Dr Pike, we were told by the NHMRC that once these products leave the laboratory they can go overseas and once they are overseas they are not subject to any ethical restraints as they are in Australia. If we send uranium or guns overseas, we have an end user certificate. We don't appear to have that in this particular embryo debate?

Dr Pike—I believe there is something in the bill about exporting embryos.

Senator BOSWELL—No, there is not.

Dr Pike—I would then certainly be concerned about embryos created here in Australia going overseas into unregulated environments, yes. I think it is certainly clear by some of the

work done overseas that there is not the same sort of ethical limitation. We have already seen that with human cloning experiments elsewhere. I don't know quite how else to answer that, I'm afraid.

CHAIR—Are there any further questions? We are nearly out of time and we have to hear from Mrs Tighe yet. Yes, Senator Harris.

Senator HARRIS—Thank you. Firstly to Dr Pike: in the documentation that you provided us with, in the last paragraph on page 23 you make a very strong statement, and I will quote:

> The parliament is being asked to cross an ethical line which it has no moral right to cross.

Would you like to expand on the reasons why you believe that?

Dr Pike—It is worded strongly and I guess it is because we hold it very important at the institute that a human rights approach to these sorts of bioethical questions is paramount. On our reading of human rights documents, a section of which appears in our submission, we believe that the notion of personhood is not a fair or an adequate grounds upon which to make a judgment on the moral status of the human embryo. However, on the membership of the human family—the human rights documents describe all members of the human family as being persons before the law—we regard that as a sort of universal kind of concept, and because of that universality, that in one sense creates the moral line which then we are suggesting is one that should not be crossed because of its universality.

Senator HARRIS—Professor Silburn, would you comment on the possibility that if there was a program that was established whereby a section either of the umbilical cord and also the blood stem cells from each child that is born, if a program was established to retain that, do you believe that could be scientifically and economically justified?

If we had a program at the birth of each child, which would not help anybody in this room but from whenever it was established, could you see merit scientifically that that specific retaining, or whichever—I am only using those two, the umbilical cord and the blood from the actual placenta—if that was kept, do you believe it could be scientifically and economically justified for a program to do that?

Prof. Silburn—I think you could justify it on scientific grounds. Off the top of my head, I honestly have no idea of the economic grounds, but certainly scientifically, but to go down that track you would have to really look at it morally as well. I do not think you could do it and take out of context society and society's attitudes towards that but, from a science point of view, to obtain that and store it is possible. In fact, it can be done.

Senator HARRIS—And would have, you believe, ultimate scientific benefit?

Prof. Silburn—There would be merit in that. I think that you would need to consult people widely on the broader issues for the community before you actually go down there, and I think that would be necessary. It would not be sufficient just to say scientifically it is okay.

CHAIR—Thank you, gentlemen, for giving us your time this evening.

[6.59 p.m.]

TIGHE, Mrs Margaret Mary, Right to Life Australia

CHAIR—I welcome Mrs Margaret Tighe from the Right to Life association.

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. We have your submission before us, and we have all read it. Are there any additional comments you would care to make before senators ask some questions?

Mrs Tighe—There is just a correction of a typographical error in the second-last paragraph of the submission. There were two parts to my submission, and I hope you have got both of them. One of them was a speech which I thought was very relevant because I engaged in a debate at Monash University with Professor Trounson in May, so I presume that is there too. In the second-last paragraph of my submission I state:

Remember the controversy over—

and then it has—

family health minister, Michael Wooldridge ...

But that should read 'former' health minister. There is no such animal as the family health minister. I just want to correct that, thank you.

CHAIR—Thank you. Are there any further comments you wish to make in addition to your submission?

Mrs Tighe—Yes. I would just like to emphasise what I believe to be the core of the issue under debate. I believe, putting it quite simply—and I believe the scientists who preceded me have dealt very satisfactorily with the scientific issues—that the passage of this legislation by the national parliament would lead to the establishing of a class of human beings to be used for the benefit of others. I know that we live in a world in which already we have lost a great deal of respect for human life because many abortions are carried out, but as well as that we have approximately 70,000 human embryos which have been treated as commodities, frozen and stored like frozen vegetables. I maintain that they have been subject to a gross abuse of human rights at the outset because they have been placed in this frozen state and they are like stateless citizens or somewhat like the lost boys in *Peter Pan*.

Looking around the room, I can see that I am one of the oldest here. I will not check with Brian Harradine what his age is, but I would venture to say that with the exception of Senator Harradine probably none of you have followed the progress of the reproductive technology industry as I have, and I know Senator Harradine has, since it began in 1980. I think it is very, very relevant, because there are some lessons to be learnt from this. Whilst we all applaud the fact that it has produced babies for infertile couples, we have to look past that and we have to look at the gradual progression, as the public have had their minds massaged and softened—the 'softly, softly, catchee monkey' approach which I have seen over the years—that gradually the scientists have wanted to do more and more with human embryos.

What you are doing with this legislation is that you are, as I said, not only establishing a class of human beings to be used for the benefit of others—and that is a very, very serious step, that is a huge quantum leap, and I think it is one you should contemplate very seriously—but also you are creating an artificial distinction between those embryos who are somehow deemed to be important and then this new class, these so-called excess embryos. You might note in my submission that I quoted from the *Merchant of Venice*, and I believe it

is very apt—Shylock saying, 'Hath not a Jew eyes? Hath not a Jew organs, hands, dimensions, senses, affections, passions? If you prick us, do we not bleed?' et cetera. I will not read it all out.

Similarly, I want to say to you: is not an excess embryo the son or daughter of his or her parents, as is the embryo which is implanted in the mother's womb? Does not the excess embryo possess all of the attributes, physical and mental, of that future man or woman if allowed to develop naturally in the same way as the embryo which is causing morning sickness to his or her pregnant mother? Is not the excess embryo a member of the human family possessing 23 chromosomes from the father and 23 from the mother? The answer to all of the above is yes, so why is it that we are contemplating legislation which is establishing this artificial distinction between groups of human beings and which is I believe in a very dangerous way saying, 'There is this category of human beings. Nobody wants them, they're going to die anyway, therefore we should be able to use them to benefit other people.' So it is a very, very serious principle—some can be used for the benefit of others.

When you are contemplating legislation you not only vote on the words; a good legislator has to look at the impact of the legislation. What can this lead to? I have dealt with many legislators in every parliament in Australia, and I have been told that by so many of them: you have to look past the actual words and see what this can lead to. So what you will be doing by passing this legislation is that you will be setting up this demand—we must have excess embryos. Sure, some of the scientists will say, 'Oh, look, you know, that will be sufficient,' but I am looking at some of their behaviour. Poor old Professor Trounson is coming in for a bit of a hiding here today, but nonetheless he has been the main protagonist of this legislation, and we have to look even at his behaviour.

I well remember when I was asked to engage in that debate at Monash University—the vice-chancellor's debate. There were three of us and opposing us were Professor Trounson, Professor Savulescu who has now gone to Oxford University, and a student in bioethics. They contacted me several days before the debate and said, 'We think it is only fair to you to let you know that we will not actually be dealing just with whether or not we should use excess human embryos for stem cell research'—that was the topic of the debate—'but we are going to be dealing with therapeutic cloning.'

I said, 'Well I've got news for you, so am I.' I had seen that program on the ABC, *The making of a human*, about Professor Joseph Cibelli at the Advanced Cell Technology Inc. in Massachusetts who was working on trying to produce a cure for a doctor from Texas who is a paraplegic. Immediately I thought, 'Yes, the writing is on the wall because many of these excess embryos will not be suitable to be used to provide these wondrous cures that we have heard so much about.'

I have sat through a number of the speeches in the House of Representatives, and I think it is very sad that a lot of those MPs genuinely believed what they said. They genuinely believe that to oppose this legislation is to stand in the way of providing cures for people. We have heard today from Professor Silburn that that is simply not the case at all. I think it is very sad that people have been given false hope in relation to this. I say that as an aside.

Ultimately I do want to stress that if you say, 'Sure, you can have these excess embryos'—and I realise that in a couple of the states the sky is the limit already and they are doing what they like; nonetheless they have already telegraphed their punches. For example, Premier Bob Carr made a comment in the *Sydney Morning Herald* of 8 April. He promised that:

… therapeutic cloning is going to be the subject of fruitful exchange between ethicists and scientists over the next years when the legislation we have agreed to will then be reviewed.

He added:

… we can address therapeutic cloning down the track.

Similarly, the *Australian* of 5 April reported Victorian Premier Steve Bracks and his concern that—and I quote:

… access to only existing surplus embryos would inhibit to some extent, research around Australia.

In the same newspaper Professor Trounson stated:

A blanket ban on therapeutic cloning could stifle research and force patients overseas.

So he is engaging in this sleight of hand, so to speak. When people become accustomed to the idea of using these excess embryos 'who are no use to us anyway and they are going to die anyway so why not use them' and then if they do not produce what they are meant to produce and there are none of these magical cures, 'We move on to the next stage.'

If you people do not seriously look at what can happen in the future, should you take this quantum leap and vote to say that there is a class of human beings in Australia today who can be used for the benefit of others, I think it will be a very sad day for Australia. We have certainly come a long way since we marvelled at the first IVF baby and we understood the joy of the parents holding that baby, but we have to stand back and look at just where we are going with this legislation.

CHAIR—Thank you, Mrs Tighe. May I just ask for some clarification? I am very confused as to where Right to Life really stands on IVF. I get very confusing messages from various people who profess to be from Right to Life as to whether or not they agree or disagree with IVF.

Mrs Tighe—To start with, there are a number of organisations that use the name 'Right to Life', and we are Right to Life Australia. Okay? You are asking me. I make no bones about it. As regards IVF, back in 1980 we were the only organisation on record which accurately predicted what was going to happen with IVF, because we were not objecting to the couples having their babies, we were not objecting to that. What we were saying was, 'Look down the track. You are going to have human embryos on a laboratory bench at the mercy of scientists.' And we have seen all of these things happen. Now here we are today with these 70,000 excess embryos. That has been our position.

CHAIR—So you still disagree with IVF?

Mrs Tighe—We disagree with it because it involves an inherent lack of respect for human life. We have had all these embryos that have been discarded; they have also been scrutinised and some of them are discarded if they are found wanting—basically because there is a lack of respect for human life.

CHAIR—So you are categorically opposed to IVF and any form of assisted reproduction, reproductive technology?

Mrs Tighe—What we are concerned about is what happens to the human embryos.

CHAIR—I am—

Mrs Tighe—Well, I have told you.

CHAIR—I am just trying to clarify in my own mind—a categorical, 'We are definitely opposed to IVF and any form of assisted reproductive technology.' Is that—

Mrs Tighe—Well, we do not have a policy on artificial insemination by donors, we do not have a policy on things like that. All I am talking about is this form of reproductive

technology which produces excess embryos and those embryos are then up for grabs, and they are going to be scrutinised, discarded et cetera, and all of these things.

I well remember in the very early days, with the first IVF baby, the scientists strenuously denying that they would ever freeze embryos, that they would ever experiment upon them. I can well remember a banner headline from the *Herald Sun* outside a newsagent saying, 'IVF scientists say no to freezing of embryos'. That was a long time ago and we have come a long way since then.

CHAIR—Is Right to Life still trying to stop IVF?

Mrs Tighe—We were very active whenever there was legislation in a state parliament, in particular the Victorian state parliament, and I maintain that it was due to our activities that there are any restrictions on what happens to human embryos at all.

CHAIR—Are you trying to prohibit IVF as we sit here today?

Mrs Tighe—I have not come here to prohibit IVF because IVF is very clearly established. I have come here today to speak against legislation which would establish a class of human beings who can be used for the benefit of others. That is what is under discussion here today.

CHAIR—I understand that, but what I am getting at is that there are many embryos that are wasted and non-viable—

Mrs Tighe—Sure.

CHAIR—in the process of IVF, and that is why I am questioning you—to clarify it in my mind because of the confusion of various people who have deluged my office claiming to be members of Right to Life.

Mrs Tighe—Well, there are a number of pro-life—

CHAIR—Some will agree with it, some will disagree with it, but none to my knowledge thus far has said, 'We will do everything to stop IVF because there are too many embryos that are wasted or not viable in the process.' That is the reason for my question.

Mrs Tighe—Our position has been quite consistent, and I make no apology for that. Nor do I make any apology for the fact that we were very active. Due to a lot of our activity and the activity of a lot of other people there were at least some restrictions imposed on the carrying out of reproductive technology.

CHAIR—I understand that. I am just trying to clarify it for my own purpose.

Mrs Tighe—Sure. I keep on saying the same thing.

CHAIR—I have had hundreds of emails.

Mrs Tighe—You must be a slow learner, Senator Knowles. Sorry.

CHAIR—That may be the case—

Mrs Tighe—I think I have made my position very clear.

CHAIR—but when one receives a multitude of emails from an association or group or whatever, then a senator is entitled, whether they are stupid or not—

Mrs Tighe—No, I don't think you're stupid.

CHAIR—to ask a question of clarification.

Mrs Tighe—Yes.

Senator McLUCAS—Given that we have an IVF program in Australia, many couples have embryos in storage and have expressed a desire to donate those embryos for use in a whole range of things. Don't you think that those couples have a right over those embryos?

Mrs Tighe—No, I do not believe that we own our children. In fact, we are not allowed to do with our children as we please and there are quite rightly laws in place to protect children.

Senator McLUCAS—But therefore are you saying—

Mrs Tighe—Pardon? Well, you may not see them as children, but scientifically they are the progeny of that couple. Unless man or nature intervenes that human embryo at that stage possesses all of the attributes that that man or woman is ever going to possess, whether it is their physical appearance, their mental and physical attributes, whether they are good at science, sport or whatever—all of that is contained there in the early embryo.

Senator McLUCAS—I would just like to take you up on that, actually.

Mrs Tighe—I do not believe that parents own their children and I do not believe that they should have this attitude to their embryos that they are or can be treated like commodities. I think that is very sad. Not everybody on IVF has that attitude towards their embryos. I know a young woman who was very saddened. She had been on the IVF program and she had seven embryos in storage. She used to come down from Hong Kong for treatment. They told her, 'Well, they have all perished.' As far as she was concerned they were her children; she had lost her children. She was very saddened by it.

Senator McLUCAS—That is not a shared view by everybody.

Mrs Tighe—I cannot hear you.

Senator McLUCAS—That is not a shared view by all people.

Mrs Tighe—No, I acknowledge what you are saying, but I am just saying I think it is only right to point out that even though it may not be palatable, nonetheless the reality is that these human embryos are members of the human family. We all began like that once; we all began as embryos. As a mother myself, I was well aware of the difference in me, even at the very early stage when I was first pregnant and there was only a small embryo inside me, that that was my child—my son or daughter—even though it was very, very early in the pregnancy.

Senator McLUCAS—In the document—and you have just made the comment there—you say that excess embryos possess all of the attributes of an embryo which is attached to a uterus wall. Don't you think there is a fundamental difference between an embryo in vitro and an embryo that is attached to a uterus wall?

Mrs Tighe—I made that point because the people who are on the IVF program hope their embryos will be implanted inside them. The mothers hope that they will be implanted inside them. So to start—

Senator McLUCAS—They are quite aware that there will be a number of embryos that are not going to be used to deliver a child.

Mrs Tighe—Yes, many of them are aware of that, but many of them also are prepared to go to court and fight over their frozen embryos. I guess it is a matter of perception. A number of these parents do value their embryos, even in their frozen state.

Senator McLUCAS—I am sure they all do.

Mrs Tighe—A number of them do not.

Senator McLUCAS—I am sure they all do. And you would be aware that the legislation actually provides for a condition so that any use of embryos will be with the permission of the couple who are the donor parents.

Mrs Tighe—I understand that, but nonetheless that does not make it right.

Senator STOTT DESPOJA—I just wanted to follow up on the issue of excess embryos, Mrs Tighe. In your submission you say:

Many parents will not want to agree to the use of their progeny (embryos) in this way.

Mrs Tighe—Yes.

Senator STOTT DESPOJA—I want to read to you a letter that was sent to me in March from Access, which is as you may know Australia's national infertility network. This is what the donor parents say:

> We care about the fate of the embryos that once had the potential to be our children, and to see that their existence had some meaning. We do not believe that to use them for research would be disrespectful. Quite the contrary. Infertile people reject the suggestion that anyone else values or respects their frozen embryos more. We value life and we value children, which is why we have been prepared to go through extensive investigations and treatment in order to try and create a family.

I am wondering what your response is to them. I appreciate that people have strong views in this debate. I have got no doubt that there are some parents who will not want their excess embryos to go to research. That is their right and, as Senator McLucas has said, there is an appropriate consent regime that is built in. But what do you say to those people given some of the comments you have made in your submission?

Mrs Tighe—What I say to them is that I very strongly disagree with them. I feel very sad, very saddened that they would be willing to allow their own flesh and blood, their own sons and daughters, no matter how small, to be used in this way, so I have to say that. I would say that to them, I would say it respectfully and sympathetically, but there are certain lines that you should not cross, Senator Stott Despoja, there really are.

If we moved this argument on a bit further, why could we not say—there are some people who are intellectually disabled, very much so—'Why could we not carry out research on them?' And if their parents gave permission for it, that would not be right, would it? Similarly there are people in a persistent vegetative state, and that could be very tempting for science to be able to carry out research on them. They might say, 'Their lives are of no further use.'

I think some of these things have very small beginnings. As students of history, as I am sure you would be, we have to be very careful. Although it might seem hard in the beginning, we have to at times decide never to cross a certain line because, as I said, they have small beginnings and they have a nasty habit of growing.

Senator STOTT DESPOJA—You made an analogy, and I know you are wary of making analogies. In your paper you state:

> Rather than draw an analogy between this and what happened to Nazi death camp inmates used for experiments because there were going to die anyway, I shall move closer to contemporary times.

Mrs Tighe, that sounds a bit like you are alluding quite strongly, and it might be an analogy. I wonder, in light of some of the discussions you have heard today and the fact that you do respect that people do have differing views, whether you would be prepared to withdraw that statement and indeed what I read as an analogy. As a student of history, I am sure there are many people in this place who would find that quite confronting language no matter how strongly we feel about this issue.

Mrs Tighe—No, I am not prepared to withdraw it, Senator Stott Despoja, because it is a very relevant point. Ever since this debate began the strongest argument I have heard—and I heard it in the House of Representatives. There were two of them: they were going to cure diseases—look at a person in a wheelchair and look at an embryo; and the other thing was, 'They are going to die anyway.' That same argument was used when they carried out experiments on people in Nazi death camps. I know that may upset you because you may think that is very strong language and we do not look like Nazis sitting around here, and I do not believe we are—I do not believe we would ever have death camps—nonetheless, I think it is a very relevant point.

We know that in China today—and I would imagine that most of the people here, probably all of them, would not agree with capital punishment; I certainly do not—they execute prisoners for a whole host of reasons. There are a lot of executions there, and we know there is this trade set up in the use of human organs. The argument being, 'They're going to die anyway. Why can't we use them?' That is happening today. Whilst I do not believe that would happen in Australia, I do think it is a relevant analogy. I have seen a lot of things happen that I never thought would happen.

Senator STOTT DESPOJA—I acknowledge the fact that you have every right to your views and I also just also wanted to clarify that you have acknowledged that that was an analogy.

Mrs Tighe—Sure.

Senator STOTT DESPOJA—Because you said you were not going to draw an analogy, and I think you did. I thought that was perhaps a touch disingenuous in the paper, but you have acknowledged on the record that it is an analogy, and I respect that.

Mrs Tighe—Sure.

CHAIR—Senator Harris has one quick question. We are running very much over time.

Senator HARRIS—This could be answered with a most succinct yes or no. Mrs Tighe, do you think a better use of the excess embryos would be for them to be made available for adoption in a process similar to that used in America, and I believe the name of that is Snowflake?

Mrs Tighe—Yes. This may surprise some of you, but we once again have been consistent in our attitude to the use of frozen embryos, and whilst we have always said that the storage of these embryos should be stopped forthwith, at the same time we have always said that we believe that they should be given a chance for life. The majority of them may not survive that, so our position is that they should stop treating them like this, and those that are in that position, give them a chance for life. I realise it would not be very practically done, but nonetheless it was interesting to note that there were people who appeared before the congressional committee in the United States and they had their children with them—children who had been frozen embryos. They gave evidence and said to the congressmen or senators, whichever they were, 'Do you think this child should have been used for experimental purposes?'

We have been consistent in our position, but at the same time I would like to make it clear that I do not believe that we should be saying, 'Oh, this is a good idea. We have frozen embryos and we can provide babies for couples who want to adopt.' No, I think that we should be stopping the procedure and giving the others a chance of life.

CHAIR—Thank you very much, Mrs Tighe, for your time this evening.

Mrs Tighe—Thank you, Senator Knowles. I was not meaning to be disrespectful before when I said you were a slow learner. I was only joking!

Proceedings suspended from 7.28 p.m. to 8.20 p.m.

ROYLES, Ms Sheila, Spokesperson, Coalition for Advancement of Medical Research Australia; Chief Executive Officer, Juvenile Diabetes Research Foundation

SHEPHERD, Master James, Youth Ambassador, Juvenile Diabetes Research Foundation

KNOTT, Ms Johanna, Director, Australasian Spinal Research Trust

TURNER, Mr Robert, Honorary Chief Executive Officer, Australasian Spinal Research Trust

LANGDON, Mr Kevin, President, Motor Neurone Disease Association of New South Wales

CHAIR—I welcome the representatives from the Coalition for the Advancement of Medical Research Australia, the Juvenile Diabetes Research Foundation, the Australasian Spinal Research Trust and the Motor Neurone Disease Association. Thank you for coming along.

I remind witnesses 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.

We have before us your submissions, and it is intended that the committee will be run in a panel style approach whereby all of you can make some comment if you wish in addition to the submission that you have put before the committee. At the conclusion of your comments senators will be invited to ask you some questions. You can decide among yourselves as to who speaks first, or whatever.

Ms Royles—I will probably kick off as spokesperson for the Coalition for the Advancement of Medical Research. CAMRA is a group of 10 organisations who believe embryonic stem cell research holds one of the greatest hopes for finding a cure for hundreds and thousands of Australians. We feel strongly that this research should not be banned in Australia. We have three of those groups represented here today—the Australasian Spinal Research Trust, the Motor Neurone Disease Association and JDRF—and each of those individuals will be talking on behalf of their own organisations and I will be talking on behalf of CAMRA.

There are three primary reasons why CAMRA supports embryonic stem cell research in Australia. Firstly, CAMRA believes that embryonic stem cell research holds one of the greatest hopes for finding a cure for hundreds and thousands of Australians with diseases and disabilities. We believe that these people should have the opportunity for a better quality of life and to not literally be protected to death by legislation.

In terms of the key stats for some of these patient groups, one person dies of motor neurone disease every day—that is a larger number than AIDS—and the life expectancy is on average three to four years. One person is confined to a wheelchair every day in Australia, and there are 100,000 children and adults with juvenile diabetes in Australia who have to inject themselves two or three times a day just to stay alive. The cost to the community of looking after these people is many billions of dollars. You might question whether embryonic stem cell research really is the best hope for a cure, and I know there has been a lot of debate about whether embryonic or whether adult stem cell research is the best way forward.

In our submission we have identified a number of research breakthroughs which, although preliminary, give us confidence that in the animal model embryonic stem cell research really

is delivering results and that it is vital to continue with this area of research as well as the adult stem cell research. In addition, what also makes us believe that this is really one of the greatest hopes for finding a cure is that globally the Juvenile Diabetes Research Foundation alone funds over $200 million worth of research. We have a panel of specialist researchers in the US who literally do nothing but scour the world for the best research on a global basis. Now we are not going to allocate $200 million worth of research on a whim, so we have a specialist group of people, and the feedback I am getting from them is that embryonic stem cell research is the area that we have the most interest in going forward, and certainly the Juvenile Diabetes Research Foundation internationally would be looking for opportunities to fund that sort of research. Finally, Catherine Verfaillie, who is one of the leading adult stem cell research advocates—in fact, she is the leading adult stem cell researcher—in addition to her work says that it is really important to continue with not only adult stem cell research but also embryonic stem cell research. So our position is, 'Let's keep them both running at the same time.'

The second reason for our support is that given IVF is legal in this country and by law excess embryos must be discarded, we believe that it should be the choice of the parents of those excess embryos to decide whether they would like to donate those embryos to research to help others less fortunate than themselves. In a Roy Morgan international poll, which I am sure has been mentioned a few times, over 72 per cent of Australians surveyed said that they would support research using excess embryos for development of therapies assuming consent of the donors. Let's listen to the community, and let's give individuals the choice to help others if they wish.

The third reason is that Australia is currently home to some of the world's best researchers, and we should do all we can to keep them here in Australia so our citizens are one of the first countries to actually benefit from these new therapies as they are developed. Monash is currently respected as one of the world's leading research institutions. Additionally, on a per capita basis, JDRF funds more diabetes research in Australia than anywhere else in the world, and given that we pride ourselves on only funding world's best research, I think that really does illustrate Australia's current standing in the research arena. I would hate to see that expertise being lost to other countries, and more importantly, our citizens missing out on therapies because we have made it hard or impossible for researchers to work here.

In closing, we ask this committee to support the pursuit of both adult and embryonic stem cell research. We are at the start of the marathon; we have two strong runners, embryonic and adult stem cells. As yet we do not know which one is going to be capable of finishing or whether in fact they will cross the line together. Let's not make the decision to eliminate one of our strongest runners before we even start. There are many, many scientific questions yet to be answered. I urge you to support legislation and give our researchers the opportunity to see whether this area of research really can deliver the benefits that we hope for people like James Shepherd, who has juvenile diabetes, for people like Kevin Langdon, who lives with motor neurone disease, and Johanna Knott, who has to live in a wheelchair because she has spinal cord injury. These people have to live with these diseases and disabilities every day of their lives. I urge you, let's not protect these people to death.

CHAIR—Any further comments?

Ms Royles—I would like to hand over to James Shepherd to talk about the perspective from the Juvenile Diabetes Research Foundation.

Master Shepherd—I am James Shepherd. I have lived with juvenile diabetes since I was five, and I am now 13. It has been quite traumatic for myself and my family, who have had to

adjust to my routine and watch me in some cases get sick and have rather frightening repercussions from the disease that I live with. In the course of my life I have had approaching 7,000 needles and approximately 16,000 finger pricks, but that is just an external factor because it is more than anything mentally difficult to cope with diabetes. For example, there is always the looming prospect on the horizon of complications which can derive from diabetes, such as blindness, kidney problems and the increased chance of death due to heart disease, to name a few.

In 15 minutes I can go from feeling perfectly fine to having my blood sugar go so low that I can hardly stand or so high that I cannot think properly and I start acting completely irrationally or in the extremes I get nausea and cannot do anything for the day. It affects everything I do. There is no break; there is no holiday. Every time I eat I am reminded of the fact that I live with diabetes, and every time I play sport I have to remember that if I do not do something about it now I will have problems later. It is difficult for me certainly, but also for my mother in particular, who until I was old enough to do it myself had to give me injections and put me in pain to keep me alive. My friends and my family are reminded of it also when they are around me, which is trying for them as well, I am sure.

There are approximately 100,000 juvenile diabetics in Australia, and there are more being diagnosed each year. I think all of us deserve a chance for a cure. As Sheila said, the cure could lie in adult stem cells or embryonic stem cells or it could lie in one of the many other types of research, but I think that every possibility for a cure should be fully explored before it is banned completely. It is a hard thing to live with, and I think we have every right to a cure and any way that cure could be achieved should be fully tested before that window is closed.

Ms Royles—Thanks, James.

CHAIR—Thank you for a very good contribution.

James Shepherd—Thank you.

Ms Royles—I would like to pass to Mr Kevin Langdon, who is the Director of the Motor Neurone Disease Association, who will be speaking in that capacity.

Mr Langdon—Thank you. My colleague Dr Paul Brock put a submission in about motor neurone disease and how it affects him. I would like to elaborate further on that, being a person with motor neurone disease myself. In 1998 my life was changed forever when I was diagnosed with motor neurone disease and given three years to live. The experience of motor neurone disease for the majority of people may be likened to entering a hall of mirrors. The diagnosis itself distorts familiar reality, pushing out of shape ideas about time and life organisation. However carefully and sensitively the diagnosis was given, the diagnosing physician felt that he had little to offer me beyond the diagnosis itself. The typical rapid progression of the disease meant that I had to adapt to a rapidly changing series of multiple disabilities, any one of them severe enough for a major life change, whilst simultaneously trying to learn the complexities of the health system, which is not designed to cope with multiple rapidly advancing disabilities.

Imagine a disease which little by little robs you of the use of your arms, your legs, and even your voice. Imagine seeing the muscles in your body slowly waste away while your senses and intellect remain perfectly in order. The ability to feel emotion—love, anger, joy and bitterness—remains intact, but one has no way of expressing them. Motor neurone disease is not a rare condition, nor is it new. Dr Jean-Martin Charcot, a French neurologist, published the first full account of motor neurone disease in 1874, 128 years ago. Now, in the year 2002, there is still no known cause or cure. Adjusting to the knowledge that I have an

illness with no cure does not mean giving up and doing nothing. It means maximising my time and energy to have what quality of life and independence I have left.

The main feature of motor neurone disease is a relentlessly progressive muscle weakness. Fatigue is also a common early problem, then the loss of muscle power, loss of range of joint movement and loss of muscle control over the joints. With the loss of mobility weakness can begin in any muscle group. The progression can be quite random. The physical effects of motor neurone disease vary from one person to another, as does the rate of progression of the disease.

Most people with motor neurone disease have a clear and active mind throughout their illness, and it is vital that they are given the means to retain as much control as possible over their lives, especially when speech is lost. In this condition more than others, the person living with motor neurone disease and their close carers are themselves the leading experts in disease management. Only we can say in the absence of any fundamental treatment how much inconvenience is worth tolerating in order to maintain personal dignity or how much dignity can be sacrificed to gain comfort or ease from our distress.

You have to make the effort to learn everything about motor neurone disease and you must have the courage and fortitude to cope with the challenges it brings. For a person who has been recently diagnosed, helping them to get a realistic but not too helpless idea of the future is very important. An illness such as motor neurone disease brings about many changes within a family and every member is affected. Each person will have their own worries and secret fears. Most importantly it is estimated that for every one person diagnosed with motor neurone disease, a further 14 people, being family or professionals and close friends, will live with it for ever.

A typical MND equipment cost for a person living with motor neurone disease, which includes mobility, bathroom, pressure care, communication, bed and seating transfers and around the clock care, is estimated at over $50,000 per person. Additional expenses are incurred with home modifications. Motor neurone disease now claims one person every day in Australia. The famous actor David Niven, before losing his battle with motor neurone disease, called it a torture that no man or woman should endure.

By maintaining a sense of hope, I know in my heart that both embryonic stem cell and adult stem cell research hold real prospects of finding a cure or treatment for motor neurone disease. The difference between motor neurone disease and other neurological conditions is the rapid irreversible transition a person with motor neurone disease has to come to terms with, from the irritation to the inconvenience of disablement, to severe disablement, to death. In some cases they can die within 12 months. There is no predicted psychological or spiritual profile for people living with motor neurone disease. Individually and collectively you must meet the physical, mental, emotional and spiritual challenges head on by living one day at a time.

Last, I would like to say that in other countries motor neurone disease is also known as amyotrophic lateral sclerosis, or ALS, or Lou Gehrig's disease. It does get mixed up, but this is motor neurone disease. Thank you.

CHAIR—Thank you, Mr Langdon.

Ms Royles—To finish I would like to hand over to Johanna Knott and Bob Turner. Johanna is a director and Bob is the CEO of the Australasian Spinal Research Trust, and they will be talking in those capacities today.

Mr Turner—I would like to state my position to start with, because I think it is relevant. I worked in the community services sector for 35 years of my life. In that sector I found how difficult it was to create new ideas and bring new treatments and therapies forward for people living in necessitous circumstances. I was CEO of the Smith Family. Just prior to my retirement my son broke his neck in a swimming pool accident and incurred a C4-5 spinal cord injury. He is a quadriplegic. Before his injury, like most Australians, I knew nothing about spinal cord injury. I have learnt a hard lesson since—constant treatment in hospital; near-death experiences when there are catheter changes; inability to feed himself or turn the page of a book; going from an active person to somebody that is completely dependent on others.

As a result of that injury I started to work as a volunteer for the Australasian Spinal Research Trust. I am CEO, and my position is that I do not expect any money from that. I am not driven by money, I have no political standpoint, and I have no religious affiliation. I simply want to see a cure for people with paraplegia and quadriplegia. I am not a scientist. As part of what I do it was necessary for me to find out about the science, to find out what was worth supporting, and as a consequence I have had to listen to the views of experts, as we all do, and that can be very difficult. Recently in Australia we have seen the experience of people coming out of America with preconceived ideas to support a particular position in Australia. Two scientists in particular, who were not recognised by their peers and who had no particular expertise in stem cell science of any sort, were put forward as experts who should be listened to.

Senator BARNETT—Who are you referring to?

Mr Turner—I am referring to—I will have to look up the names—David Prentice and William Hurlbut.

As a balance to that, the letter we received from Paul Berg, who is a Nobel laureate and Cahill, Professor of Cancer Research and Biochemistry at Stanford, sent us a list of 41 Nobel laureates in science and medical science who fully support the continuation of embryonic stem cell research. They know that it does not present a cure at the moment; they do recognise that it presents the greatest hope for the future, and their signatures are there. Whom should we believe? Two scientists who were brought out for a particular purpose or 41 Nobel laureates from around the world who say that embryonic stem cell research is valid and should be continued because it does hold great hope?

At the end of the road, as far as I am concerned, there is a simple choice, and it comes down to embryonic stem cells. They are there; they have been created; donors wish them to be used for medical research; and if they are not used for that, they will be discarded, simply discarded. On the other hand, they could be used for medical research which may—we realise it is called research; we do not know the answers yet; if we knew the answers we wouldn't be talking around this meeting—produce hope for the future, they may produce therapies for people with a whole range of afflictions including spinal cord injury.

My simple answer to the question is that that is the decision that needs to be made. As far as I am concerned it comes down to offering the Australian public hope for the future or telling people in wheelchairs, 'It's tough luck. You're a cripple and you've got to live with it for the rest of your life.' I hope that we can send a message of hope to people. Thank you.

CHAIR—Thank you, Mr Turner.

Ms Knott—Thank you for the opportunity of allowing us to present to you today. Like Bob's son, I have a similar injury. I have a C5-6 injury, which means I am paralysed from the

chest down. Last month I had the anniversary of my skiing accident which happened soon after my arrival from England to live in Australia. I had to acknowledge that for 10 years I have not been able to eat, wash, go to the bathroom or get dressed without someone else's help. Some people may be able to get used to living like that, but I am not one of those people. I have a keen interest in research, and I am deeply disturbed by any attempts to block scientific progress.

Many hundreds of thousands of Australians suffer from serious or currently incurable diseases or conditions. In fact, one in eight suffers from neurological disorders alone. Twenty thousand—plus people in Australia have severe spinal cord injuries, and that rate grows by one per day. Our government is supposed to do the greatest good for the greatest number of people, and I believe we have a moral responsibility to help others. But time is crucial. If scientists are forced to attempt to make adult stem cells behave like embryonic stem cells you could waste five years or more, and many people just do not have that time.

When I first had my accident I was given little hope of the possibility of a cure. The fact that I could not accept this diagnosis led me and others to set up the Australasian Spinal Research Trust. Since that time we have been able to fund projects at leading research centres in the main states in Australia. Australian scientists are contributing to worldwide research in the spinal cord area which looks at six vital areas. I am no scientist either, but those six areas are neuroprotection, which basically means cell damage; growth inhibitation, which is the damaged axons and protection of those axons—an axon is the long arm part of the nerve that sends messages; axon guiders; the nerve circuitry; cellular replacement; and rehabilitation. Every day exciting progress is being made and embryonic stem cell research while early days is vital to many of these areas. For example, scientists at Washington University have already successfully turned embryonic stem cells into nervous system cells when injected into the spinal cord of injured rats.

Medical research in Australia directly contributes to Australia's intellectual capital and ensures that we are the first to benefit from any therapies developed. As a country we have positioned ourselves well in the emerging biotechnology area with world respected scientists. But with tighter legislation these researchers will be forced to continue their work in more supportive environments like the UK and Singapore, where they are already being lured. There is a certain irony, I have to say, in that some of the parliamentarians who have been part of an environment encouraging scientists to go commercial and make money from Australian scientific discoveries over the last decade could, via a moral conflict, encourage them to leave.

It is imperative that we protect important areas of medical research that offer hope to hundreds of thousands of Australians. I do not expect a cure tomorrow or even next year, and I do not intend to overstate the promise of research, but how can you overstate hope? Thank you.

CHAIR—Thank you very much. Do you wish to conclude with anything, Ms Royles?

Ms Royles—No.

Senator STOTT DESPOJA—First of all, Mr Turner, thank you for your reference to the Prentice evidence. I alluded to that in my first questioning on this many weeks ago. Would you be willing to table the Berg correspondence to which you referred?

Mr Turner—Yes, I think it is on public record.

Senator STOTT DESPOJA—I think that would be of interest to the committee. Something I have asked of all witnesses who talk about scientific evidence and make

reference to possible research or cures is that they provide these citations. I know, Ms Knott, when you were referring to some of the positives and the benefits you referred to research. I am happy for you both to take that on notice and other witnesses too, to perhaps provide the committee with any specifics that you have in relation to the evidence that is in your submissions before us. A question to all or any of you in particular. Your submissions are clearly in defence of the legislation. Can I clarify whether there are any changes that you would like to see made to the legislation before you?

Ms Royles—With the legislation as it currently is, I think where we are at now is we want to get the legislation through as quickly as possible. This has been debated for months and months. We want to get clarity for the researchers so they can move forward within a sensible type ethical framework, which I think the legislation provides. So our position is: let's get a sensible framework into the legislation, vote on it, and let's provide clarity and move on, And let's actually see what this research can deliver. If down the track the legislation needs looking at in light of new evidence or where the science is going, let's make that decision then, but let's get the decision made and see what this can actually deliver.

Senator STOTT DESPOJA—Are there any other comments on the bill in its current form or any amendments you would like to see put forward?

Ms Knott—I think as a group we generally agree with that.

Mr Turner—Yes.

Senator STOTT DESPOJA—I do not know whether you were here or you heard some of the witnesses before you—two witnesses previously. There was a lot of discussion about the degree of lobbying of politicians that has gone on surrounding this legislation over a number of years, to quote that witness. There was also a particular witness who felt that we were being influenced by emotive arguments. The most previous witness referred to the fact that it was quite emotive to see people in wheelchairs and to be confronted with people talking about various diseases. I think as legislators we are quite capable of making logical, rational debates and decisions without being swayed inappropriately, but I found that notion that we are somehow being swayed by inappropriate lobbying, either by scientists for commercial and other reasons or by groups such as yours—I know that it is a fairly full-on question, but I wanted to give you the opportunity to respond to that, the notion that witnesses have suggested that—

Senator BOSWELL—How many witnesses have said that—

Senator STOTT DESPOJA—With respect, I do not mean to misrepresent the witness.

Senator BOSWELL—No, well you cannot come in here and put the wrong words in people's mouths, because none of the previous witnesses did say that this group used emotive—

CHAIR—Senator Stott Despoja did not say the witnesses said that this group had come and inappropriately lobbied anybody. Senator Stott Despoja fairly reflected the view that had been put by a previous witness about other people who had approached honourable senators about this subject. I allow the question to stand and ask if there is anyone who would like to make comment on Senator Stott Despoja's question.

Ms Knott—I would like to say that even without your question it has been quite obvious that this subject has come up a number of times in the media, so I do not think that by raising it we are going to be at all surprised by it. I think you have to understand that people like myself—in fact all of us—have been involved in this area of research for a long time because our lives are affected by it. It is not just a case of, 'Well, here's an opportunity; let's get

involved in it just for the sake of getting involved in it.' Our lives are heavily influenced by wanting to change them. I want to walk again; Kevin wants to find a cure for what he is suffering from; James does not want to live with juvenile diabetes. These are things that we are not just pulling out of the cupboard to suit a situation that is currently being tabled.

The reality is that we do follow very closely, and we have done for a number of years, what research has gone on around the world, and I think we do have a good sense of what is credible and what is not. So we have a right to try to explain our views on that, and also to try to help you understand what it is like to live like this, because it is incredibly difficult. I think it is important that people in the community, through you, understand that, so I do not think it is inappropriate at all.

Mr Turner—I did say at the start of my few words that people do not really know very much, particularly about spinal cord injury, and it is hard to remove the emotion from it completely. What mainly comes back from people who suffer from that is that people would only have to spend a few hours in this chair and they might start to understand it. Perhaps we do inadvertently talk about the affliction because that is the whole purpose, that is what we are here for. We are trying to help people with therapies. We talk about a cure because it is shorthand, but what we mean is the ability to do something—to lift a glass, maybe walk—but we certainly do not unrealistically hold out hope of going into the 100 metres at the Olympics. We are very careful about the way we approach that.

Mr Langdon—I would like to say that with motor neurone disease, as I said earlier, the first full account of that was 1874. Of the large amount of research being done on this, most of it has been done in the last five years and the momentum is starting to build up. We are starting to have an ageing population. Onset for this disease is age 50 and upwards, and there is going to be an increase in the number of people with motor neurone disease. People are coming to us in all states, and it is increasing. In Queensland this year we have more people being diagnosed with motor neurone disease than last year. So the signs are already there. You have to live this to know what it is like each day; to be told that there is no cure, and to be told by a neurologist that you should go home and get your affairs in order—'If you want to go and have that overseas trip, go and have it because there is nothing that can be done. See you later'. We have to have hope that that will change.

Senator STOTT DESPOJA—Thank you for that. I was not suggesting that you had been lobbying in an inappropriate way; I just wanted to get to the issue of emotion in the debate as opposed to, as one witness says, 'the facts'. I think it is important to get that on record.

In relation to some of the evidence that you provided, Ms Knott and Mr Turner, in your submission you refer to the National Academy of Sciences in the United States. Have you referred to or are you aware of the Academy of Science in Australia and any of their evidence, and do you have a view—they have not appeared before the committee yet—as to whether they are a credible organisation from which we can derive information for them to present as witnesses to this committee? If you do not have a view on that organisation, that is fine.

Ms Royles—No.

Ms Knott—We are aware of the Academy of Science in Australia, and our understanding would be that they are credible scientists, yes.

Senator STOTT DESPOJA—Can I just once again clarify that as a group—it is very clear from your submissions to me, but I just want to get this on record again—you are advocates of both adult and embryonic stem cell research?

Mr Turner—Yes.

Senator STOTT DESPOJA—You have no particular preference one over the other; you recognise both?

Mr Turner—Yes, that is right.

Senator STOTT DESPOJA—James, as the youth spokesperson, you have obviously quite a number of contacts with presumably young people through juvenile diabetes. Have you consulted with peers and friends and other young people who are in a similar situation to yourselves? Do they have a view on this debate and maybe even this legislation?

James Shepherd—The youths I have spoken to with my situation do not often particularly know much about stem cell research. I am certain, and I think I can safely say, that all of them want a cure and nobody wants to live with this, but on this particular debate I do not know anyone with juvenile diabetes who actually understands it—which includes myself as well.

Senator STOTT DESPOJA—I would not say that that necessarily applies just to younger people; I would say it is probably a reflection of the broader community.

Senator BARNETT—Can I say at the outset that I vigorously welcome you all to the table and congratulate you all on your advocacy, your role and your efforts to put forward the views of your members, the different groups that you come from, and I specifically acknowledge Kevin Langdon, who is an old colleague in the Motor Neurone Disease Association. Kevin will remember we worked together when I was President of the Motor Neurone Disease Association of Tasmania. Kevin was involved in New South Wales. My father died of motor neurone disease on 25 May 1985 at the age of 58, so I can relate to and have a lot of empathy for the pain and suffering and the need for a cure. As James Shepherd has just said, everybody would support the need for a cure.

From my perspective I have had to dig deep and consider my own personal position on this legislation—which was not easy, as a person with type I diabetes like James—knowing that at the moment there is no cure and that you are subject to five injections a day or an insulin pump or whatever, so the issues that face you, I face. I just want to put that on the record. I know Kevin is aware of that and others in the different organisations, and I want to compliment you on your efforts and your advocacy because I think it is excellent, particularly the JDRF work that you do for people with type I diabetes and the enormous amount of research. I spent years trying to raise money for research for both motor neurone disease and now diabetes in the last five years since I have had it. Thank you for the work that you do and the excellent efforts that you make.

I guess there are different ways and means to relieve pain and suffering, and an issue for us in this committee and as parliamentarians is where we draw the line. Just last week the legislators decided to draw the line on cloning—all different types of cloning: therapeutic cloning and other types of cloning. I think there is pretty full support in the parliament for opposition to cloning, so I thought I would just throw the question out to the different groups in terms of your support for cloning, because it is pretty much accepted that you can get medical and health benefits for terms of relief of suffering via cloning, yet it is deemed that that is a line for some people to which we say no. In other parts of the world it is allowed, so I just thought perhaps you could respond to that question and anything else I have said if you want to.

Ms Royles—I guess I would say that this issue is not about cloning. I think that we have agreed that across the board we do not want reproductive cloning. We voted on that; that has been banned. The issue here is around whether we are going to use excess embryos that will be discarded anyway and allow individuals, or the parents of those embryos, to make the

choice about whether they want to put those into research. That is my understanding of the issue.

Senator BARNETT—What is the JDRF position on cloning, or therapeutic cloning?

Ms Royles—In terms of therapeutic cloning—I take off my CAMRA hat and put on my JDRF hat—we oppose a permanent ban on therapeutic cloning. That is JDRF's position. Having said that, we recognise that there is quite a considerable amount of research that has to be done before we get to the stage where therapeutic cloning may or may not be useful. Our position is, 'Let's get the embryonic stem cell research happening so we can actually see whether this is something that is beneficial.' By the time we really understand how we make that work, it might be that we do not need therapeutic cloning any more, that we can actually clone the stem cell so we do not need to clone the embryo to produce matched DNA stem cells, which is really the ultimate goal. I know that progress has been made in that area already. So we are not saying, 'Yes, we need therapeutic cloning'; JDRF's position is that we would prefer not to have a permanent ban on therapeutic cloning. Does that answer your question?

Senator BARNETT—In part it does.

Mr Langdon—Because of the extremely stringent quality of accountability that has been put in—now I am talking as the Vice President of the Motor Neurone Disease Association of Australia—we are happy with that. People will be accountable, and that is not a problem as far as people with motor neurone disease are concerned. The main thing that we are looking at is that embryo cells and adult cells are both looked at for the research.

Senator BARNETT—The point I am making is that cloning—therapeutic cloning, as some people call it—can provide some medical benefits. Are you saying to us that you do not support therapeutic cloning, or are you saying that you do support it, that you want to leave the way open for it in the future?

Ms Royles—CAMRA have not gone into the cloning territory at all. CAMRA does not have a position on cloning. We came together as a group of organisations to support embryonic stem cell research using excess embryos. As CEO of JDRF, I can have an opinion about therapeutic cloning, which I have expressed, but I cannot speak for the other members of CAMRA.

Senator BARNETT—I have separate submissions here from different groups; I am just asking you the question.

Mr Turner—Our view is very much one of wait and see. We recognise that the pace of scientific research is increasing. The number of scientists going into this area is multiplying each year. People who five years ago would not have given any credence to this sort of research now are starting to believe in it, including clinicians in hospitals. We are quite happy to go along with this situation and wait and see, because we do not know what this research will bring out. There is, as Sheila says, already a school of thought that there may not be a need for therapeutic cloning, somatic cell transfer—call it what you like. 'Cloning' is a bad word for us because people have used that to conjure up ideas of unborn foetuses having bits torn out of them for the use of medical science. That is the reason we steer clear of it, not the fact that these cells could be used beneficially. But it is a wait and see view, and we do not know.

Senator BARNETT—You prefer to leave the door open for now?

Mr Turner—Yes.

Ms Knott—We are totally not in favour of human cloning. It always has to be clarified that there is a difference between human and therapeutic cloning, which obviously you are very much aware of.

Senator HARRADINE—What is the difference in the process?

Ms Knott—In the process?

Senator HARRADINE—Is it not exactly the same process?

Ms Royles—Can I pick that up?

Senator HARRADINE—I am asking Dr Knott**.**

Ms Knott—I am not actually a doctor. Basically, we are not in favour of human cloning. I would be surprised if anyone that would come to see you would be in favour if it.

Senator HARRADINE—I am genuinely trying to see what your understanding is.

Ms Knott—Therapeutic cloning is when the nucleus of a cell is removed and combined with the DNA of the person suffering a condition. From that, the embryo, when it is developed to the blastocyst stage, is able to be put back into the person suffering the condition, and the benefit possibly over embryonic stem cells is that it may be less likely to be rejected by the body.

Senator HARRADINE—That is a clone—

Ms Knott—It is being discussed and considered because in England it has already been approved after extreme debate by the House of Lords as to whether or not it should be allowed. But at this stage we are only talking about embryonic stem cell research from discarded IVF embryos, because that is what this bill is about.

Senator HARRADINE—I will leave it there.

CHAIR—Ms Royles, do you want to add something to that?

Ms Royles—Yes. It is essentially the same process.

Senator HARRADINE—It is exactly the same.

Ms Royles—The difference between reproductive cloning and therapeutic cloning is exactly as Johanna said. For both of them, it is where the nucleus of the original cell is extracted and a new nucleus is inserted. Reproductive cloning occurs where that is transplanted back into a female human and it develops into a cloned baby. Therapeutic cloning is where that cell does not get transplanted back into a human. It cannot grow into a baby. It does not have the cells in it that grow into placenta, for example. It is just grown in a petrie dish. So it cannot become a cloned human being. That is my understanding of the difference between the two.

Senator HARRADINE—That is an interesting understanding. Did I hear you say that you could clone embryonic stem cells? Did I misunderstand you?

Ms Royles—There is some recent research—I can get the information for you—whereby the embryo is not cloned; the stem cell was extracted from the embryo. The nucleus of that stem cell was extracted, and there is no way that that stem cell could grow into a new human being, because it is just a stem cell. It can only grow into other cells. That is the new thinking about why therapeutic cloning might not be required, which for us is great news because we are absolutely opposed to reproductive cloning and, if we can find a way of creating matched DNA cells without requiring cloning, that is really exciting news for us.

CHAIR—Mr Shepherd, were you wanting to make some comments?

James Shepherd—Basically, I want to say that I think it is necessary to draw the line somewhere. Everyone I know that even lightly breezes over the topic thinks that cloning is completely immoral. I, myself, am not completely sure on therapeutic cloning, but the cloning of another human being is to all present I am sure completely wrong and immoral. But the thing that worries me is that it is during this argument that the word 'cloning' is used quite liberally. For example, when people have asked me exactly what I am doing here I say, 'Have you heard of embryonic stem cells?' and they say, 'Oh yes, it is cloning' or something like that. It is a difficult topic to go into. We are here in support of embryonic stem cells; cloning is a completely separate issue that does not really need to be mixed into the same topic.

Senator BARNETT—I think that discussion and debate is helpful, because, as you can see from our point of view, we need to be able to consider all the ramifications of where to draw the line. You talk about drawing the line somewhere. Witnesses are drawing the line on cloning or reproductive cloning or therapeutic cloning, so you have to draw the line somewhere, and that is our task in considering the evidence. Sheila Royles, in your submission in the third last paragraph, you say:

> Assuming the appropriate ethical and scientific guidelines are in place, it should be the moral choice of those individuals that drives the donation of excess embryos into medical research—

meaning the choice, I assume you are saying there, of the donors, the mother and the father of the IVF embryo. My question then is that on reading that it implies that the mother and the father essentially have property rights over the human embryo. Is that the way you see it—they have the right to determine what happens to that embryo, no matter what, so they can do pretty much whatever they like with it? That is the first question. The second relates to it, and it involves the fact that in many cases it is not uncommon that the father is anonymous. In that situation what would happen?

Ms Royles—I will start with the first question. No, I do not agree that they have rights over everything to do with that embryo. I think that, given that IVF is legal in this country and given that by law those embryos have to be discarded—and really a lot of this is around the moral or ethical question of: is it an embryo, a living being at that point with rights, et cetera?—is it appropriate to put legislation in place that says, 'Yes, we think that if you personally have the moral position or ethical position where you feel that it is appropriate to do research with embryos, then let us allow that person to make the decision.' But if, for example, I underwent IVF and I decided that it was against my religious position and that I wanted the embryo to have rights and I did not want it go into research, then let that be the choice. But being able to operate within the legislative environment, I think it should be down to the individual to make that choice about where their current position is in line with their religious beliefs or whatever. What was the second question?

Senator BARNETT—The second question was that it is not uncommon in IVF situations for the father to be anonymous. What would happen in that situation where you require the consent of the donors?

Ms Royles—I think it is important that the right approval is taken. Given that there are currently 70,000 embryos within Australia, then let's look at using those ones where we can get the right agreement that is required.

Senator BARNETT—So would you prioritise those 70,000 so that those where you knew the father and the mother who were the donors and you got their consent, you would use those, and then you would put down the list on that 70,000 those where the father was anonymous?

Ms Royles—I do not really understand where you are coming from.

Senator BARNETT—If the father is anonymous and you do not know who the donor is, would you still make those embryos available for research.

Ms Royles—That depends on what the legislation says.

Senator BARNETT—What do you think? That is what we are sitting here for. What is your view? If you do not have a view, that is okay.

Mr Turner—I certainly struggle with your use of terms. I would say 'donors'; you are talking about 'mother and father', which implies a child. I certainly do not see it that way, under no circumstances. I see a group of cells in a test-tube and on the end of a pin and I can certainly not subscribe to that mother and father concept.

Senator BARNETT—Mr Turner, the legislation provides for consent.

Mr Turner—Sure.

Senator BARNETT—The consent has to be provided by somebody.

Mr Turner—It does. You used both terms yourself.

Senator BARNETT—Sorry?

Mr Turner—You used both those terms yourself. You said 'the donors', but you also used the term—

Senator BARNETT—Who are the donors?

Mr Turner—The woman in the case of the embryo and the man in the case of the sperm.

Senator BARNETT—Right, and you agree that you require their consent?

Mr Turner—I would say so, certainly. In fact I think there is a very strong ethical claim from people writing to newspapers saying that they do not want to see those embryos destroyed because they want to see them used for the benefit of people and of science.

Ms Royles—I have had time to think about this. It should be both parents. Both of them have contributed to that.

CHAIR—If someone is anonymous and wants to remain anonymous, it is going to be pretty darned hard to go and find them and dredge them up and say, 'Now, do you give approval for this excess embryo to be done.' I have to say, Senator Barnett, I am struggling with the question too, because if someone is anonymous they are anonymous.

Senator McLUCAS—There was a comment earlier, and to identify those that have two identified donors should be something that is a practical solution to this issue.

Mr Turner—I do not see a problem.

Senator BARNETT—Mr Turner, you have referred—and I cannot give the exact wording—in your introductory comments to two scientists whom you said were not respected by their peers.

Mr Turner—Yes.

Senator BARNETT—One of those, and you checked your records, was Professor William Hurlbut—

Mr Turner—Yes.

Senator BARNETT—He was appointed to President Bush's bioethics commission. Why would you think he is not respected by his peers?

Mr Turner—That is the indication that we got, as a stem cell scientist.

Senator BARNETT—On what basis do you make that—

Mr Turner—Because he was not involved in stem cell science. The description of him is as a trainer of undergraduates and a bioethicist and a spokesman for a particular church group, but not as a stem cell scientist. He has had no funding from the American institutes of science, he has had no publications on stem cell science.

Senator BARNETT—Okay, thank you. The other one was Professor David Prentice.

Mr Turner—Yes.

Senator BARNETT—On what basis do make—

Mr Turner—On the same basis. In one particular radio interview that I heard take place on a morning show he represented himself as an adviser to the American Senate. He is in fact a scientific adviser to Senator Brownback in America, who has got very extreme views on stem cell sciences and would, in fact, see women locked up if they even went overseas and had any therapies from stem cell science, so it is a very extreme view that he takes. He is a scientific adviser to Senator Brownback, not the American Senate. He is not a recognised stem cell scientist by the 41 Nobel laureates that signed—

Senator BARNETT—On what basis do you say that?

Mr Turner—He is not recognised by the 41. Peer review is very important in this area, not the review of people like me. I listen to what those people say.

Senator BARNETT—Have those 41 scientists said that Professor Prentice's is not credible science?

Mr Turner—No, the Nobel laureate Professor Paul Berg.

Senator BARNETT—And you will table that document, please?

Mr Turner—Yes.

Senator HARRADINE—I think it is important, since a member of the Presidential Commission on Bioethics has been reflected upon seriously, to get the matter straight. Where did you get that information?

Mr Turner—From Professor Paul Berg, the professor of cancer research. He is a Nobel laureate, a professor of cancer research and biochemistry.

Senator HARRADINE—And he said that Professor Burke was what?

Mr Turner—He said that Professor Hurlbut—

Senator HARRADINE—He said that Professor Hurlbut was a representative of a church group—

Mr Turner—Well, here you are.

The other spokesman in your midst—

this is when they were in Australia —

is William Hurlbut, MD, apparently put forward misleadingly as professor at Stanford University but who in fact is more of a volunteer undergraduate in stature whose passion for bioethics is in keeping with the most fundamentalist views of the Catholic hierarchy.

Senator HARRADINE—That is extraordinary. None of that came through when he was here.

Mr Turner—I am not surprised. It was that sort of exercise, I think.

Senator HARRADINE—That is extraordinary!

Senator BARNETT—Which document is that? We need to get a copy of that, Madam Chair.

Senator HARRADINE—Can you table a copy of that?

Mr Turner—Yes. I understood that all of the senators had received a copy.

Senator JACINTA COLLINS—No. I have not received that sort of tripe.

CHAIR—Senator Harradine, have you concluded? Senator McLucas was making a point.

Senator HARRADINE—I raised that matter because a person's character has been reflected upon.

Senator JACINTA COLLINS—I think there is an adverse reflection there.

Senator HARRADINE—Maybe that might be able to be settled elsewhere.

Senator McLUCAS—Earlier today we had evidence about the use of the word 'cure'. It has been put to us that it is misleading to use the word 'cure'. I would like to ask all of you this, because some of you have used that word and, Mr Turner, you did qualify your use of the word. Given that it has been part of our discussions tonight, I wonder if you would like to explain what you think embryonic stem cell research could deliver, and touch on the use of the word 'cure', if you would, please?

Mr Turner—I use 'cure' when I am doing the job that I set myself to do, which is to raise money for scientific research. I use it as a shorthand term for getting through, to mass audiences and the people I am talking to, what we are trying to achieve. I always add the rider that a cure could be in the form of the ability to regain touch, to be able to touch your finger with your thumb, to be able to pick up a pen, to be able to turn a page—things like that. Maybe the golden chalice is for people to be able to walk again. I think all of those things are possible, but it depends on the level of injury, the completeness of the injury and the length of time that the person has suffered the injury and muscle atrophy and wastage and so on. So it means a lot of different things. Mainly it means a therapy that will add to the quality of life of a person suffering the injury.

Mr Langdon—As a person with motor neurone disease and also one who is meeting and talking all the time to people who are newly diagnosed, I can say that we talk about the treatment and a cure. When someone has been diagnosed by a neurologist and told they have three years to live and to go home and whatever, the first thing asked is, 'Why isn't there a cure for this?' Most times, when someone is diagnosed with this, they have never heard of it before. The fact is that there is not enough awareness, and people just go away and die somewhere, and those who do not come to terms with it then commit suicide—which is on the increase with motor neurone disease, because people just do not come to terms with it. But we always talk—and I do myself—first of having a treatment which will then lead to a cure.

Ms Knott—I concur with what Bob Turner was saying. On the one hand, it could mean small symptom improvements, like being able to move a hand more, or to get control over the bladder. On the other hand, it could be a lot more. In the last year we have heard about adult stem cells from the olfactory nerve, in the region of the nose, being injected back into the spinal cord. That is happening in Australia, but in Israel it is a little further ahead, and a woman has actually gained some improvement, some slight movement, from the work that is being carried out there. So it is very difficult at this stage to say exactly what it does mean. I totally agree that the word is used a little too loosely, but we would definitely hope for at least

small improvements and possibly more, with the flexibility that embryonic cells can potentially offer.

Senator McLUCAS—It probably reflects the hope for this.

Ms Knott—The hope to cure.

Mr Langdon—Yes.

Ms Royles—With juvenile diabetes, it really means living without insulin—which is a long way to curing it. Already in Canada people with type I diabetes are living without insulin through successful transplantation of insulin-producing islet cells. The big challenge is that there is a severely limited number of transplantations. In the US last year there were 1,400 pancreases available for transplant. When you look at the number of people who have type I diabetes, we are way off. We need to find another way of producing insulin-producing beta cells that can be transplanted. Certainly in the mouse model, we have already got proof of concept and, if we translate that into clinical trials, we potentially have a great source of insulin-producing islet cells. Obviously we still need antirejection drugs until we can overcome that, but for someone like James it means that he does not have to have three or four injections a day just to stay alive.

James Shepherd—I pretty much agree with what Sheila said.

Ms Royles—That's good. I have trained him well!

James Shepherd—I think getting the pancreas to produce more insulin would not actually do much. I would still have to have the needles, the finger pricks, the food in portions and the thinking about it, and exercise. Until I can live without the needles, there is really no significant difference. So when I use 'cure' in relation to juvenile diabetes I use it with its literal meaning.

Senator McLUCAS—One last question—probably to you, Ms Royles: has either CAMRA or JDRF done any analysis of the potential loss from the brain drain from our scientific community if we were not to progress with this legislation and were therefore to rule out the use of embryonic stem cells? Have you done any work on working out what would happen to our scientific community if that were to occur?

Ms Royles—As chief executive officer of JDRF Australia, it is something I am very concerned about, because I know that over the coming years JDRF will fund more embryonic stem cell research, assuming it goes the way we hope that it will go—and we have a great centre of excellence in Australia currently. I am really concerned about some of the initiatives that the Singapore government is implementing in their Industry 21, which is really to create knowledge industries that are going forward; and that is where their growth is going to come from. They are pumping a lot of money into creating centres of excellence, particularly around biotechnology. I am concerned that if we do not really position ourselves quickly—which is why we are keen to see the legislation to get through and provide some clarity—we are going to lose some of those researchers, particularly from Monash, which from a science perspective is a very well respected centre; and that is what I really want to avoid.

James Shepherd—Can I say before we shift,—and this may be a bit off topic but, if we go any further I probably will not be able to mention it without completely leaving the ballpark—that Senator Barnett said during his first question and speech that he could relate to those of us here with certain diseases. Something I would like to point out—I always forget something in my speech—is that it is not often that people without diseases relate to us. The media commonly refer to us as 'these people who deserve a transplant', and stuff like that. Even when I am talking, I say 'we'. Subconsciously people distance themselves. They think,

'That's them. I couldn't have that', whereas it is possible for anyone here to walk into hospital and walk out knowing that they have one of the diseases represented here. So the point should be made that we are just normal people who are unfortunate enough to catch these diseases; we are not a completely separate race of individuals.

Senator McLUCAS—That is a point very well made.

Senator HARRIS—A very good point. Firstly to Mr Turner and Ms Knott. In the closing section of your submission you make reference to the study by Roy Morgan International 2001 revealing that most Australians, up to 72 per cent, approve of scientists using stem cell extracted from excess embryos to treat disease. Prior to using that in your submission, did you have a look at the actual questions that were structured? One of the concerns that we have as a committee is that you can most definitely slant the type of response that you are going to get by the way you put the questions. My question to you is whether, prior to using that in your submission, you went back and looked at the actual questions themselves as well as the process of data collection.

Mr Turner—My answer is no.

Senator HARRIS—To Ms Royles, with the incidence of type I diabetes, we have had a figure of approximately 100,000 cases in Australia. I will assume that is in the reasonable ballpark. The committee has also heard evidence that, if embryonic stem cells were used, there is the possibility that it would require at least seven embryos to provide sufficient stem cells for a single treatment. So simple mathematics tells us that with 70,000 spare embryos available, seven of which it takes per treatment, that gives us the ability to do approximately 1,000 treatments. How would you see the appropriation of that one in 100 application? Are we actually creating a further dilemma—I am not saying that the process is not correct, but are we creating an enormous dilemma in going down that path?

Ms Royles—Can I ask a clarifying question? Where did you get the information about it requiring six embryos?

Senator HARRIS—At some of either committee hearings or in some of the lobbying, which is a word that has been used around here. The figure was put forward that it would take a minimum of seven embryos to extract sufficient stem cells to be able to then convert those into insulin producing cells. If that evidence is correct, then we are looking at one in 100, even in Australia. I think in America is it over 600,000 type I diabetes, and they have a similar problem.

Ms Royles—I am really interested to know where those statistics come from because I am struggling to believe it. The reason I say that is because one of the most exciting things for me about embryonic stem cells is their ability to replicate really forever, and once you have that stem cell line those individual stem cells that can be coaxed to become insulin producing beta cells. Really I am struggling to know where that fact would come from. It might be that that is in the context of getting the initial experiment happening, but in terms of on an ongoing basis, to me it does not make sense.

Senator HARRIS—It is not your understanding?

Ms Royles—No.

Mr Turner—Can we can have an opportunity to clarify that, not here but at a later date? I am sure Bernard Tuch would be able to tell you about that. Hasn't he been before the committee?

Senator HARRIS—This just emphasises some of the difficulties that the senators are facing in actually coming to an understanding of the complexity of the issue in front of us.

CHAIR—I think we will have to get clarification of those figures, Senator Harris. I have not heard those figures either.

Senator HARRIS—I will get those for the committee. Just briefly, if I could ask James, from the point of view of a person who suffers diabetes—and we have diabetes in my immediate family—from your own personal point of view, how do you believe that this legislation could be used to best assist you and people with juvenile diabetes?

Master Shepherd—I am not sure I can answer that.

CHAIR—James has actually given a very detailed position prior to your coming in. All the witnesses gave a detailed submission, which is on the *Hansard*, Senator.

Senator HARRADINE—I would like to ask Mr Langdon about community attitudes. How do you find community attitudes? How do you feel about the community? Are we living up to it as far as the issue is concerned, on disabilities in general?

Mr Langdon—As far as the issues go, my feedback from my people—I am also vice-president of the national association as well as being state president, and I am talking to people every day and I have a lot of information sent to me—is that within the community of motor neurone disease they want it done yesterday.

Senator HARRADINE—No, I am asking you about how people who do not have—well, we have all got disability—

Mr Langdon—Today I was picked up from my home by a taxidriver from the outer suburbs of Sydney. He saw me with my walking stick and wanted to know what was the matter and so forth, and I began to talk to him about it. By the time I got to the city—he lived at Auburn, so Moslem I would say he was, but the questions he was asking me, I was very impressed, and we had this—

Senator HARRADINE—I am sorry, you misunderstood —

Mr Langdon—What, are you talking about what you are doing here?

Senator HARRADINE—No, I am talking about does the community give enough support to persons with disabilities to be able to live as far as possible without too much—

Mr Langdon—No. Awareness of motor neurone disease is zilch compared to awareness of MS and Parkinson's disease. When this came out, they talked about Parkinson's disease, Alzheimer's disease and MS, but motor neurone disease did not get a run.

Senator HARRADINE—No, I noticed that.

Mr Langdon—People with motor neurone disease, you had to get out there and tell people that this is a neurological disease as well. As I said earlier, approximately you are looking at about $50,000-plus for day-to-day living for someone to live with motor neurone disease.

Senator HARRADINE—What about governments generally?

Mr Langdon—In New South Wales we have been very fortunate to get funding through the state government, but that has taken a lot of hard work with just little bits coming in all the time, but it is still never enough. Our associations throughout the states and also in Tasmania provide equipment—beds, wheelchairs and all that—at no cost. What happens within the system is that someone will apply, they want a manual wheelchair, but by the time they go through all the red tape and so forth they need an electric wheelchair or they are bedridden

and it is too late. So we, as associations, provide all that when it is needed, because some of these people are only around for 12 months for two years—

Senator HARRADINE—By the time it gets to them.

Mr Langdon—Yes. So I would say it is not enough. People go into a nursing home and they are put in with people with Alzheimers disease. Now here is something—it is called a nursing alert—that we have introduced. People fill this in when they go into a nursing home to alert the staff to simple things: communication; breathing; eating and drinking; 'I can't lift my arms or my shoulders; I can't understand or hear normally.' We have developed this for each person who goes into a hospital or a nursing home so they can fill it in, because there have been times when people have been taken to the toilet and left there because they cannot talk. Again, it is a matter of awareness. Getting back to this debate, if this legislation is passed, then it is going to start to make a change for those people and eventually, hopefully, a treatment will be found and these people will not have to suffer indignity like this.

Senator HARRADINE—That, Mr Langdon, is what we have to look at to see whether the money would be best put into research that is likely to get results rather than research which is purely conjectural and has not been—

Mr Langdon—As I said earlier, we are now approaching an ageing population, and the onset of this disease occurs at age 50. As I was saying to Senator Boswell before, I have statistics here to show that it is on the increase in Queensland, and it is on the increase around Australia. So as the population ages, more people will be diagnosed and there is a bigger cost to the community and to associations like ours, which have to find money to support these people.

Senator HARRADINE—Yes. I put it to you: is there any study that has been done which has gone to the proof of the concept of the use of embryonic stem cells to cure motor neurone disease?

Mr Langdon—No, not yet. Nothing.

Senator HARRADINE—Ms Royles, you are wearing two hats at the moment, are you?

Ms Royles—Yes.

Senator HARRADINE—The Juvenile Diabetes Research Foundation: is that part of the American association?

Ms Royles—Yes, we are one global organisation. We raise money locally but all our research is coordinated from the US. But all the money I raise down here goes to Australian research, and I actually pull additional funds down from the US because we fund far more research here than I could raise money for here.

Senator HARRADINE—With respect to Bernard Tuch—you mentioned him just a while ago—does he receive any of your—

Ms Royles—Yes, Bernie receives about $1 million over three years for the work he is doing in the liver field, not in embryonic stem cell research or any stem cell research.

Senator HARRADINE—And not any insulin work?

Ms Royles—Yes, it is all related to diabetes. I can double-check for you afterwards, Senator Harradine, exactly what it is. It is my understanding that it is looking at whether liver cells can produce insulin, so looking at whether we can get a different part of the body to produce insulin.

Senator HARRADINE—Where do those liver cells come from?

Ms Royles—Where do the liver cells come from?

Senator HARRADINE—Yes. What is the source?

Ms Royles—Sorry, I was not being—

Senator HARRADINE—No, what is the source of the liver cells?

Ms Royles—I do not know. You would have to ask Bernie.

Mr Turner—The person's own liver or another donor?

Ms Royles—My understanding is that it is the person's own liver, but I would have to double-check. I am not across—

Senator HARRADINE—Professor Tuch has had for a long time a project which has utilised aborted foetuses which are about 18 to 20 weeks old. Over the years this has not gone anywhere. In that circumstance, and indeed in the circumstance of the use of embryonic stem cells, do you declare to your donors that the source of the material is embryonic stem cells or foetal material?

Ms Royles—There are two comments I would like to make about that. Firstly, we do not fund Bernie Tuch for the work he is doing in that area, so I do not have an issue with explaining to donors about that because we do not fund him for that work. Secondly, in terms of the use of aborted foetuses, if that is the phrase we are using here, there has been legislation about that since 1983. This is not a new practice. This is something that has been legislated for quite a number of years. It has been raised as part of this embryonic debate but I think it muddies the water.

Senator HARRADINE—Are you saying there is legislation that bans the use of aborted foetuses?

Ms Royles—No, the legislation allows the use of that material. It was developed in 1983.

Senator HARRADINE—What I was asking you really was: does the association declare that some of the money is going for, say, embryonic stem cell research?

Ms Royles—In our annual report we say where all the money goes to, and we do detail—

Senator HARRADINE—What about the general public?

Ms Royles—The annual reports are available to the general public.

Senator HARRADINE—Yes.

Ms Royles—I am sorry. I do not understand your question, Senator Harradine.

Senator HARRADINE—I am asking you the question because you started off by saying, if I can get it right: 'Embryonic stem cell research provides the greatest hope for finding a cure for a number of diseases.'

Ms Royles—Yes.

Senator HARRADINE—Where is your proof of concept on that?

Ms Royles—In the submission that we made there were—

Senator HARRADINE—I know the submission, but that was not proof of concept, with respect. Are you saying that that is proof of concept?

Ms Royles—In the animal model our scientists have created insulin-producing beta cells from embryonic stem cells in the mouse model.

Senator HARRADINE—So what? Where does that go? That has not been utilised; that insulin has not been utilised for the purpose.

Ms Royles—We have cured diabetes in a mouse using embryonic stem cell research, coaxing them to become insulin-producing beta cells, and our research typically starts in the animal model before we move to human trials.

Senator HARRADINE—That has not been replicated and there is some question mark about that.

Ms Royles—It has not been replicated?

Senator HARRADINE—Yes.

Ms Royles—What do you mean?

Senator HARRADINE—Obviously when there is the publication of a particular finding there needs to be a replication.

Ms Royles—I can certainly look into getting you the details on the other experiments.

Senator HARRADINE—The reason I am raising the question is that you need to have extensive preclinical experimentation in animal research before undertaking human studies. Would you agree with that?

Ms Royles—Absolutely.

Senator HARRADINE—Under the circumstances, if this legislation does not go forward you would still then be needing to undertake extensive preclinical experimentation on animal models.

Ms Royles—I think that is the next step. My question would be how quickly we are going to get there. I think with the speed at which this type of research is moving we will very quickly catch up with moving into clinical trials. My concern with our making the decision to ban that here is that I do not think the legislation will move quickly enough to turn that over, given the speed at which the research is moving.

Senator HARRADINE—I have not seen anything to show that, and there have also been a number of scientists who have another view about that.

Ms Royles—Can you give me specifics?

Senator HARRADINE—I have given you specifics. For example, you and Mr Langdon mentioned quite correctly that motor neurone disease was not mentioned. There were a lot of other things, including Alzheimer's and a number of other diseases. On the question of Monash, do have some connection with Monash?

Ms Royles—We fund researchers there.

Senator HARRADINE—You fund researchers in what area?

Ms Royles—We fund Andrew Aliphanti and Martin Pera. Again, I would have to check what specific research we fund.

Senator HARRADINE—You fund Martin Pera, do you?

Ms Royles—Yes.

Senator HARRADINE—I would be interested to know.

Ms Royles—Sure. I could get that information for you.

Senator HARRADINE—Thank you very much. Do you agree that the intellectual integrity of a scientist depends on whether or not that scientist, having undertaken his experiments and examination, submits the results to a peer review journal and requires it to be accepted before that scientist trots it around the traps?

Ms Royles—Yes.

Senator HARRADINE—There was a notable exception to that recently, wasn't there?

Ms Royles—Are you referring to Professor Trounson?

Senator HARRADINE—Yes.

Ms Royles—Yes.

Senator HARRADINE—Is that a matter of concern to your foundation?

Ms Royles—I think it was an unfortunate incident. I have not spoken to Alan Trounson about it so I do not know what specifically happened there, but my understanding is that it was not his intention to mislead. I am sure there are different opinions around the room. The fact is that when you look at proof of principle, okay even if you exclude that, there are a number of different research breakthroughs that would indicate that embryonic stem cell research does hold potential, even if you exclude that one entirely.

Senator HARRADINE—Mr Turner, you described a bunch of cells that you could not see on top of a needle. Have you seen the bill that talks about experimentations are permitted on human embryos up till 14 days?

Mr Turner—That seems to be the consensus of scientific opinion. I would follow that—14 days.

Senator HARRADINE—What is so special about 14 days?

Mr Turner—Things happen within that embryo. It starts to develop beyond the stage of being a group of cells that could not exist by themselves. The concept of a human being then being put into dry ice and frozen, that hardly conveys the thought that that is actually an independent living creature. It is a group of cells at a developmental stage. As a non-scientist, I personally am happy to accept 14 days as specified in the legislation.

Senator HARRADINE—Does that mean a distinct individual human entity is not relevant for 14 days?

Mr Turner—How far back do you go? Parts of it, no; obviously there are things that come together, cells, but they still have to develop further. Sperm is the start of it, but it is not in itself—an egg is not capable by itself, and neither is the further generant capable of self-existence. Later, in 13 days, we accept that that is a reasonable line to draw.

CHAIR—Senator McLucas said she had a further question.

Ms Royles—Can I quickly tell you something. I want to ask a question about the embryonic stem cells in motor neurones. There was actually an article published less than four weeks ago in the *Cell* journal which talks about the success of converting embryonic stem cells into motor neurones, whatever you call them, axons I think. I am happy to table that with this summary.

Senator McLUCAS—This is an opportunity to respond to a statement that was in one of the earlier submissions that was put to us by a Dr McCullagh, where he said he was highly critical of what he called 'the exploitation of highly vulnerable people living with disabilities'. He went on to say, 'Individuals with major chronic disabling conditions are a resource to be

manipulated in TV stations'. I just thought I would ask your groups, given that you represent people who are living with diseases or disabilities, whether you feel exploited. Do you feel manipulated, and what do you say to people who try to speak for you in that way?

Ms Knott—I think it is sad that you would try to take on an opinion like that without actually living through the condition, but I for one was responsible for founding the Australasian Spinal Research Trust, so no-one could say I was manipulated into doing that. It is something that I cannot bear, living like this. I see other people around me who cannot bear it and they have the choice to join up, and they have or they have not. I certainly would not try to manipulate others to join, but I decided that it was something I felt strongly about. I feel strongly about that, so I have been one of the people to try and get other people involved, so no.

Mr Turner—Certainly, one of the things for myself, one of the things they fight against is being talked down to like that as though they have not got the ability to discriminate between what is exploitation and what is not. When I take him out in a wheelchair—I often do that, I am a secondary carer, I have to be—people talk to me instead of talking to him simply because he is in a wheelchair. This is symptomatic of that: 'They don't know what they're doing; poor fools. Somebody has their hand up their back manipulating them.' Nothing could be further from the truth.

James Shepherd—Can I ask how is it being suggested that we are being manipulated?

Senator BARNETT—What page, Senator?

Senator McLUCAS—They are not numbered, I am afraid. It is in section D of part 2 of Dr McCullagh's submission. He basically just makes a bland statement and says that people are being exploited and are a resource to be manipulated in television studios.

James Shepherd—I do not think I am being exploited in any way because of my disease. If I am being exploited, then I do not see why someone would be more liable to be manipulating me than they would someone else. People would not know that I am any different unless they see the needle or the finger prick or I have a diabetic episode. I cannot see any reality behind that statement. I have not been pushed into doing anything that I have done for the Juvenile Diabetes Research Foundation. I would like a cure, not only for myself but for all of the other 100,000 people that live with it.

Senator McLUCAS—A very ambassadorial statement, Mr Shepherd.

Mr Langdon—When I was diagnosed in 1988 I had never heard of motor neurone disease; I knew nothing about it. It took me two years to come to terms with the fact that I was told then I would be dead in three years. I got involved with the association in 1990. I went through sheer hell for two years to try to help other people because I heard the same thing when I met other people—'Never heard of it before. What is this?' I wanted to try and inform the community about it. There are times when I have had falls in the street and people have gone past commenting that I am drunk, or my speech has been slurred because I have been overtired. Straightaway they think you are drunk. When you say you have motor neurone disease, people think it is something to do with the NRMA. These are the sorts of things that we have got to get out there. We need to alert the community and tell people about it. I have been working now since 1990 and I live on a disability support pension. I do not get paid for anything I do. I do it while I still can, because I am one of the lucky ones who are still out and about and able to educate people about this.

CHAIR—When were you diagnosed, Mr Langdon?

Mr Langdon—It was 1988.

Senator BARNETT—A long three years.

Mr Langdon—Yes. The community needs to be informed. As I said to Senator Harradine earlier about people wanting to know why there is not a cure, it is getting to the point now where more people are being diagnosed. The number is growing: Vietnam veterans, Gulf War veterans—all these people are starting to come out with motor neurone disease.

Senator HARRADINE—Could I just ask a question? I have not picked up where McCullagh had said that, but I am just raising from—

Senator BARNETT—Second last page, Senator, under D. For your reference it is on the web; it is a public document. You can have a look at Dr Peter McCullagh's submission. It is probably best to read the whole thing and then you can look at in context. It is available; it is a public document.

Ms Royles—Are they on the web now, because they were not?

CHAIR—They will be soon.

Senator HARRADINE—I am not raising the question that the senator raised, but I just wanted to raise another question. Are you aware that Dr McCullagh raises this question about stem cell claims about degenerative diseases? He says:

> In reality, in some of the most energetically promoted claims, it is highly unlikely that they have anything to offer. As already mentioned above, the judgement of one of the most authoritative neuropathologists in Australia is that the stem cell claims for treatment of degenerative neurological diseases are 'fairyland'.

I think the person we were talking about was a professor from Melbourne University.

Ms Royles—Who was it?

Mr Turner—Is he a researcher or a consultant?

Senator HARRADINE—No, this was the person who was tops on neurological diseases in Melbourne.

Senator McLUCAS—He has not referenced that statement. He does not actually tell us who the most authoritative neuropathologist is so—

Senator HARRADINE—He says he does beforehand, but I cannot pick it up quickly enough.

Senator BARNETT—Professor Masters, is it?

Senator HARRADINE—Professor Masters.

Senator BARNETT—The Australian Society for Medical Research. Is that the one?

Senator HARRADINE—Where was that?

Senator BARNETT—Australian Society for Medical Research. I do not know if that is the one you are talking about.

Senator HARRADINE—Professor Masters, that is the one.

Senator McLUCAS—It is actually hard to connect—

Senator HARRADINE—I raise that question because one should not raise false hopes.

Ms Royles—It depends whether you believe they are false.

Mr Turner—We would agree. Has that person been published in a registered medical magazine?

Senator HARRADINE—I am sure Masters has.

Mr Turner—Can we find out which publication it was?

Senator HARRADINE—It is in here.

Mr Turner—Does it have peer review?

Senator HARRADINE—It is in this submission, and if you could check out for Professor Masters.

Mr Turner—It is not so much the person but, as you rightly pointed out before, has it been subject to peer review and has it been published in a reputable magazine?

Senator HARRADINE—Masters is a well-published person.

Mr Turner—No, that particular comment you are talking about.

Senator HARRADINE—No, this is part of a submission here, which says:

As already mentioned above, the judgement of one of the most authoritative neuropathologists in Australia is that the stem cell claims for treatment of degenerative neurological diseases are 'fairyland'.

I think he made that comment on the *Science Show*.

Ms Royles—I think he is entitled to his opinion. I think he is probably one of the few scientists who would agree with that. In a debate such as this there is always going to be a difference of opinion, but I would not hang my hat on one person saying that 'stem cell claims for treatment of degenerative neurological diseases are fairyland'. I would look at the other hard facts and whatever world renowned scientists are saying and where an organisation like JDRF is putting its money.

Senator BARNETT—JDRF and Ms Royles, you mentioned earlier about the funding for Martin Pera. Can you just advise us if the JDRF is funding—just take Australia first and then take the US—human embryo stem cell research?

Ms Royles—No, we are not funding any human embryonic stem cell research in Australia. I would have to check for you about research in the US. In terms of Martin Pera's research, it is about stem cells but obviously it is not embryonic stem cells because it is not allowed in Victoria. I am very happy to get some information to you, if that would be helpful.

Senator BARNETT—If that is not too difficult.

Ms Royles—No, I would be very happy to do that. Can I just ask a clarifying question? In terms of things we have agreed to get for you today, do we get a list or do we go through *Hansard* or how does it work?

CHAIR—We will follow up a list and provide it for you if that is the most convenient way, and then we can just crosscheck it.

Ms Royles—I have got most of it down, but I am not sure about everything.

CHAIR—That is fine. There will be a checking mechanism for you.

Senator HARRIS—I think to a degree as a committee we have erred—I know I have personally erred—in that your group has clearly indicated to us that you support both adult stem cell and embryonic stem cell research. I do not believe that we have allowed you to give or requested sufficient reasons for your support of adult stem cells. Without extending the committee hearing now, could I ask you whether, if there are any issues relating to adult stem cells that you wished to have brought to the committee, they could be forwarded to the committee?

CHAIR—Ms Royles has really set out a case for both—

Senator HARRIS—I know, but we have not questioned and given them the ability—we have focused only on embryonic stem cells.

CHAIR—If I may just finish. Ms Royles actually set out a case for both in her introductory comments, as did most of the other witnesses. I do not know whether they wish to add anything in particular to the comments that they have already made, but I thought that they had set out a very clear case for both forms of research, not just one. If the questioning has been primarily directed to one form of research then that has been a decision of honourable senators.

Ms Royles—If I can pick up on that, as you quite rightly say, it is really important to continue with both adult and embryonic research. The challenge that you are all facing is that adult research is not controversial; embryonic research is controversial. That is why we have focused on those issues very firmly, because we do not know who is going to win the race. JDRF's perspective is that it is likely that both of those two types of stem cells are going to have different applications, and I do not think that one particular type of stem cell, either adult or embryo, is going to be the solution to everything. I think it is going to end up being a mix.

Ms Knott—Yes, and ASRT would support you, and I think we are already funding adult stem cell research in Australia—in Victoria and Queensland I believe—and we will continue to do so. I guess our concern is that indications are that adult stem cells may not be so flexible and may not have the ability to replicate themselves quickly enough, and for that reason we would like both types of research to continue at this stage.

James Shepherd—If I am going completely down the wrong track, disregard what I am saying. But from what I understand, embryonic stem cells have the potential to become a cell in the body whereas adult stem cells come from a specific part of the body, so it is harder to manipulate them into becoming anything but more of the cell they come from. Adult stem cells may hold the cures or improvements but apparently embryonic stem cells have a greater possibility. It would be a wasted chance not to start research on either of these areas.

Senator BARNETT—I draw the attention of the chair to Catherine Verfaillie's research from the University of Minnesota—which I am sure you are aware of—which was published in *Nature* magazine and which I was interested in reading. It indicates that her research on adult stem cells—and this is only one piece of research —has the ability to differentiate in a similar manner to the human embryonic stem cell research, albeit her personal view was that both forms of research should continue. Others have the view that because her research said that adult stem cell research can have a similar outcome that the adult research should continue. So there are different views on it, but that is the research that I bring to your attention.

Ms Royles—We are absolutely aware of that but the challenge with adult stem cells is—I think it is really exciting research and I am delighted that that research has come out—that those cells are a lot harder to isolate. The other challenge is that unlike embryonic stem cells adult stem cells cannot replicate forever. In terms of having an abundant supply of stem cells, currently the feeling is that embryonic stem cells are far superior.

Senator BARNETT—It is a matter of abundant supply or adequate supply, but that is the debate we are having.

Ms Royles—Here, yes.

Senator HARRADINE—And CAMRA?

Ms Royles—Yes.

Mr Turner—There is also an opinion that adult stem cells age with the body, so mine are not going to be much use to anybody.

Senator HARRADINE—The Children's Medical Research Foundation is no longer a member of CAMRA, is it?

Ms Royles—It never was a member of CAMRA.

Senator HARRADINE—Have you not heard of the Children's Medical Research Foundation?

Mr Turner—We have heard of it, but it is not a member of CAMRA.

Ms Royles—It is not a member.

Senator HARRADINE—Not now?

Ms Royles—Never has been.

Senator HARRADINE—Never has been?

Ms Royles—No.

Mr Langdon—The members are listed on the circular here that we put out.

CHAIR—May I, in closing, say a very sincere thank you to you all. I do not wish my comments to sound in any way patronising, but I think that you have certainly shared with senators and this committee a very special part of your lives, regardless of the position the senators come from in their final decision. I thank you for giving the Senate your time and your experiences because I think they have been exceptionally valuable.

To you, James, I think one day we will probably see you on this side of the table. You are a very effective spokesman for your group of people. Well done! Thank you to you all.

Committee adjourned at 10.17 p.m.