COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

HOUSE OF REPRESENTATIVES

STANDING COMMITTEE ON LEGAL AND CONSTITUTIONAL AFFAIRS

Reference: Scientific, ethical and regulatory aspects relevant to human cloning

WEDNESDAY, 1 MARCH 2000

MELBOURNE

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HOUSE OF REPRESENTATIVES

STANDING COMMITTEE ON LEGAL AND CONSTITUTIONAL AFFAIRS

Members: Mr Andrews *(Chair)*, Mr Billson, Ms Julie Bishop, Mr Cadman, Mr Kerr, Ms Livermore, Mr Murphy, Ms Roxon, Mr St Clair and Mrs Vale

Members in attendance: Mr Andrews, Mr Cadman, Mr Murphy, Ms Roxon, Mr St Clair and Mrs Vale

Terms of reference for the inquiry:

To review the report of the Australian Health Ethics Committee of the National Health and Medical Research Council entitled *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings* dated 16 December 1998.

Committee met at 9.09 a.m.

PARTICIPANTS

BECK, Professor Felix, Consultant, Howard Florey Institute, University of Melbourne

CHALMERS, Professor Donald Roderick Curr, Chairman, Australian Health Ethics Committee

FISHER, Very Reverend Dr Anthony Colin, Episcopal Vicar for Health Care, Catholic Archdiocese of Melbourne

FORD, Reverend Dr Norman Michael, Director and Member of the Board of Management, Caroline Chisholm Centre for Health Ethics Inc.

HACKER, Dr Sandra, Vice President, Australian Medical Association; and Chair, AMA Ethics and Public Health Committee

MATTHEWS, Dr Philip Geoffrey, Chairman, Human Research and Ethics Committee

MENEY, Mr Christopher Laurence, Co-President, Association of Catholic Families

MUEHLENBERG, Mr Bill, Substitute, Festival of Light; and National Secretary, Australian Family Association

PALMER, Dr John Richard, Bioethical Coordinator, Royal Australian and New Zealand College of Obstetricians and Gynaecologists

PERA, Associate Professor Martin F., Senior Research Fellow, Monash Institute of Reproduction and Development, Monash University

PIERCY, Dr Eloise Claire (Private capacity)

PIKE, Dr Gregory Kym, Principal Research Officer, Southern Cross Bioethics Institute

PULLIN, Reverend Dr Christopher John, Consultant in Bioethics and Committee Member, Anglican Diocese of Melbourne Social Responsibilities Committee

RANSOM, Miss Helen Louise, Information Officer, Youth Concerned with Cloning

ROGERS, Dr John Graham, Chairman, Ethics and Social Issues Committee, Human Genetics Society of Australasia

SHORT, Professor Roger Valentine (Private capacity)

SIDHU, Mr Sarjit Alexander, President, Youth Concerned with Cloning

SKENE, Associate Professor Loane, Associate Professor and Reader, University of Melbourne

STRNAD, Mrs Halina, Convenor, Submissions Committee; Past President and Membership Secretary, Humanist Society of Victoria Inc.

TIGHE, Mrs Margaret, President, Right to Life Victoria; and Chairwoman, Right to Life Australia

TOBIN, Dr Bernadette, Director, Plunkett Centre for Ethics in Health Care, St Vincent's Hospital

TONTI-FILIPPINI, Mr Nicholas (Private capacity)

TROUNSON, Professor Alan O., Deputy Director, Monash Institute of Reproduction and Development, Monash University

WALSH, Dr Mary Dean, President, Ovulation Method Research and Reference Centre of Australia

WEBER, Ms Jennifer Irene, Executive Officer and Council Member, Council for Marriage and the Family, Catholic Archdiocese of Melbourne

WILLIAMSON, Professor Robert, Director, Victorian Clinical Genetics Service and Murdoch Childrens Research Institute

CHAIR—I declare open this public meeting of the House of Representatives Standing Committee on Legal and Constitutional Affairs as part of its inquiry into the scientific, ethical and regulatory aspects of human cloning. On behalf of the committee, I welcome all witnesses and members of the public here today. As you may know, the committee was given a reference by the Minister for Health and Aged Care to review the report entitled *Scientific, ethical and regulatory considerations relevant to the cloning of human beings* – a report written by the Australian Health Ethics Committee of the National Health and Medical Research Council.

For the purposes of the committee operating in a public forum format, it is our intention today to take evidence on the major issues in relation to the committee's terms of reference. This will cover the current status of

the science, the ethical concerns raised by the scientific processes and the legal responses to the issues. It will allow members of the public to put their questions and concerns forward for consideration by the committee and witnesses. In the interests of orderly proceedings and fairness to all, ladies and gentlemen, can I draw your attention to the procedures in the discussion paper and can I also ask the participants to observe strictly some procedural rules.

Firstly, if this forum is to constitute formal proceedings of the parliament and attract parliamentary privilege, then questions and answers and comments will need to be directed through me as chairman. If participants wish to raise issues for discussion, I would therefore ask them to direct their comments through me. Similarly, at the relevant time, if members of the public have questions, then they should be directed through me as chairman also. I will discuss some arrangements for these questions shortly.

Secondly, can I advise the various participants who are giving evidence today that, although the committee does not require you to give evidence under oath, the hearings today are legal proceedings of the parliament and warrant the same respect as proceedings of the House itself. The giving of false or misleading evidence is a serious matter and may be regarded as contempt of parliament. The evidence given today will be recorded by Hansard and, provided proceedings are conducted in a way outlined, will attract parliamentary privilege.

As indicated in today's program, proceedings are to cover the three major aspects of the terms of reference; namely, the scientific, ethical and regulatory issues. This first session this morning on scientific aspects will begin with brief statements by witnesses. These will be followed by questions from committee members and other witnesses and then we have a period of time for questions from the public, should there be such questions. Some of the issues for discussion during this session are set out on page 15 of the committee's discussion paper. If witnesses wish to raise additional key issues to these, would they please outline these briefly during their addresses.

I propose to call on those members of the public who have indicated to the secretariat staff that they wish to ask a question relating to the scientific aspects of the inquiry. Members of the public who wish to ask a question are invited to obtain a question form from the secretariat staff and return the form to them. Questions relating to ethical and regulatory aspects should be put to the afternoon's participants. For the accuracy of *Hansard* and to assist in a fair allocation of time, the form requires the question to be written briefly and that the person putting the question identify himself or herself. At the end of the session, if the question has not already been answered by participants, then I will call in turn on the persons who have written questions. They will then be invited to ask the question publicly. If there is not time for all questions to be asked, then the committee will endeavour, where possible, to pursue those questions at a later time and to make the answers public.

Before I call on those participants who are to make short statements on the relevant scientific aspects, it is our intention to invite Professor Don Chalmers, the Chairman of the Australian Health Ethics Committee, to make a brief introduction to this forum. We thought that that was appropriate, given the fact that the committee has been asked in effect to review the report of the Australian Health Ethics Committee on this subject. I therefore invite Professor Don Chalmers to make some introductory comments.

Prof. CHALMERS—I thank the chairman and members of the House of Representatives Standing Committee on Legal and Constitutional Affairs. By way of background, the Australian Health Ethics Committee is a body created under the National Health and Medical Research Council Act. Under the terms of that act, the minister can make requests and make references to that body. In fact, that was done towards the end of 1997, when there had been reports of cloning – particularly the cloning experiment involving Dolly from the Roslin Institute in Scotland – and when there had been efforts by UNESCO to produce a declaration in relation to the human gene and human rights.

During 1998, a working party of AHEC considered the scientific and ethical issues involved, including the regulatory issues, and handed a report to the minister at the end of 1998. It is important to note that that was a report from a committee to a federal minister. It did not follow the procedures for the publication of guidelines as prescribed under the terms of the NHMRC Act. In those cases there have to be procedures involving formal public consultations. We did not do that – the working party took specialist advice from scientists, ethicists and so on to inform the committee. They were not published in the form of guidelines.

Essentially, we gave four recommendations so that as an interim measure it was appropriate that the minister could confirm article 11 of the UNESCO declaration, which essentially stated that reproductive cloning involving the intentional creation of another human being using cloning techniques was a prohibitive practice and that it would be appropriate for the federal government to, in reality as well as symbolically, state that that was a standard to which this country aspired. We stated that we felt this was an area in which it was appropriate to introduce state and territory legislation. It is a recommendation which was consistent with previous recommendations in relation to in-vitro fertilisation, published after public consultation by AHEC. We felt that that legislation should include some form of statutory authorities which would be able to give permission, regulate, license and monitor. Finally, we felt that this was an area where the information coming before the

public was at times rather garish and excitable. It was very important, in view of the science involved, that there should be efforts to ensure that the community debate was not only conducted but also conducted in an informed fashion.

We also should state that we felt that there were ways in which the science could be supported. We suggested it might be worth investigating the establishment of an animal colony for the conduct of some of the primary work. We felt also that in the interim the NHMRC could consider establishing a formal two-tier structure so that any experiment which was accepted in a non-legislative jurisdiction and was subject to an approval by an ethics committee should be reviewed by some larger overriding committee comprised within the NHMRC. I hope, in the very short time that I have been permitted to chair, it will be helpful to our deliberations if we try to draw out one or two implications of the report.

First and most importantly, the committee looked at the source of the material to be involved in cloning. Some of those procedures were directed towards the use of the human embryo. It was the assumption throughout the terms of the report that the legislation in the various states and the principles embodied in a number of national reports suggested and led to no other conclusion than the fact that this country has a view about the integrity and dignity of the human embryo and that research should not be conducted on the human embryo, except according to prescribed regulation. Secondly, we were conscious of a growing body of international opinion represented by official documents – such as the Universal Declaration of the Human Genome and Human Rights and the European Convention on Human Rights and Biomedicine – which set standards in relation to the conduct of research in this area. Thirdly, we felt that, although the language perhaps is not perfect in the use of terms such as 'reproductive' and 'therapeutic cloning', a distinction could be made between any steps to clone a human person and any efforts to clone human parts. We felt that was a distinction that might help some of the discussion.

Fourthly, I think it is important to state that we took the view, from the evidence we had before us, that there was a capacity to conduct some of this science in this country and that there was potential. How large that is I think has become clearer over the years since we reported. There is a question about the reality of the benefits to be derived but there is undoubtedly a potential there. We were also conscious within the science that a number of animal experiments were proceeding where there were efforts to try and produce disease resistant animals which would be able to lower the use of antibiotics in the food chain. We were conscious also of the development of xenotransplantation – trying to develop transgenic animals – where the human gene transplanted in the animal could therefore perhaps produce an organ suitable for transplantation to humans without the possibility of rejection; and, finally, the use of transgenic experiments to try to develop proteins and medicines from animal sources.

Fifthly, we were concerned that this country has an effective system of regulation of the public areas of research but in many cases we are not quite so strong in the area of private organisation regulation. Our feeling is that much of this work could be done in the private sector and for that reason regulation beyond the NHMRC framework might be required. Sixthly, we pointed out that there is an extraordinary investment internationally and nationally in the biotechnology area, and those commercial interests are a very noticeable aspect of this work. Seventhly, one of the ways in which we were talking about regulating is a way in which one might want to monitor developments – require official reports from time to time so that there can be a proper mapping of the development of the science and the procedures. Again, we felt that regulation was necessary for that and, in that form, legislation.

Finally, we felt that if the science is to proceed, as a community we owe it to the scientists to try and clarify, through legislation, those circumstances in which procedures may be acceptable after consideration and those cases in which a line may be drawn and where this country might prefer not to follow those particular procedures.

In closing, our report was considered by the Academy of Science and I believe there will be some discussion during the course of today. It might be helpful if I very briefly state that I think there were points of confluence and concurrence in both the reports. For example, the Academy of Science agreed that we must ensure that there is proper and adequate informed community debate in this area. Secondly, they also accepted that there is a capacity in Australian science to play a part in this new science. Thirdly, I think they agreed that there should be some form of regulation, although, as we will see later, there were some differences in the way in which that may be implemented. But I think that will be clarified later. I hope, Chair, that that is a helpful introduction and background.

CHAIR—I will now proceed with the scientific presentations. We will begin with the Monash Institute of Reproduction and Development with Professor Trounson and Associate Professor Pera.

Prof. TROUNSON—Thank you. We are pleased to be here. I would like to assure the committee that the scientists working in this area have very strong feelings that the cloning of the human person, or reproductive cloning, is not something we think is medically justified. We have had those agreements placed in the societies

to which we belong – the Fertility Society of Australia and the Australian Society of Reproductive Biology. We are very firmly against reproductive cloning or the cloning of people. Where some of the problems arise is what you mean by cloning. I think this still requires some definition of what we are talking about. You can clone a gene and that is gene cloning; you can clone a cell and that is cell cloning, or you can clone an embryo and that is embryo cloning. Possibly you could clone a person and that would be reproductive cloning or cloning of people.

Overhead transparencies were then shown—

Prof. TROUNSON—What we are really concerned with – and historically the two things have become interlinked – is that we believe there is a very strong reason to conduct research on the formation of human embryonic stem cells. Originally, cloning and embryonic stem cells were linked because it was thought, prior to Dolly the sheep, that the only way of cloning a person was through embryonic stem cells. That is shown to be incorrect now. You can clone at least ruminant animals and rodents – mice, sheep and cows – from all cells of the body.

So the two things were linked, and that is why they were present in the NHMRC's regulations. That is why we are still dealing with them in a linked fashion, which is probably, I think, unfortunate. What happens in the derivation of embryonic stem cells is that you actually take embryos that are no longer required by the patients – that is, at the end of their interest in IVF treatment — and you would normally either donate those embryos to other patients, if that is a possibility, or you would use them for research if that is a possibility, or you would discard them, you would throw them away in some sort of way — leave them on the bench or throw them out.

Some six or eight years ago I did a sabbatical leave at the National University of Singapore. My colleague Professor Ariff Bongso and I were very interested in the possibility of generating human embryonic stem cells. The Human Research and Ethics Committee of Singapore agreed with us. They gave us permission to go ahead and do that. We set out to attempt to derive these cells. What happens is that if you take an embryo at the completion of its use – it is normally frozen so you thaw it out – and actually remove what is known as the inside cells of what is called a floating blastocyst up there, and you plate it down on a cell monolayer. You then allow those cells, which are undifferentiated cells – they have the capacity to form all cells of the body hypothetically – and then you are able to grow those in culture indefinitely and eventually produce cells which you can then differentiate into the primary lineages of tissues of the body, that is, ectoderm, endoderm and mesoderm.

We did that, and Dr Pera will describe those experiments briefly and the outcomes to you. We derived two cell lines from four embryos. We now have enough cells to keep all of us working at the Institute of Reproduction and Development on this subject of embryonic stem cells for ever more. We do actually want to rederive these embryos because there has been a draft document produced by the National Institutes of Health on procedures relating to working on human embryonic stem cells and human gonadal cells. I have given a copy to the chairman.

This would be a benchmark for the way you derive, use and work on embryonic stem cells. We believe that the rederivation of the cells under those particular guidelines would be a benchmark way of working with these cells. If we want to derive four new lines of embryonic stem cells we would theoretically use eight embryos and we would not really want to use any more ever again. We would have enough cells there to supply all the research institutes in Australia, and probably world-wide, with cells to work in this area. I want you to have an idea of the numbers of embryos that may be involved in the derivation of these cells.

The important part of what these cells can mean is that once we have these embryonic stem cells – and they are shown in cartoon form at the top – you can get them to differentiate down the mesoderm cell line and form blood cells and muscle cells; all the blood cells of the body, all types of muscle cells including heart muscle cells. And we indeed see, from the embryonic stem cells that we have formed, muscle cells beating in culture and we now are able to form some of the blood cell types that would be of some importance in the body. If you look at the ectoderm line, which is on the right hand side as I look at the slide, you can form nerve cells, neuronal cells. These are cells that form very frequently in our cultures. They would be candidate cells for work in association with neuronal diseases and the possibility eventually of transplantation to patients with stroke, Parkinson's disease, Alzheimer's disease and so on.

The middle line, which we ourselves are most interested in, is the endoderm cell line, which goes to form cells of the lung, gut and liver. Nobody has actually done any work in that area, so the understanding of how those cells would form is completely unknown. This is the research that is presently occurring at the Monash institute. This is what everybody in every one of the institutes in Australia wants to do: they want to obtain some of these cell lines, form the cells that they are interested in and examine whether they are of some interest to their experiments. It is more like a branch of a tree; at every intersection there there would be factors that we need to discover that direct the cells into those various states. So it is truly a discovery program on which our

colleagues and our associates have set out in a major way. This work is currently being done in Singapore, at the National University of Singapore, in our institute and at the Hadassa University in Israel.

We are not in any way interested in a cloning procedure at the present time, and this cartoon in a way shows the argument about why some people would want to be interested at the moment in it. If you derive these embryonic stem cells, they are still foreign and therefore may be subject to rejection by the body because they are foreign tissue. That may not be the case if they are put in protected areas, such as the brain or the spinal column – they may not be rejected there; but if they are put into soft tissue places they may well be rejected. So the reason that people would be interested in cloning in this respect would be that you may want to derive the embryonic stem cells from the sick individual, the baby or the adult person who is ill, take a cell from that person, fuse it with an egg cell and then produce an embryonic stem cell.

We think that by the time we are interested in transplantation – and I believe that is four, five, six, seven, eight years time – there may be other options rather than going that route. If we understand the differentiation pathway, then we will probably understand the dedifferentiation pathway, so we would hope, in the fullness of time, that if you do need a neuronal cell transplant we may be able to take a small number of cells from your liver and then run it backwards up the dedifferentiation pathway and produce your neuronal cells. These are aspects of research which will need to come in the future. But if you wanted to try and do the transplantation procedure at the moment you may want to derive the embryonic stem cells from the sick individual and, hence, that is the reason there is some interest in a cloning procedure in association with stem cells.

Finally, I believe the derivation of these cells is one of the biggest breakthroughs in human medicine. I think they have been correctly described by Roger Short and others as the mother of all cells. There is no way in which anybody can derive the base cell lines that are of interest through any other way than making embryonic stem cells. There is no other way of doing it. This needs to be research and eventually medicine for the whole of Australia and for the whole of the global humanity. We need to be participating in that, we have a very frontline position at the moment, and we want to. All the research institutes that I know of in Australia that are working with cells for transplantation or of interest in understanding the derivation of cancers want to collaborate with us, they want to obtain cells. I guess if we were prevented from ever doing this work they would probably buy the cells from the United States under the auspices of the NIH, National Institutes of Health, but we would prefer that we would work together here in Australia, utilising these extremely interesting and, I believe, extremely valuable cell lines.

CHAIR—Thank you, Professor Trounson.

Prof. PERA—Mr Chairman, members of the committee and ladies and gentlemen, thank you for the opportunity to address this forum today. I would be happy to answer specific questions about our research program if you are interested but I thought I would speak directly to some specific questions that have arisen on page 15 of the discussion document.

There are four areas I would like to speak to: first of all, the question of the application of embryonic stem cells and the time frame in which some of these applications may be realised; secondly, I would like to speak to the issue of alternatives to stem cells derived from embryos; thirdly, I would like to address the Australian position in this area, where we stand, and what possible barriers to progress exist; and, finally, I would like to outline what is at stake for Australian research and biotechnology when you are deliberating about our involvement in this field.

If we begin with the applications of embryonic stem cells, basically I see these in four areas: basic research into human development and disorders thereof, including birth defects and certain types of childhood embryonal tumours; secondly, the discovery of novel protein factors which may be used to drive tissue regeneration and repair if administered therapeutically; thirdly, the development of in-vitro human cell models for drug discovery and toxicology in the pharmaceutical industry; and, fourthly, the development of tissue for transplantation, which has really attracted the most attention.

I point out to you that the first three of those applications really by and large do not require any access to cloning technology whatsoever. They can be achieved pretty much with stem cell lines derived from embryos – a very small number of stem cell lines, as Alan pointed out. It is only the fourth one where the cloning technology really comes into play. It might be that for the third application we might want to use the cloning technology to make cell lines from individuals with particular genetic susceptibility to disease but, by and large, for much of the research cloning really is not required.

Turning to the second overhead, if we talk about the time frame I am only thinking in a 10-year time frame. I think the first set of objectives, basic research on human development, is already happening. We are already using the cell lines to identify new genes expressed in early human development. I think within the next one to 10 years we will see the identification of factors active in tissue regeneration and repair. The in-vitro models for drug discovery and toxicology will come on line perhaps in two to three years time, and I think transplan-

tation is really the longest goal in terms of time frame and we will see that happening within perhaps five to 10 years before the beginning of clinical applications.

Going to the next overhead, there are alternatives to stem cells derived from embryos for certain purposes. We might consider adult tissue stem cells. There are some tissues – skin is an example – for which we can obtain the stem cells from adult tissue and propagate them in culture dishes and expand them. This has been known in skin for many years from the work of Howard Green and James Rheinwald. Unfortunately, for many tissues it is impossible for us to grow and expand stem cells from many adult tissues in the laboratory. Also, if you are talking about a patient's specific cells, it requires that some healthy stem cells be present, and we can imagine many circumstances in which that would not be the case.

The second area of alternative is that of transdifferentiation or dedifferentiation, taking an adult cell of one tissue type and somehow reprogramming it to form a different desired type of tissue for transplantation. There are some very exciting recent advances in that area and it has some potential, but I have to point out to you that the mechanism, and even a basic phenomenology of what is going on in these experiments, is very poorly understood at present and it may be a long time before we know how to control that process. I also point out that for many years there have been examples of transdifferentiation in animal tissues which are very well described but as yet the mechanisms remain unclear. So there will be an awful lot of work before those observations are translated into any sort of application.

Turning to the next slide, if we consider unique roles for stem cells derived from embryos, these include the study of early human development and its disorders and contraceptive development. These early embryonic cells may be the only way to identify new factors that are active on early, very primitive, progenitor cell populations. An example is the factor known as LIF discovered on mouse stem cells which turns out to have many activities on different types of adult cells and many interesting potential applications.

ES cells play a unique role as a source of progenitors for tissues in the adult where stem cells are not present or well characterised. Finally and most importantly, basic research on embryonic stem cells will teach us what pluripotentiality is. What is a primitive undifferentiated cell? What gives it the ability to turn into all those types of adult tissues? It is really this basic research, perhaps the identification of key genes that control that feature of embryonic stem cells, that may eventually teach us how to eliminate the need for embryos and how to reprogram adult cells — which many of us would like to be able to do. But it is only by studying pluripotent cells that we will learn that.

This slide considers the Australian advantages in this field. We have several groups at the forefront of the work. It is not just us. Peter Rathjen's group in South Australia is doing very innovative work in embryonic stem cell biology. Australia, as a whole, has a longstanding track record on reproductive biology, growth factor and stem cell research. Although the developmental biology community here is small, it is of very high quality and makes very significant contributions on the international scale. I would add to that, of course, the more recent efforts in human genomics at many centres throughout the country which will very much support this work.

Considering briefly what are the potential barriers to progress, I see a lack of national research guidelines or strategy as one barrier. Secondly, the biotechnology industry relative to that in the states is small. There are moves to address that in the various states, including Victoria. But I pointed out to people that a trickle-down effect that takes five or 10 years to come through is too late for us in this business. Restrictive legislation could hamper the work very seriously. Finally, I would like to point out that if there is no national government funding, we will have to rely on private capital. That will very much reduce our ability to collaborate and to disseminate the technology. In other words, our backers will not want us giving cells to our competitors or technology to our competitors that will threaten their intellectual property position. We are very much in favour of government funding and of a mixed economy to speed progress in the dissemination of the technology.

Finally, what is at stake? It is very clear if you travel in the United States now and attend conferences that ES cell technology is going to have a major impact on biotechnology and on the pharmaceutical industry. It is likely through transplantation medicine to have a major role in what is now called regenerative medicine. Since I work in an institute where many of my colleagues are involved in agriculture, there will be likely spin-offs in agriculture and agricultural biotechnology as discoveries in human ES cell biology are applied to other species. That is what is at stake and that is what one will be forgoing unless we have an active program in this type of research. Thank you.

CHAIR—Thank you, Professor Pera. Before I call on Professor Short, it would be useful to know whether any other participants are planning to use overheads or slides. We have a monitor, as you can see, but for some technical reason it is not working.

Rev. Dr FORD—I would like to use some this afternoon.

CHAIR—We will deal with that this afternoon. Whilst it is sometimes suggested that having eyes in the back of your head is a useful attribute for politicians, we actually do not.

Prof. SHORT—Perhaps the way that I could be most useful to the committee and to the members of the public here would be to give a rather superficial review of the issues that I see facing us. Firstly, from reading the background documents, there is the widespread concern by non-scientists that scientists are using the terminology 'reproductive and therapeutic cloning' to conceal something. That is absolutely the reverse of our intention. I think several of us feel that it may not be the most appropriate terminology — and Don Chalmers has referred to this — so if anyone could think of a better terminology, we would be delighted to accept it.

The reason we make a distinction between reproductive and therapeutic cloning is that reproductive cloning was meant as reproducing another adult individual. Therapeutic cloning was meant as cloning a tissue or an organ which could be used to treat a disease. The two are completely distinct and there is no fear or possibility that one might shade into the other, as has been suggested in some of the evidence. So if we are at fault in using obscurantist terminology, please put us right, not by criticising it but by developing something that is clearer. I think there is uniform agreement in scientific circles around the whole world that reproductive cloning, creating a new adult individual or a foetus by cloning technology, is not something that we want to see, and I do not feel it needs any further discussion.

May I therefore concentrate on therapeutic clothing and bring out the second point that does not seem to be widely understood from the background documents. Here is Dolly the sheep, published exactly three years ago — at the end of February 1997 — by Ian Wilmut, showing that you could take a differentiated somatic cell and put it into an enucleated, unfertilised egg and get a new individual. I remember very distinctly talking to Ian Wilmut about four months after the publication of that paper and saying to him, 'What do you think this means for humans?' He said, 'I don't know; I can't quite think where it will go next.' What caused the excitement was a completely different discovery — the discovery of primate and then human embryonic stem cells. Human embryonic stem cells only were revealed in November 1998. By combining these two technologies, you get a new product which is a therapeutic cloning — it is a cloned embryonic stem cell. And it is the cloned embryonic stem cell that we are particularly fascinated with from a scientific viewpoint.

To put your fears at rest, to generate cloned embryonic stem cells you do not need to put a human embryo into a uterus. All you need is an enucleated unfertilised egg into which you can put a somatic cell nucleus and the rest of the procedure is done in tissue culture. True, the egg has to be donated by somebody, but since it has lost its nucleus it has lost its nuclear DNA, and we are only talking about putting somatic cells into that enucleated cell. So there is no thought in the scientific community of putting cloned human embryos back into somebody's uterus. I think that points needs to be made clearly because there is obviously confusion from the background documents that we have on the part of some people as to what the scientific intentions are. It may be that we have not clarified ourselves sufficiently in the past.

I have been trying to do some reading as to why people think that life begins when it does. In fact I have just published a paper in *Nature* this week called *Where do human babies come from?* which I will pass to the chair. You may be interested. It seems to me that one could allay the fears of Catholics, at least, because if we take the Catholic viewpoint as expressed in donum vitae, that life begins when the sperm meets the egg, in therapeutic cloning no sperm meets an egg. We are taking an enucleated egg and we are putting a somatic cell into it, so is therapeutic cloning even creating life in terms of the Catholic definition of life as described in donum vitae? It is certainly not creating life according to the donum vitae definition.

If I can conclude by following on from Martin's example and going through your issues for discussions very briefly, I think we have now talked about therapeutic cloning. On the probability and likely time frame, it is anyone's guess – I think we would all probably go by the five to 10 years. There is an enormous amount of work to be done before we can actually see potential applications. What is the potential for developing stem cell therapies that do not rely on cells from embryos? As I have just said, in therapeutic cloning we are not creating an embryo, as per the definition of embryo, so I do not think that is a major issue. And Martin has explained, and so has Alan, the possibility that we may be able to partially dedifferentiate cells in the future so that you do not have to go back to an embryonic stem cell; you may be able to develop the technology to take liver tissue and get a liver stem cell. But that is for the future – no-one has done that yet.

On the issue of the range in hitherto untreatable disorders that may become amenable, I would like to make a very important plea, which I think will be emphasised by my colleague Bob Williamson, because it is in his submission. I do not know if there is anyone in this room who is HIV positive, but if there were my sympathies would be with them. Kofi Annan, the UN Secretary-General, has just said in a public lecture in London – the Princess Diana Lecture – that, for the first time, human civilisation is threatened by a disease, AIDS, and we owe it to humanity to do all that we can to preserve human life. The latest figure, as of January this year, given by the WHO-UN AIDS program, is that today there are 50 million people who are HIV positive.

Therapeutic cloning might be able to save their lives. How? You take a scraping of your own buccal epithelium, because the cells in the lining of the mouth have no receptor for the HIV virus and so are uninfected. You could put the nucleus of one of those cells into an enucleated egg and, in vitro, in the way that Alan has described, culture your own cloned embryonic stem cells. And, if we could find the magical way of differentiating those cells, we could produce your own lymphoid tissue, which would restore your immune system and so save you, at least in the short term, from the devastating immunological incompetence created by AIDS. I agree wholeheartedly with what Bob Williamson has said, that we should not be considering the ethics of whether we should be using therapeutic cloning; we should regard it as highly unethical to ban it.

To come on to just one or two of the other issues, I do not need to repeat what Martin has said very elegantly about the status of Australian laboratories. Let me just end with the suggestion – and it is the only point with which I would really disagree with the AHEC document – about the feasibility of establishing an Australian facility for stem cell research in non-human primates. May I refer you all to the wise words of Alexander Pope:

The proper study of mankind is man.

I cannot think of a single piece of evidence that we gleaned from primates that helped in the development of human artificial insemination and in-vitro fertilisation. All the in-vitro fertilisation technology, much of it pioneered here in Australia by Alan, depended not one jot on any information obtained from a primate. It was obtained from humans. To set up a primate colony to try and do embryonic stem cell research would be ducking the issue and diverting scarce resources from the real core of the question, which is to study human embryonic stem cells, particularly those produced by cloning. I do not think there are any other issues that I would like to comment on. Thank you very much for your time.

Prof. WILLIAMSON—The Murdoch Institute is now the Murdoch Children's Research Institute. The institute's 350 staff makes it the largest institute focusing on neonatal, paediatric and public health in Australia in this field. It is very much concerned with developing new therapies for genetic and acquired genetic diseases in children ranging from thalassaemia through to leukaemia and other diseases that affect particular groups. It also includes the Victorian Clinical Genetics Service that offers clinical care and counselling for all children born with inherited and genetic disorders in Victoria. We are very pleased and proud of the fact that we offer counselling to everyone. We have clinics at the Mercy Hospital, Monash, and Royal Melbourne. We are able to offer services to those of all views. We are very pleased at the feedback we get that we do so with sensitivity to the views of all people in Victoria.

I want to deal with two or three specific issues. Firstly, I want to state unequivocally that our service sees no medical reason that could justify reproductive cloning. We have considered this. We deal with every one of the genetic and acquired genetic disorders in Victoria. We are responsible for this and can see no justification. In addition, as biologists, most of us feel with greater or lesser emphasis that reproductive cloning would reduce autonomy and diversity, all of which are good biological systems, quite apart from personal views, religious or otherwise, that lead us to be against them. There are very good reasons to be against reproductive cloning. As a member of the WHO ethics committee I also saw these views reflected in the WHO documentation on this. However, stem cell research is extremely important clinically.

I occasionally use the term 'embryonic stem cell research' but it does not seem useful to me any longer to use the term. Embryonic stem cell research seems to imply that a stem cell is derived from an embryo. Let's consider the sort of situation that I envisage in the next two to three years. A seven-, eight- or nine-year-old child has leukaemia, has been thrown into remission and then goes into relapse. A skin cell from that child is taken and the mother of that child donates eggs, not embryos. The eggs are enucleated. The child's skin cell is passed through the egg to generate a clone of cells in a tissue culture dish. That clone of cells is then differentiated, in ways we do not yet have the full power to do but are beginning to develop, down a cell pathway which means it can be used to replace the bone marrow of that child. It is wrong to call these embryonic stem cells because no embryo has been involved. No embryo has been created or destroyed. What we have done is to turn a skin cell into a cell that is totipotent and has the potential to redifferentiate, to reform, into a bone marrow cell.

If one went through another 20 procedures and put that cell into a uterus, one would have one chance in a thousand of developing an embryo from that cell. But, if one takes the line that just because one could do that that this is an embryo, then one ends up in the reductio ad absurdum position that every cell in our body is an embryo and every time you wash your hands you are killing a thousand or a million embryos. This is clearly not true. Some commonsense has to enter into it. Since no embryo is destroyed and since the purpose of this is just to keep the cells growing in culture, I actually cannot see that there are reasonable objections to this.

I think that the issue of destruction of embryos is a separate issue. But I do not see any reason to call these embryonic stem cells; I would call them totipotent stem cells because they are not derived from embryos and they are not being used to make embryos. Why call them embryonic? It is just confuses the issue. It just raises a red flag to some people, totally unnecessarily.

Before making my next point I would like to say that I, personally, am someone who is very, very committed against reproductive cloning. I would actually be in favour of having legislation to prevent reproductive cloning. I have no difficulty at all with that.

The second point I would make is about being competitive in this field. We are competitive in stem cell research. In particular, Professor Trounson's group and Professor Rathjen's group in Adelaide come to mind. We do not work on stem cell research in this sense within my institute. However, we are doing a great deal of work on how to use the human genome project in order to treat inherited disease – diseases like thalassaemia, which is particular common in Greek, Italian and South-East Asian communities, and cystic fibrosis, particularly common in Scottish and Irish communities, and so on. If we want to treat these diseases, we have to have the ability to use stem cells as part of our understanding of the way in which these genes function. If we do not have a strong stem cell technology within Australia, anything we develop will have to go to the States or Europe in order to be further developed. I think this will undermine the fledgling, developing Australian biotechnology industry which is so much a future of our country's development. One should remember in this context that, of the seven million new jobs that have developed in the United States over the past 10 years, 3½ million have developed in microtechnology and biotechnology in small and medium enterprises. That is where the growth sector is. If we do not have the ability – and it is not an embryonic stem cell ability, it is a stem cell ability; the two are not the same – then we are going to put at risk much of the development which many institutes in Australia which do not have a specific interest in embryology nonetheless have a downstream interest in. I should add that I very much agree with Professor Short that we do not need a primate facility in Australia. I think that would be a backward step.

The final point I would to make is about regulatory mechanisms. There are, as you know much better than me, problems concerning the division of power between states and Commonwealth as to exactly where mechanisms stand. In general, I do not hold up the English regulatory mechanisms as a model in most fields, having lived there for some years. However, in this particular field, the idea of having a regulation that by law anyone, public or private, who proposes to carry out experiments in this area has to refer them to an expert committee appears to me to solve two problems. The first is the state-Commonwealth problem. Since this would be a regulatory legislation, I understand it would be legitimate for it to be Commonwealth and therefore apply to all states and territories. The second is that it would cover public and private. It would cover the entire section. It would be legally binding but it also would be flexible to meet new advances.

The legislation in Victoria was only enacted five years ago and it is now hopelessly out of date in terms of dealing with the new technology. I think it is the one thing everyone around this table would probably agree on. I think that regulations which are compulsory but which do not give all of the definitions – which change – would be a great advantage.

CHAIR—Thank you, Professor Williamson.

Prof. BECK—Most of my colleagues have now pointed out the major issues concerned with cloning, and I really have just one point to make which I think underlines to some extent what Roger Short has said. Recent advances in reproductive biology and in medicine have highlighted the somewhat arbitrary nature of defining the inception of a human being. From time to time we have had various definitions of what that is. They have included fertilisation of the egg, fusion of the sperm and egg nuclei; implantation of the fertilised egg, gastrulation, the appearance of the neural plate and the first signs of nervous system function. All sorts of things have been suggested as being the time at which a human being starts.

As Roger pointed out very cogently, the cloning of sheep from adult nuclei which are located outside the ovary and the testis have eliminated the concept of the unique nature of the fusion of sperm and egg in creating a human being. The debate should therefore be moved from this somewhat esoteric philosophical approach to a practical approach, and that is the approach we have heard from the scientists here this morning.

As I pointed out in my written submission to this forum, we have to consider three levels of cloning: whole animal cloning; cell cloning and tissue cloning; and, finally, DNA cloning. Clearly, as we have heard unanimously from all the scientists here, the first of these, when applied to humans, is unacceptable in civilised society, whereas the other two already confer major benefits to the medical community. They hold out, as we have very cogently heard today, quite untold promise for the future.

However, all these three levels of cloning carry risks, as we know, and they confer the benefits that we have heard of. My plea is that, without a factually based understanding of the science that underlies these things, it is impossible for us to arrive at an ethical modus operandi. I would like you to bear in mind this arbitrary question of when does a human being start and what is an embryo? It really is, in my opinion, a myth nowadays in terms of scientific knowledge.

CHAIR—Thank you, Professor Beck. We will open the forum to some questions from members of the committee. Can I just seek to clarify something which is not entirely clear in my own mind on the basis of the various presentations. I understood from what you were putting to us, Professor Trounson, that creating the

stem cell lines — which you have done and which you may wish to do in the future in accordance with the NIH guidelines — involved the use of some embryos. But then I was listening to Professor Williamson and Professor Short speaking about using somatic cells with an enucleated egg for the purposes of creating stem cells. Do I understand that to be a different process which does not involve embryos; that what Professor Trounson has done and may do is something entirely separate from what you were talking about and that we ought to divide the two in terms of the way in which we approach them?

Prof. TROUNSON—I should let others comments. As practical scientists, we would use exactly the same techniques to derive the initial embryos for therapeutic cloning as we would for the embryonic stem cells, except that we would use a nuclear transfer procedure to establish those embryos. In calling them embryos, very few of those embryos at the present time in any species will go through to term. It is a very low efficiency process, if you like.

A cloning or a nuclear transfer procedure produces a great array of developmental problems that really do not allow the embryo to go to term, or, if it does, it often has major developmental abnormalities. So there are some serious downstream problems of going to term with those kinds of embryos. But in some work in the mouse, which we are eventually going to be publishing, one would think that if you are able to produce embryonic stem cells, then apparently they have a normal capacity with respect to forming any tissue of the body. So, for some reason, if you can produce the embryonic stem cells they are perfectly useful, but if you are going to try and produce a live born offspring, then that is terribly difficult and very inefficient. You occasionally get a good outcome – that is, a normal lamb, a normal Dolly, or a normal whatever – but it is more like one in 200, one in 300 of these events that turn into normal, otherwise they are developmentally abnormal if you try and grow them through to term. So there is a distinction at the present time in the entity that is formed and I agree with what they are saying, but I do not want to mislead anyone that the structure of the embryo that is formed just prior to producing the embryonic stem cells looks in the culture dish much like a fertilised embryo.

Prof. WILLIAMSON—You have raised a key point, and it is actually quite a difficult point. They are different, but they touch at a certain point and then go apart again. I will discuss it in terms of human development because, to be honest, I have never worked on animals and I am more interested in the human side of things.

Suppose you are really interested in finding out what happens at the earliest stages of embryonic development because you know that certain problems can arise then which lead either to death of the embryo or to handicap later in life. In that case, if you want to study this you probably want to take an eight-cell or a 16-cell or a slightly later embryo and disaggregate it, because in that way you have the best opportunity of getting cells at an extremely early stage which can go in any direction whatever. That works one time in five, something like that – it is a pretty successful procedure. You can, if you want, take those cells and play tricks on them, roll them up, join them with other cells and have a very outside chance of actually generating a living organism from them – perhaps one in 300, one in 400. They are derived from embryos and they could become embryos again, but, as we have said, no-one particularly wants to use them that way.

The experiment Roger and I have talked about is to take an egg, not an embryo, and take the nucleus from a healthy somatic cell and pop it into the egg. You have to get rid of the nucleus of that egg or inactivate the nucleus of the egg, but that is very easily done. You then grow those up to give very early lineage cells. This is actually much harder to do than what Alan has said and it does not work as well, and sometimes the cells are not quite as early, so it is a little more difficult. But the important thing is that this is not from an embryo. From my point of view there are ethical issues involved, but there are very practical issues involved. If I have a seven-year-old girl with leukemia, I need a cell from her. If I started with an embryo it would not be a cell from her. It would be crazy to start with an embryo. I want to start with a cell from her. So, from my point of view, it is not an embryonic stem cell in the sense it is from an embryo; it is a cell from the seven-year-old girl that is making this lineage.

It must be admitted, to be totally frank about this, that if we took a few thousand of those cells and rolled them up and tweaked them and treated them in a particular way, it is in principle possible, once in 1,000 times, once in 5,000 times, that one could generate a living organism from it. So in a sense you are not starting with an embryonic stem cell, but you are coming to a point where you are getting cells that have a certain equivalence in their ultimate ability to how they could operate. My view is that the way to solve that problem is by saying that you cannot use the cells in that way. But, in fact, the cells that I am discussing were not derived from an embryo in the first place.

CHAIR—I would like to follow this through so that I am clear, and so perhaps the other members of the committee are too. In a sense, for the purposes of discussion or thought about what we are talking about, are we really discussing two processes which are separate and have a different origin but which may touch at a certain point, if I can put it in language as broad as that?

Prof. WILLIAMSON—From practical points of view, one of the differences is that I know that some people, including some people in this room, have a major problem with the idea of the destruction of an embryo. Some people do not. The process I am describing does not involve the destruction of an embryo. There may be other issues involved down the line, but that is not an issue in this particular process.

CHAIR—We may get to that discussion, no doubt, but I just want to try to clarify what we were talking about scientifically before we actually reach that, Professor Short.

Prof. SHORT—Your analysis, Mr Chairman, was spot-on. You are called 'The inquiry into regulatory aspects of human cloning'. Growing human stem cells, which is what Alan started talking about, has nothing to do with cloning. But growing cloned embryonic stem cells is what all of us are interested in, and cloned embryonic stem cells, as Bob has just said, do not require the destruction of an embryo. At the moment, growing stem cells alone – the ones mentioned in the reports published in 1998 – requires the destruction of fertilised human eggs.

CHAIR—It does seem to me that the expression 'cloning' creates all sorts of problems regardless of where one sits in this debate, and we would be better not to use the word 'clone' at all.

Prof. SHORT—I think you are absolutely right. It creates a very negative impression in any group that you talk to – and I have been doing a lot of public speaking about this recently. Some schoolteachers told me just last week that they were horrified that I would talk about identical twins as being clones – which they are – because it was such an offence to identical twins. It had never occurred to me that the word was so negative that people would actually object to it in that sense.

Ms ROXON—I would like to follow up on that issue. Professor Williamson, I can understand why your approach is a nice approach if you are trying to get around some of the ethical issues that some people raise. I would like an explanation, perhaps from you and maybe also from Professor Trounson or Dr Pera, about the research being done on embryonic stem cells – the processes. It sounds to me as though you are still at a stage where that research is actually going to inform greatly the processes which you say are two or three years down the track. It seems to me that if you try to separate one from the other in a way that is perhaps ethically popular, you will actually be tying your own hands for the future research you might want to do. I would like a comment on that, because it may be that I do not understand the processes properly.

Prof. WILLIAMSON—You understand the processes. There is only one thing that I would expand on and perhaps disagree on. The reason we are doing this is not because it solves an ethical problem. It does solve an ethical problem, but that is not the reason. The reason – going back to my seven-year-old girl – is that the only way we can get a cell that is compatible with her and avoids all the problems of transplantation is to take a cell from her and go through this process. It just happens that that also means we do not need to use an embryo. But the purpose of doing it is not primarily to avoid those ethical issues. I am quite pleased that it does avoid those ethical issues, but that is not the underlying reason.

You are quite right about the kinds of research that Professor Trounson is carrying out and the greater understanding. You did not see his slides because they were behind you. One slide showed stem cells going down three different pathways: blood, liver and so on. In the next bed to the seven-year-old girl there may be a seven-year-old boy who has a problem with his liver called Wilson's disease. We may want to treat that by putting a gene into a cell and getting it to differentiate into a liver cell and not into a blood cell. The work being carried out now on embryonic stem cells made from those small number of embryos that Professor Trounson referred to is precisely the work that we are going to rely on to tell us how to do that.

You cannot just take a totipotent stem cell and put it into a patient because it causes cancer. You have to kick-start it down the right line. That is the research that Alan is doing. It is, from our point of view, very important research. I would hate to see that research delayed by four or five years or moved offshore from Australia because I believe that would result in people who could be treated not being treated. I think it would be bad for our country if it did move out of Australia.

Prof. PERA—I agree with Professor Williamson. As we pointed out, many of the goals of embryonic stem cell research, or whatever you want to call it, can be achieved by making a small number of cell lines from embryos. I think that the research will inform the goals that Professor Williamson wants to address. What we have to bear in mind here is that, in terms of animal experiments, embryonic stem cells derived from embryos are the gold standard of a pluripotential stem cell. In other words, we understand that they can colonise every tissue of the body and give rise to normal cells in the mouse. There are still some questions over what the capacities will be of potentially stem cells derived from nuclear transfer. There are experiments in hand to address this, but we still do not know, so I think we will still have to refer back to that gold standard.

The same applies to stem cells derived from gonads, which we have not talked about too much. That is another approach that has been used in the United States. There are some questions over the developmental po-

tential of those as well, for particular reasons, so we need both prongs of approach. What is very clear is that we do not need to involve hundreds and hundreds of human embryos in this exercise, in any event.

Mr CADMAN—Professor Trounson, from your description and my information, it seems to me that the process you used by going to Singapore was a device to circumvent Australian law or regulations. Therefore, it appears to me that, if you adopt a strict legal approach, you use the technique to circumvent Australian law. Is that right?

Prof. TROUNSON—You can view it in that way. Professor Bongso was going to derive human embryonic stem cells. I believe they have an enormous potential. They derived the initial cell lines that were then sent to us to see whether we could grow them indefinitely and then, with the help of our scientists, see whether they could differentiate. There is nothing illegal about those activities and nothing at all that is against Australian law in doing those things.

Mr CADMAN—Okay. The information I have is that the NHMRC guidelines say Victorian and South Australian legislation prohibits the production of embryonic stem cells. Is that right?

Prof. TROUNSON—No, they do not prohibit that. They prohibit the work on embryonic stem cells to clone a human person. If you were intending to do that, then that would not be permitted under the NHMRC guidelines. There is nothing else in the legislation that would prevent you from doing that, except for experimenting on embryos. If you were to produce an embryonic stem cell line from human embryo that would otherwise be thrown away that could be construed as an experiment on an embryo. But that is not considered in any way illegal in Singapore.

CHAIR—Just to clarify that, is it your advice that once you have a stem cell line here in Victoria, it is not illegal to reproduce what you have got as long as it is not used for the purposes of developing an embryo and researching upon that? If it is simply to reproduce Petri dish after Petri dish of the stem cell line, that is something which is quite legal in Victoria?

Prof. TROUNSON—I took that advice and gave you that information yesterday. Right from the beginning I went to see Judge Marks, who was the head of the Victorian Standing Review and Advisory Committee at the time, and that was his advice. I have followed that up with succeeding ministers of health in the state of Victoria, and I think I have informed every federal minister of health of that. We have also taken advice where we could from our university. We have discussed it again recently with our ethics committee, and they have reviewed the issue and come back with exactly the same advice. Yes, universal advice has been given to me.

Mr CADMAN—There is a follow-up question. Some of you have hinted at Australia's role in an international sense. Do you see any value in international agreements in this field, or will somebody who is not a signatory do the cowboy stuff and run off and be uncontrolled anyway?

Prof. TROUNSON—I believe that international agreements which are good international agreements are very important. There have been some bad international agreements, and I guess you could point those out too. In the sense that we could get some international agreement, it would be very good. That is why I gave the chairman the draft guidelines from the National Institutes of Health. They have had a very specific view about working with embryos. Now they have a very specific view about wanting to work with human embryonic stem cells and have produced some draft guidelines. They would want people to adhere to those guidelines for funding and for support of research through the United States. I believe that set of guidelines is, at the moment, probably the international gold standard. I think we could probably get everybody to agree to adhere to those standards and that would certainly make a difference. If we can get other agreements that will bind people into working in that way, then I think it would be agreeable.

I would have to say that this area does involve a lot of interest from the commercial sector. These are biotechnology companies, and in the United States and in other places they have not been terribly well subjected to regulation. That tends not to be the modus operandi in the United States, but I think in this particular case it is going to be very difficult to pass cells around to colleagues and to link up without those base agreements. I think that is one of the ways in which you can actually enforce some of the global aspects of this research.

I would say also – we have actually showed the committee the cells growing in the lab yesterday – that this is very difficult work to do. When they handed out the first cells from the Rhesus monkey – I think they were handed out to about 50 laboratories – there were only three labs in the world that could actually grow these cells and one of them was ours. They are very difficult cells to handle. That will probably change as we get better at doing it. But there are some barriers that are practical ones. There are other barriers which I think organisations like the NIH and the Australian NHMRC should put in place and which we should all agree to in a global way. I think that would be good. There may be other ways of doing it, but that has not been a common way in which to regulate medicine.

Mr CADMAN—Have you got in your mind a pattern of progression?

Prof. TROUNSON—Yes, my own view is that we should all agree to adhere to some –

Mr CADMAN—You mean in Australia?

Prof. TROUNSON—I think we ought to adhere to some guidelines that are set up by the NHMRC, and that we ought to have some committee process that allows enough flexibility to understand where the work is going, to pick up the opportunities and to crush, if you like, or prevent those thing that we are, as a community, not wanting to see happen.

Mr CADMAN—And then internationally?

Prof. TROUNSON—There may be mechanisms better known to the political world than to me, but I think we ought to agree to NIH. I think we ought to visit the UK, and maybe some of our European colleagues, who work at the same kind of level, the NHMRC or national institutes of health in those countries, and get broad agreement that we would like to operate under one plan. But I would have to say, Mr Chairman, having worked in Australia, where there are totally different laws in every state in Australia governing IVF and other aspects, it has been terribly difficult to get a national consensus in a political sense, and a hope that there would be a very effective one globally would be a hope rather than I think a reality in the short term.

Prof. WILLIAMSON—Speaking now wearing a World Health Organisation hat – I am a member of their committee that deals with this – no international guidelines can totally solve problems because in general nation states do not subscribe to international guidelines. However, the Helsinki agreement has proven that, at least in some cases, international guidelines can play a very positive role, in this case in relation to torture carried out by or in the presence of medical doctors, in reinforcing the rights of individuals to say no and making whistle blowing very much easier.

The great advantage of an organisation like the WHO or UNESCO participating in this rather than NIH is that we are dealing with an international community now which does not necessarily see things coming from the United States as being the be-all and end-all of regulatory processes, particularly in view of some of the commercial considerations that are involved. I would guess that international guidelines will only have meaning in most countries of the world if they come from the WHO, UNESCO or a similar body. I do not think they solve the problem but I think they make a contribution to solving the problem, and I think Australia is in a very good position, as we are respected in international organisations, to play a part in commencing this process.

Mr MURPHY—Professor Beck, you mentioned the need to define a human being. I would be interested to know your definition of a human being.

Prof. BECK—The purpose of what I was saying is that it is an indefinable entity in scientific terms. Philosophically one might ask: when does the soul enter the body? In practical terms, what we are talking about in early human development is a ball of undifferentiated cells: no heart, no muscle, no nervous tissue, no function in that respect, but a potential to function in all these respects if differentiation is guided along the right pathway. So your definition is as good as my definition as to when the entity of a human begins.

If I cut myself shaving, I lose a few million blood cells, many of which contain nuclei. Each of those nuclei potentially, as we have heard today, if transplanted into an ovum under certain circumstances could, in theory – indeed, it would be very unlikely to happen every time – give rise to a whole individual, because every single cell of the body contains a complete copy of all the genes that are required to make a functional human being. So the whole concept of when the human being starts is a philosophical one rather than a biological one, because of the continuity of the germ line. In fact, DNA is replicated and replicated and there is no real point of distinction between a cell belonging to an adult human being and a cell belonging to a cloned successor of that human being because they both contain the same genetic material. So I cannot answer your question, I am afraid.

Mr MURPHY—I suppose I asked the question because you talked about the need to define a human being. You probably put a proposition to us which is not possible and certainly will not get agreement.

Prof. BECK—My point was that we cannot define a human being in those terms and that we have to take a practical approach as to what the potential is of embryonic stem cells in producing tissues of a human being, but not in making a whole human being because that concept is a nebulous one.

Mrs VALE—I have a very short question for Professor Short, and I am sure it was a question perhaps, Mr Chair, that you asked when I had to leave the room. At this stage I would just like to clear up some confusion. You spoke about, in therapeutic cloning, that no sperm meets the egg so we use an enucleated egg and life is technically not begun, and yet my understanding from Professor Trounson is that the stem cells which you were using for research were actually originally derived from an embryo; is that correct?

Prof. SHORT—Yes. Professor Trounson started by talking about human embryonic stem cells which are derived from a blastocyst and grown in culture.

Mrs VALE—But you are talking about a different process altogether?

Prof. SHORT—We would all like to take that research – it is very valuable research to continue – on one new stage and develop cloning of embryonic stem cells which does not involve creating an embryo as usually defined.

Mrs VALE—Has that process of which you speak —

Prof. SHORT—That is therapeutic cloning.

Mrs VALE—And that is actually happening now; you have got that procedure to do that.

Prof. SHORT—No. As far as I am aware, and I defer to the other experts, I have not seen a paper or heard a report yet of anybody who has produced cloned human embryonic stem cells. But there are many people trying to do so and I am sure —

Prof. WILLIAMSON—Not humans, no; of mammals.

Prof. SHORT—No, not of humans, but of mammals, yes.

Mrs VALE—Would Professor Trounson like to make a comment?

Prof. TROUNSON—Yes. There are only two groups in the world that are working on human embryonic stem cells that we know of because they are the only two groups that have the cells, and that is Wisconsin research group and ourselves. If the cells are passed out, depending on what agreements you pass those cells out, other people may or may not want to do what Roger Short and Bob Williamson are talking about.

I think what we would say at the moment is that, if you are faced with a dying child or a dying person, immediately you might want to move to that as quickly as possible. Dr Pera and I believe that we need to prove that embryonic stem cells derived by that route are in fact normal. We are doing that kind of work in the mouse to try and get some indication. We have not proposed to do that in a human. We are so busy trying to understand how the cells grow and multiply and differentiate we have not got to that point yet. So there needs to be some experimental work done prior to utilisation of that. There needs to be some modelling work done in the mouse. Hopefully we will be in a position shortly to be able to publish on that. That would give us some strong feeling that that would be a way to progress if needs be.

There may be other options created in the next several years. We are talking about blue-sky research. At this point in time they are quite right. If you had a dying child at the moment, if you really wanted to try and do something, that would probably be the way that you would try and do it. But we would have a lot of reservation about using the cells for transplantation, even if we had an apparently pure cell line in our culture dish today. In several months time, we might feel more reassured that those cells will stay being nerve cells or the kinds of cells that you want for transplantation. But in our laboratory today, we cannot put our hand on our heart and say that we know exactly that they are a pure reliable cell line as yet. It is just very early times.

CHAIR—Professor Trounson, if you can multiply the egg cells that you have, is there any need to clone them at all?

Prof. TROUNSON—You may want to clone them because you want to make them compatible for transplantation. Because they have been derived from an embryo that has another genotype they may be rejected if you put them into another person. That may not be the case if you put them into a so-called protected area. Behind the blood brain barrier is a possible protected area and in the spinal column may be another protected area. We may be able to use these cells under some circumstances as universal transplant cells. We would still need to do the experiments to demonstrate even that. It is a little early in time to be too definitive about it. At the present time, as far as we understand immunology and these cells, if you actually did a transplant to a soft tissue area in a human person, they might well be rejected. Graft versus host disease is a very serious consequence of doing a transplant of foreign tissue.

Prof. BECK—I come in about embryonic stem cells in general, taking up Roger Short's point about human embryonic stem cells. There is great variation in stem cells between different species. For instance, it is very easy to grow mouse embryonic stem cells; it is very difficult indeed – and possibly has not been achieved yet – to grow rat embryonic stem cells. That brings us back to the point of primate research. It really is not the same thing to try and grow a stem cell from a primate rhesus or a macaque and to grow a human embryonic stem cell. That is why I would agree with all of the colleagues that have put forward a view that primate research, in this context, is probably not the best way of using limited resources.

Ms ROXON—I would like to ask about our biotechnology industry that a number of you have referred to. Professor Williamson said today – and I know other scientists have said so in their submissions – that you are quite keen that before research is undertaken, the proposal go to some committee of peers and perhaps community members set up through AHEC or any of the other organisations that would approve research. What are the consequences of doing that? Presumably, it is still a relatively competitive area and any person or researcher who thinks they are on the cutting edge of some very viable new discovery is not going to be keen to make that publicly known before they have proved whatever they may want to prove. It may be something that

we deal with more when we get up to the regulatory discussion later in the afternoon, but I would be interested from a point of view of the impact it has on the research you are undertaking on how you see that working.

Prof. TROUNSON—There is a very good parallel at the present time being developed by the federal government for genetically modified organisms. You have exactly the same situation where you have a lot of commercial and multinational interests in genetically modified plants and animals or organisms generally. In tendering the proposal to this committee, I think it would need to be thought of in a confidential way to protect the intellectual property. I think that is incumbent in the genetically modified organisms.

Ms ROXON—Presumably, you would be the first group of people to be saying you would want scientists and researchers who are working in the area to make up part of that review committee. I think various submissions have said that – a strong view that you need people who are actually practising in the area to be on it. So, even if it is treated confidentially, won't there be people being exposed to that?

Prof. TROUNSON—The business world has developed these mechanisms very well: if you have a conflict of interest, you must step away from it. It can be put in place that this information contains intellectual property which is only visible in camera by the rest of the committee, which does not contain a potential person who could end up as a competitor. I think most of the time this is not going to be a very important issue but there needs to be processes involved that protect intellectual property rights because it is very certain that there will be a mixture of funding, both public and private, that works in this area. There will be a lot of patenting going on for enabling technology, which is really what we need in Australia to make our biotech industries very strong. So, in any committee process and in any way of looking at these things, we have to protect the intellectual property rights as we consider the issues.

Prof. WILLIAMSON—Some of us do not actually have links with biotechnology companies, myself included. I think the United States actually has shown it is possible to do this. The hearings in the United States are held in public but commercially sensitive details can be filed in private. I sat on the regulatory committee for genetic manipulation in the UK for 10 years and it was remarkable how rarely issues of commercial sensitivity came up. The exact designation of the constitution, say, of an ES cell that is going to be used for therapy must be put to the Therapeutic Goods Authority here and to a local ethics committee here. These are the bodies that actually have the right and are empowered to look at issues of safety which have to do with these detailed issues. The sorts of things a national regulatory body looks at are broad-brush principles that often will apply to several groups. The sorts of issues that we have been talking about, the distinctions which both the chair and one of your colleagues raised about something that involves using an embryo and something that merely involves passing something through an egg, relate to activities which 10 or 15 different departments will have an interest in and the committee should be in a position to often general guidance. In fact, the most valuable guidance the committee can offer is general guidance, because the specific responsibility ultimately lies with the local ethics committees in human experimentation and with the TGA when it comes to therapeutic goods safety.

Mr CADMAN—Professor Williamson, in your submission you indicate:

The senior staff of Murdoch Institute is divided as to whether reproductive cloning should be made illegal.

Could your describe what you mean precisely by 'reproductive cloning'? Do you mean the production of embryonic stem cells?

Prof. WILLIAMSON—No. That statement has to be read precisely. By reproductive cloning I mean the creation of a living foetus or individual. But the statement there says 'illegal'. There are one or two of my colleagues – a minority of my colleagues, but nonetheless one or two of my colleagues – who agree with what I said, in that there is absolutely no medical need for such a procedure, and agree that it would be a waste of resources to carry out such procedures in terms of the national effort. But one or two of my colleagues do not believe it should be made illegal because they think that the law should not interfere in matters which they see as essentially matters of privacy in the context of reproduction. That is not a view I personally hold and I would say the majority of members of our staff do not hold that view. I do not know whether Dr Rogers, who is a member of our staff, wants to offer further comments on that. But there is one member of our staff who feels quite strongly that the law should not intervene and feels in principle that the law should not intervene in reproductive issues, even in an issue such as this. That is not a view I personally hold.

Mr CADMAN—Dr Pera, your submission appeared to go further than Professor Williamson's did in that some of your assertions in your slide presentation seemed to go beyond Professor Williamson's stance. Is that right?

Prof. PERA—In what respect?

Mr CADMAN—For instance, the third dot point is:

Source of progenitors for tissues in adult where stem cells are not present or characterised

From what I can deduce, this may or may not be true. That seems an assertion that you appear to be sure of, but the evidence appears to indicate that, in most instances, there may be cells but they are not found yet.

Prof. PERA—We do not know whether they are not found or they do not exist. I am just saying they are not found at present.

Mr CADMAN—Not present or characterised?

Prof. PERA—Yes.

Mr CADMAN—And therefore you see the embryonic stem cell process as an alternative process to other ones described by Professor Williamson?

Prof. PERA—It may be that the process described by Professor Williamson will be able to replace anything that an embryonic stem cell would do. We simply do not know that yet.

Mr CADMAN—But you argue then to replace it with the production of embryonic stem cells. You are saying Professor Williamson may eliminate the use of embryos, but your argument appears to be for the production of embryonic stem cells in the meantime as a process to further develop the science.

Prof. PERA—That is correct – on a very limited basis.

Prof. WILLIAMSON—As you realise, we did not coordinate what we put forward –

Mr CADMAN—No. I need to understand what the difference is.

Prof. WILLIAMSON—and obviously we have differences. The differences are not so much differences in how we interpret where we are at the moment. They are really differences implicit in where we are coming from. Professor Trounson and Dr Pera are people who are very interested in early embryonic development because it illuminates all kinds of issues about fertility and about handicap, which are complex and are back at that stage. I am very interested in developing new methods of therapy for children who have genetic and acquired genetic diseases. We do not differ. I think their work is very important. I hope they think our work is very important. We are looking at things from a different point of view, primarily because we have our origins scientifically in wanting to look at different questions.

Mr CADMAN—Good. I needed to have that clarified, because your statement appeared to be very clear in your submission. If that is the case, could I put it to you that, given your comments about the significance of international agreements and whether or not they can be made to stick or whether they can be realised, there is the potential for the process that is being used in the use of embryonic stem cells to be used in the cloning process of a total human or to bypass anything Australia does?

Prof. TROUNSON—I think you are asking a question. You can use any cell. Why bother about an embryonic stem cell? We can use a cheek cell. You do not have to go to an embryonic stem cell.

Mr CADMAN—No. I am not advancing an argument. I want to know where the facts are; that is all.

Prof. TROUNSON—The fact that it is an embryonic stem cell has no particular relevance. You can use any cell of the body to attempt to produce a cloned offspring. There is no particular merit that we know about in the human in wanting to use an embryonic stem cell. So I do not think that what we are wanting to do is necessarily relevant. You were asking about –

Mr CADMAN—I am asking about the next step, not what you are doing.

Prof. TROUNSON—We are trying to discover, in that tree, how those cells differentiate from being embryonic stem cells that have no phenotype – they do not know what they are going to be. How do they become liver cells, nerve cells, skin cells or pancreatic islet cells? How does that happen? Can we control those cells ending up at those end points in a somatic cell dish in large enough numbers for transplantation one day? That is one option. Deriving the factors that allow you to get to those end points: there will probably be medicines that are derived from that knowledge of how they get there; then there are ways in which you can actually do all the current work we are interested in just by using those cells in the beginning. It is a discovery program of trying to understand how those cells get from that point to the final, bottom point. If we understand all of that, the option is that maybe then we can understand how to drive them in the reverse process. If that happens, then we probably will not need to use embryonic stem cells; we will be able to use the defined cells – the somatic cells – in linking them, pushing them over that linkage from being liver cells to nerve cells.

Mr CADMAN—I guess I expressed myself badly. You have described a process for the use of reproductive stem cells, and your clarification has been good. But what about the reproductive cloning, if you like, as the next stage using something being done offshore and suitable cells brought into Australia, even though there seems to be general agreement that that process, at this point –

Prof. TROUNSON—They are separate issues.

Mr CADMAN—I know they are but so were stem cells, at one point.

Prof. TROUNSON—Yes. But, if we treat them as separate entities, what we agree on, and what we would like to see, is to make sure that people do not do reproductive cloning for selfish interests, because that is what it appears to be. We cannot find any real medical reason for wanting to clone a person. You would have to say that it is for selfish reasons. You want to replace a child who died or, for some other reason, you want to see yourself as a cloned individual. We would like to put in place barriers that would prevent people from doing that. That has nothing to do with embryonic stem cells, because you do not need those cells to do it. You can do it from any cell.

Mr CADMAN—At one point did not the governments and the national body regard that as a barrier that needed to be applied to the embryonic stem cell?

Prof. TROUNSON—That was before Dolly the sheep. Before Dolly the sheep we thought that maybe the only way we could clone a human was from embryonic stem cells. Dolly the sheep et cetera has shown that that is not true.

Mr CADMAN—I have got it, thanks.

CHAIR—Would you like to add to that, Professor Pera?

Prof. PERA—No, I think it is adequately covered.

CHAIR—I do not think there are any other questions from the committee members at this stage, and I know there are a number of participants at the table who have questions. But I am proposing to have a short break, because we are ahead of time, and I think that would probably be welcomed by all.

Proceedings suspended from 11.04 a.m. to 11.25 a.m.

CHAIR—I know that a number of the participants at the table have questions and I will take them in the order that they have indicated that they have questions, starting with Dr Ford.

Rev. Dr FORD—I have a couple of questions that arose during the scientific discussion which are important in terms of not only understanding that but also the ethical implications. One is related to Dolly and embryos and the second is the meaning of totipotency. My understanding is that Dolly originated from a mammary somatic cell which was placed in an enucleated egg which was reprogrammed and which then produced a cloned embryo from which Dolly derived. Is that a correct understanding?

Prof. TROUNSON—Yes.

Rev. Dr FORD—Then I fully agree with what Dr Pera and Professor Trounson were saying a moment ago, but, in Professor Williamson's case of the seven-year-old girl, if a somatic cell is taken and put into an enucleated egg you at least create a temporary embryo before you get to the ES cells that you want; it would be the same as the first stages of Dolly.

Prof. WILLIAMSON—There are many definitions of an embryo, as you well know. In the Victorian legislation an embryo is defined as the union of an egg and a sperm that goes through syngamy. If you were to accept our Victorian parliamentarians' definition, then clearly this would not be an embryo. If, on the other hand, one would say, 'Dolly must have been an embryo because Dolly implanted and grew in an uterus,' clearly at that stage Dolly was an embryo. From my point of view, I will never make an attempt to take those cells and treat them in such a way so that they could become what I would regard as an embryo, which is a viable collection of cells that has the potential to develop into an organism, into a human being.

You cannot say that every ES cell is an embryo, because that is just a nonsense. All we have here are a collection of cells grown in tissue culture, and it does not seem to me that they constitute an embryo. If you went through a set of further procedures, which I do not think we should go through, you could perhaps turn this collection of totipotent cells into an embryo. My personal belief is that what we are proposing to do in creating a totipotent cell from a somatic cell by passing it through an enucleated egg does not constitute creating an embryo because I think if you go down that path you finish up in the unsustainable position that every cell in our body is an embryo, and that is clearly not true.

Rev. Dr FORD—I agree that if we take fusion of sperm and egg as the paradigmatic definition of an embryo it does not fit into that, but it would be an artificially constructed embryo. I will leave that aside for a moment. Perhaps somebody else might want to pick up that point.

The next question is about this word 'totipotent' that has been floating around. It comes from the Latin word totus, which means the whole, the complete. I think that in the natural fertilised egg, be it sheep or human, when it is at the two- or four-cell stage, the whole four cells will be totipotent in the sense – I call it the strong sense – that it can produce the whole offspring, which would mean placenta plus all the cell types. The fertilised egg would be that also. But a second meaning of totipotentcy has been used this morning, and I think Professor Beck used it: that they could contribute to all the cell types. Now your embryonic stem cell could be one

of these, but it is not totipotent in the first sense of being able to produce the whole offspring because it cannot produce placenta. So I think it is crucial to discriminate between these.

ES cells are derived from the inner cell mass of a blastocyst, which is an embryo. If you remove the cells from the inside of that then, when they are treated and put on a monolayer, they become the ES cells. Once they are moved outside the blastocyst, they are no longer an embryo. They cannot be one, because they cannot produce the placenta. In other words, the embryo is destroyed to create them but, once you have them, they are no longer an embryo. This is where I was asking for somebody to remind me of the facts, but I think the original vaccine for some of the immunisation programs that are used today was obtained from an aborted foetus many years ago. Nobody worries about using these vaccines today. There is no connection with the abortion of 30 or 40 years ago.

If I am right in understanding that there is a bank of ES cells, what is the difference between the use of the vaccines that came from an aborted foetus 30 years ago and the use of these ES cells that are banked up around the world for those who did not have an involvement in the destruction of the embryo that produced those ES cells? Underpinning all this is the very definition of 'embryo' — and I will come to that this afternoon — in a philosophical, ethically relevant sense. The other one is the definition of 'totipotent'. It can mean 'capable of producing a whole offspring', and I think that is the ethically relevant one. If it is totipotent only in the sense that it can contribute to all the cell lines, that is not an ethically relevant sense. I ask the scientists: do they agree that there are two uses of the word going around?

CHAIR—Professor Pera and Professor Beck wish to reply, Dr Ford, but can we restrict ourselves to comments about scientific questions rather than stray into the ethical? Otherwise, we will be here all day. I know these things are related and it is difficult to do that, but I would prefer if we could keep to the science this morning.

Prof. PERA—I would like to refer to a scientific aspect of Dr Ford's comments and emphasise that the distinction between embryonic stem cells and embryos goes further than just failure to form the placenta. Embryonic stem cells also lack a key essential feature of any animal embryo, and that is the ability to generate the animal body plan. Embryonic stem cells on their own cannot form what we call the axis of the body. They do not know how to form a head, a tail, a left and a right, a belly and a back. That is the key process in animal development. Embryonic stem cells in the mouse can do that only if they are placed into some sort of embryo. So embryonic stem cells can produce only disorganised growths. If it is occurring in an animal, we call this a teratoma—it is a type of tumour. So this is a very key distinction. It is very important indeed, and it needs to be made very clearly.

CHAIR—Professor Beck, would you like to comment?

Prof. BECK—No. That is exactly what I wanted to say.

Rev. Dr FORD—I fully agree.

Dr PIKE—I might ask just a couple of questions. The first one relates to how immortal ES cells are, and that would then relate to the numbers of embryos required for this sort of research to show some fruit. In the National Bioethics Advisory Commission (United States), NBAC, report they say that ES cells in culture are not stable indefinitely. As the cells are grown in culture, irreversible changes occur in their genetic make-up. Thus, especially in the first few years of human ES cell research, it is important to repeatedly derive ES cells to be sure that the properties of the cells that are being studied have not changed. I would also have thought that, if transplantation research were to really take off, large numbers of embryos would be required for that research to come to fruition, not only perhaps because of the lack of immortality of ES cells but also because of the nature of scientific research and requirement for repeatability.

Prof. PERA—I would take strong issue with the conclusions of that report. In both our laboratory and that of James Thomson, embryonic stem cells have been passaged for years through hundreds of divisions while maintaining a normal carrier type, while maintaining all the markers we expect of embryonic stem cells and while maintaining the ability to give rise to a range of tissues in the body. It is true that if they are maintained under suboptimal conditions—and this is always a bit of a struggle—they can certainly readily differentiate, or they may develop genetic abnormalities, as happens in a mouse. Maintained under proper conditions, embryonic stem cells are immortal and will maintain a diploid carrier type. They also maintain another biochemical marker of immortalised cells, which is the expression of an enzyme called telomerasi, which is necessary for maintenance of normal chromosomes constituation over long periods of division.

Prof. WILLIAMSON—On your second question, to the extent that we acquire, whether through ES cell research or other means, the ways of differentiating a totipotent cell down a particular lineage, once we have that information and once we have the information on how to maintain and multiply early stem cells in culture – and these data are being acquired very rapidly indeed–we will not need to use any embryos in order to do transplantation research.

Dr PIKE—One further question related to the assumption of the problems with immune rejection. My understanding is that there are significant inroads being made into understanding why rejection occurs and I think Professor Trounson has already highlighted that there may or may not be rejection. Is it not possible that those problems would be dealt with, given that there may be a genetic substrate to immune rejection, at about the same rate at which so-called therapeutic cloning would be achieved?

Prof. TROUNSON—You are asking me for speculation, a dangerous thing in science. Of course that is possible and there are many strategies to look at these cells that are already derived, or derived in a proper fashion, I should say. You could actually try and remove some of the histobility antigens. I do not know what that would end up doing, but there are a lot of other strategies that may need to be looked at in due course. I think what we are saying is that right at this moment it would be a bad news thing if you closed the door on the only option that we might have at the present time to generate compatible cells. But whether that is going to be the case when we are ready to do the work I think is another matter, and it is speculation.

Prof. SHORT—If I could just add to that, if you or I needed a blood transfusion there is no way known to science that we would survive an incompatible blood transfusion.

Prof. WILLIAMSON—As a very small addition on this one, I do know the research that is going on in this field. The research is mostly trying to make things better but along the existing lines. At the moment if you have any experience of children getting treatment for bone marrow transplantation, for leukaemia or thalassaemia, the problem is blocking the rejection. Most children who die die because of rejection, because of immunological complications. Things may get better, but I do not believe we are going to see the revolutionary change that this particular approach could bring. The important thing about this approach is that it actually does away with the problem. It does not find a better way to treat the problem, it actually does away with the problem. That is why it is so important.

Mr TONTI-FILIPPINI—One of my questions has already been addressed in a way, so I will take some licence, if I can, with the wording of the question. The first question is: is it possible to obtain an embryonic stem cell other than through development to the blastocyst stage, whether that is from a normally produced embryo or whether that is from an embryo produced by nuclear transfer?

Prof. PERA—There is one brief report in the literature on mouse embryonic stem cells that describes derivation, I believe, from an eight-cell stage. It is a bit unusual, but it has been reported in perhaps one instance.

Mr TONTI-FILIPPINI—Okay. The second question is: is there work occurring in Australia using somatic nuclear transfer from a human to animal ova?

Prof. TROUNSON—Not to my knowledge. It is something that has been discussed in the literature and there have been some experiments in the United States, but I have no knowledge of anyone actually doing it. I suppose that kind of work would be most likely done in our lab, and it is definitely not at this point in time. I guess you are asking if you could derive embryonic stem cells using an animal egg carrier, so that it could not be a human embryo. It is a good question. It probably needs to be explored not in a human in the first instance but maybe by composing two animals—a cow and a mouse—to see whether the derivation of mouse ES cells is possible by that route. It has been discussed. I am not aware of anybody who has done any experiment in it, but I think it is one that ought to be done at some stage—not with a human cell in the first instance but by trying to derive mouse ES cells and using those.

Mr TONTI-FILIPPINI—I guess it would be speculation, but what would be the capacity of what you produced were it possible to do it in that transgenic fashion?

Prof. TROUNSON—Again, I think it would be pure speculation. There are a couple of concerns, of course. There are retroviruses that are species specific, and you would have a little concern about that. There are also organelles in the egg which have to function in association with the nucleus, and theoretically you would have a human nucleus trying to function with mitochondria and other cell organelles in the cytoplasm. Whether that would not allow the cell to function properly in particular organs or in particular cell types is not known at the moment. Clearly, experiments in the United States showed that these embryos could not develop at all when they were put back in animals. They composed pig, monkey and mice nuclei and they were put into cow eggs. None of those developed at all when they were put back in their respective species. All we can say at the moment is that they were incompatible with embryo development, but nobody knows anything about whether they would be functional and normal when grown as ES cells. It is too early to decide.

Ms WEBER—My question concerns the distinction you are making between reproductive and therapeutic cloning. You have ruled out reproductive cloning. What do you see as being wrong with reproductive cloning?

Prof. TROUNSON—From my point of view there is no medical reason for doing it. It is simply a selfish reason. I say that most of those proposals have come from individuals who want to be cloned or from families who want a member of the family cloned. It is not for a medical reason but for another reason. As a medical

researcher and a professor of medicine, I am not supportive of non-medical reasons for involving such technology.

Mr TONTI-FILIPPINI—Isn't there the possibility of treating couples who may have inheritable disorders by using a cloning process? Wouldn't that bypass the disorders in some cases?

Prof. TROUNSON—No, I do not think so. If you are talking about genetics, you would have to repair the genetic problem. You are talking about an enormous development of technology before you could even think about that. I have been on hypotheticals with people who have tried to think that there are good reasons for doing it. But I still do not think the reasons they brought forward were in reality, despite the entertainment value of them, justifiable in a medical sense.

Mr TONTI-FILIPPINI—What about the mitochondrial disorder?

Prof. WILLIAMSON—The mitochondrial disorders would not be treated well in this way. They key thing is that, if you wanted to treat mitochondrial disorders using this type of approach, the right way to do it is to fertilise an egg with a sperm and then transfer the new nucleus into an egg from an egg donor so that you actually do get, if one accepts IVF –

Mr TONTI-FILIPPINI—That is a form of cloning.

Prof. WILLIAMSON—No, it is not a form of cloning at all. The essence of cloning is that the genome comes from one person; it is a direct copy of a genome of one person. Here you have a sperm fertilising an egg, just as in normal reproduction. It is not cloning at all because it has absolutely no more in common with the genome of the parents than any other child has in common with the genome of his or her –

Mr TONTI-FILIPPINI—It is cloning a human embryo; you form an embryo, and then you clone it.

Prof. WILLIAMSON—No. I am sorry. This is a fairly important point, Mr Andrews.

Mr TONTI-FILIPPINI—You take the nucleus from an embryo that you have formed – or a zygote you have formed – and put it into an egg.

Prof. WILLIAMSON—The essence of cloning, as I see it, is that you are creating an identical copy of an existing individual so that you have more than one copy of an individual. For instance, if we decided to clone Nick Tonti-Filippini we would take one of your somatic cell nuclei and pop it into a fertilised or unfertilised egg and then grow it up. The essence of the clone is the fact that it is an exact copy of you, me or any of the rest of us. The essence of cloning is not in the technology; we already have IVF technology which goes through a whole variety of processes but does not involve cloning at any stage because it never makes an identical copy of an existing organism.

Embryo splitting is another form of cloning but it is not worth going into at this time. The key thing about all of the cloning processes is that they involve making an identical copy of a genome and reproducing it as an identical copy. If you allow normal fertilisation to take place so that you have a new individual in terms of their genome and everything about it, by normal fertilisation, I think you cannot possibly call that cloning. All you are doing is using some sort of reproductive technology in order to ensure the survival of that in greater or lesser health.

Mr TONTI-FILIPPINI—What you have described of forming a zygote and then transferring the nucleus from that into an egg, means that you have now created a copy of that first embryo, which would fit the description of cloning in the Victorian act, I am afraid.

Prof. TROUNSON—Maybe I can help. If I was trying to correct that disease I would actually take some mitochondria from another source and just introduce it into the egg because I think that would probably correct the problem. I do not think we would bother to do what you suggested we were going to do because it would just be much more difficult.

Prof. WILLIAMSON—The Victorian Clinical Genetics Service really is responsible for all of these conditions. We have looked at it in detail. We have actually spent days looking at it and asking, 'Is there any possible medical justification?' We cannot find any medical condition for which there is any justification for reproductive cloning. We really have been through it.

Mr TONTI-FILIPPINI—The man who cannot produce sperm could have his own genetic trial by using a cloning process.

Prof. WILLIAMSON—That is a bizarre request. Remember that there are very good reasons in terms of autonomy, diversity and family against going down this path. So I believe it would require a good medical reason to put it to —

Mr TONTI-FILIPPINI—Treating infertility has always been thought to be a good reason.

Prof. TROUNSON—If I could answer that again. It is a speculative procedure. Could we use a somatic cell from a completely sterile man or woman to make an artificial egg or sperm? At the present time we do not

know that we can do that. In fact, Professor Monk, who is an expert in that area is here. I think her views on that might be interesting. There are very major barriers that would probably prevent you from getting an outcome to that. At this stage we would have no idea about how to overcome those barriers. I do not think I want to spend the time to explain it but it is called genomic imprinting. At this point in time it would be purely speculative to suggest that it might be a treatment and very way-out at the moment, at least in a scientific environs. There is no indication that we could do that in a mouse at the present stage, for example.

Mr MENEY—My concern is from a very ordinary point of view. I am certainly not a person who is deeply versed in bioethics or indeed science but I do think that the use of the terms 'therapeutic' and 'reproductive' tends to focus on what the intended purpose of the act is, rather than what is actually done. I just wonder whether that introduces a degree of confusion in the mind of the common person for a start. My second point is on a related aspect. Professor Short was saying before that, because it is not a sperm and an egg, it is essentially not an embryo. But once again we are not then focusing on what the natural development of that would be. We are not focusing on the outcome in this case which we were focusing on when we were using the terms therapeutic and reproductive. It is this type of confusion that really does make it difficult for the ordinary person to understand what is going on. I will read a quick quote from the last issue of *Australasian Science* that talks about this problem of technical language:

> The argument that the public "just don't understand" or that they "would agree if they could gasp the technical difficulties" is inappropriate and unhelpful and probably contributes to a further finding that "citizens expressed a distinct lack of trust in scientists and those that seem to be controlling research.

That is a UK study and I am certainly not casting any aspersions on the learned people here but I do think that the confusion that results is due to the sorts of terminology that people use. In fact, they can actually shape the debate in the minds of the common person by the words they use. To suggest that science is just pursuing this in a very analytical way is probably a bit beyond the pale, because I think it really does paint a certain picture in the mind of the ordinary person. I wonder whether any of you would like to comment on that.

Prof. SHORT—As to reproductive versus therapeutic, as I said, I did not particularly like the terms the first time I saw them used. Reproductive refers to what you have done—you have reproduced an individual and made another copy of him. Therapeutic refers to what you hope to do to develop a therapy for one individual from his own tissue. You may think that is an inconsistency.

Mr MENEY—But I would be right in saying that that would necessitate the disaggregation or dismemberment of a body that could develop into –

Prof. SHORT—No, not for therapeutic.

Prof. WILLIAMSON—No, that is the point we have been making all the way along. If you take a somatic cell and put it into an enucleated egg, you are not disaggregating any form of embryo at all; you are growing the ES cells in a dish from that.

Prof. SHORT—If I could come to this issue of the embryo, because this is going to touch a lot of the discussions that you will have this afternoon when I am afraid I cannot be with you. The Warnock committee in Britain, which was set up to regulate in-vitro fertilisation, very wisely refused to define what they meant by an embryo. They just talked about the 14-day stage when the primitive streak which is to be the future individual appears in the egg. If we try to define the moment at which life begins, we are on a hiding to nowhere because life is a continuum; the sperm is alive and the egg is alive. Some people would define the beginning of life as when sperm meets egg. Others would define the beginning of life as when you can first see the primitive streak. I think that trying to split hairs about differing ethical and doctrinal definitions about the moment that something is an embryo really will not help us in the overall debate, because life is a continuum.

Prof. BECK—It might be worth saying that every cell in the body has a nucleus which contains all the information to make all the tissues of the body. So, carrying on from what Roger says, there is no difference in the information contained in a fertilised zygote or an adult cell. It is merely the question of how that cell has differentiated and which of the pieces of information are allowed expression. The program in each cell nucleus is identical, whether it is an adult or a zygote.

Mr MENEY—But we have had some of the gentlemen representing the point that, whilst all of these cells would not develop to fully functioning human beings, there would be a potential for that in some small number of cases.

Prof. BECK—Yes, because in an adult cell there about 100,000 genes in every cell nucleus. Some of those are expressed and some of them are repressed. The cells are not actually making muscle proteins if they do not happen to be muscle cells. But they still contain the genes that could make muscle proteins if they were switched on. In other words, the totality of information in each cell nucleus is identical. It is merely that certain nuclei express certain genes, other nuclei in different types of cells express different genes and, in the zygote or

in the fertilised egg, they express a smaller number of different genes again. In terms of total information, they are all the same.

Prof. WILLIAMSON—I do not think that was the point. Every cell in your body has the potential to develop into a new embryo and a new living person like you—every cell in your body does, ironically, apart from your sperm. But, in order to do this we have to go through 15 or 20 very inefficient, very ineffective and I think, in some cases, unethical steps. The real question is: at what stage do we say that something has stepped over that line? It clearly would be foolish to say that your skin cells are an embryo. You would not believe that; I would not believe that.

Mr MENEY—I am not suggesting that.

Prof. WILLIAMSON—On the other hand, if we took your skin cell and passed it through an enucleated egg and grew up a lot of them on a dish and then shocked them, treated them and bound them together in some sort of way, at one time in a thousand those cells might turn into an embryo. It is your skin cells. So at what stage do we actually say this has become an embryo? That is the question Norman was asking, and it is a very good question. Each of us would draw the line at somewhere different. Everyone would accept, if we went through that process and we had a seven-month foetus, that that must be an embryo. Everyone would accept, I assume, that when you wash your hands you are not washing off a whole lot of embryos. Somewhere in between those two something has happened. Remember, we have never gone through a fertilisation in syngamy step. We are all sitting here together. I do not think we know the answer to that question. This is where new technology is coming up and I do not actually think we know the answer. I actually think there may be more consensus around this room than you imagine around some of these issues.

CHAIR—Are there any other questions from participants? We have some from Dr Rogers, Mrs Tighe and Dr Fisher. Before I come to new questions, Professor Chalmers was seeking my attention earlier and I presume it was on the same point.

Prof. CHALMERS—No. These were actually two questions of clarification. I am conscious that a report will be written and I would hope that that report will further adumbrate some of the difficulties that are being discussed now. Could I ask a question of Martin Pera. In your presentation on the application of embryonic stem cells, you talked in terms of the advantage for understanding of basic human development, novel factors for tissue regeneration, drug discovery and also the way in which we might actually find tissues for transplantation. You attach some time frames, ranging between zero and 10 years.

I am quite conscious that we should not speculate and that some of the biotechnology has been notoriously overambitious in some of its time frames. Would you wish to revise some of those time frames or perhaps put onto the record why you have chosen those? I am very conscious that at many stages in genetic development comments are made in public that I think give optimism and hopes where none should, in fact, be invested in the public. I think, as we move forward, we have to be cautious. Could we perhaps elaborate on that?

Prof. PERA—I will go through my list again for you. With basic research on human development, I have said that, beginning now, I think there is useful information coming out. That is pretty straightforward as we analyse gene expression in these cells. We are discovering new genes that may play a role in the early human embryo. So I think that is ongoing now. I think that that is a reasonable time frame.

If we consider the identification of factors that are critical in tissue regeneration and repair, we have our own program aimed at discovering new factors that is ongoing at the moment. We are also looking at combinations of factors which are known in the mouse embryo to affect certain developmental processes. So I do not think that discovery of those factors which may influence human early development will take longer than this time frame. Whether or not they have a therapeutic application is another story. They may well have an application ex vivo in terms of manipulating stem cells but, perhaps in terms of a protein that we would administer to patients, that may be a more challenging issue and is more difficult to predict.

I am relatively certain that within a fairly short period of time you will see publications describing the manipulation of embryonic stem cells in vitro by known factors. I do not think that will take so long. In terms of in-vitro models for drug discovery and toxicology, we have already made significant progress purifying neural cells from human stem cells. I think that already in the mouse stem cell model there are collaborations between drug companies and basic research to produce neurones for testing drugs. I think the toughest one is this issue, finally, of transplantation. I have put that at a less optimistic time frame; 10 years may in fact be a minimum. I would say that now in the United States there are clinical trials using neurones derived from embryonal carcinoma stem cells, which is actually a cancerous form of a pluripotent stem cell. They can be turned into postmitotic neurones through certain processes, and there are already phase 1 trials in the United States looking at this. I do not advocate that particular approach, but I just mention it to show you where we are in that respect. Everything stops at 10 years here because I cannot think beyond that time frame personally.

CHAIR—And your second question, Professor Chalmers?

Prof. CHALMERS—I particularly draw the committee's attention to the issue Volume 20, No. 2, dated 15 January, of *Genetic Engineering News*, which I think is a very useful publication for telling us where the science and commercial developments are going. This is really a question to the full panel of scientists here. I think much of the debate we have heard is to use human material to the exclusion of primary animal work. As I am sure the scientists are aware, a large of number of companies such as Infigen, Advanced Cell Technology, Pharming of Leiden, Genzyme Transgenics and Geron Bio-Med are in fact using the pathways of animals and in fact using transgenics to develop drugs, xenotransplantation and replacement cells. Could we, perhaps, try and tease out why we are not going that way – I think I probably do know the answer – and is it a different pathway?

Prof. TROUNSON—We are going that way. It is just that the agricultural sector, which is the one producing the biopharmaceuticals through animal milk or through other ways, does not receive the same degree of attention that the present issues attract. There are very advanced proposals in the state of Victoria which include the relocation of some of these biotechnology companies to utilise these technologies in the form of pharmaceutical production systems. They are an important way of producing very cheaply medicines which are currently very expensive. If we really want to make very cheap medicines, pharmaceuticals, for widespread use in this country and the rest of the world, we need to produce them much cheaper than we currently do. That is the whole idea of those things, so it is ongoing.

I think the xenotransplant area is probably a bit confused at the moment – confused in the sense that there is research going on but there are also issues of a retroviral nature which need to be addressed. The scientific community and the regulatory bodies in Europe and in the United States are struggling a bit with that, so I do not know how that is going to end up. It may be that xenotransplants become a very effective way of providing tissues, or they may just stop because of the risks associated with retroviruses and mad cow disease and the prion diseases, which are pretty much unknown at the moment. But, as you will know from newspapers of what happened in the United Kingdom, these can be pretty serious considerations for any kind of transplant therapy.

There are, in these different areas, proposals for Australia to be very much involved in biotechnology and, in partnership with major biotechnology companies and pharmaceutical industries, to become part of the worldwide movement in biotechnology. It is a global movement. We can be a partner and we can be leading in some aspects of it, but not in all of them. We are in various places entering that in major ways. There is a composite of scientific advances in Australia that make up this whole area. I think the one we are talking about, with embryonic stem cells, is probably as big and as important as any of them. That is why we are talking to you.

Mr CADMAN—Just a point of clarification: what is meant by xenotransplants?

Prof. TROUNSON—Making an organ – say, in a pig, a pancreatic organ – which, when you then transplant it to a human recipient, would not be rejected.

Mr CADMAN—Xeno meaning all species?

Prof. TROUNSON—Across species.

Mr CADMAN—That is a similar term to transgenic?

Prof. TROUNSON—Transgenic is to put a gene in, and that is exactly what they are doing to make these xenotransplants: putting human genes into pigs to see if they can make those tissues compatible for transplants in a human.

Prof. WILLIAMSON—In the case of treatment for genetic diseases and cancer, the animal models have been used very extensively. Most of the problems of transplantation have been solved with animal species because animal species tend to have a very restricted genetic diversity. Animal species, whether agricultural or laboratory, tend to be inbred. Humans, of course, are outbred; we are very diverse, as you can see just looking around the room, and therefore the problems ultimately have to be validated. Certainly in the case of treatment for genetic disease and cancer we are now at a situation where, to be honest, I am not saying animal experiments are not valuable – there still are valuable experiments that can be done – but the time has come where the research really has to be validated using human systems.

CHAIR—We indicated that at 12.10 p.m. we would take questions from members of the public. I intend to do that and then come back to the three questions on the table so that we keep faith with those members of the public who are here and want to ask questions. At the moment I have one question from Mrs Gawler. Do you wish me to read out the question as you have written it or do you want to ask it yourself?

Mrs GAWLER—Perhaps, Mr Andrews, you could read it out.

CHAIR—If I do not get it correct, please correct me. The question is: will the offshore activities of Australian research institutes such as the Royal Children's Hospital and the Murdoch Institute, when funded or contracted by China or by other states and countries, be scrutinised, monitored, regulated or governed by Australian ethical guidelines or by international guidelines?

Prof. WILLIAMSON—I do not know why the Murdoch and Royal Children's Hospital research institutes do not do any offshore research. All our research is done on the 10th floor of our own building. We have never done any research anywhere other than in our own building. That does not mean I cannot envisage situations where we would not have collaborations, but in the case of our institute we have never done it.

Mrs GAWLER—I was present at a meeting last Friday morning at the Royal Children's Hospital where an organisation called RCHI was named by its manager. He explained that they had the resources of your institute and the Murdoch Institute and he mentioned the 370 research people. He said that they had just received funding from the Chinese government for a project. He did not say that it was a biotechnological project. However, one would presume that this RCHI organisation could tender for such projects if the Chinese government or another government might put out tenders.

Prof. WILLIAMSON—Now I know what you are referring to. RCHI stands for Royal Children's Hospital International. It is not a research body at all; it does not do research. It is basically a body – in fact, Dr Rogers can comment on it much better than I can – that is involved in training doctors in developing countries to the standard of medical care and ethics, ironically, that we expect of first-rate medical practitioners. In the case of China, the question of ethics is very relevant. Basically, RCHI does not have a research component, which is why I was mystified about it. All research would go through the Murdoch Children's Research Institute. Certainly, as of now, we have no intention of doing any offshore research, although we would look at such things on a collaborative basis. All of our research goes to our ethics committee at the Royal Children's Hospital which is an independent ethics committee, and all of the research involving all staff will go to that ethics committee under any circumstances – certainly as long as I am director.

Prof. CHALMERS—The importance of Mrs Gawler's question from the National Health and Medical Research Council's view is that under principle 1.20 in the new national statement — and this is the only country in the world that I am aware of which has a single national statement for research involving all humans; it has been approved by all the learned academies — there is now a provision which actually requires the ethics committees in this country, when approving research which will be conducted extraterritorially, to comply with national guidelines here as well as the guidelines which apply elsewhere. I think that is an extremely important national standard.

CHAIR—Are there any other questions from members of the public?

Dr McPHATE—My name is Alan McPhate. I am the current president of the Humanist Society of Victoria. I am a retired general practitioner after 40 years of general practice in the country. I am also a marriage guidance counsellor, so I am interested in your previous reference and congratulate you on it. I am also on an ethics committee at the West Gippsland Hospital where I was before I retired. It seems to me that the scientific members brought forward a consensus. While I can see why historically a lot of people were upset about what would happen to embryos, given this very nature of the new discovery of the stem cells, I cannot see what we can now be critical of. As a marriage guidance counsellor, I always look to see the things we have in common and whether we can resolve things by negotiation and I think that, because we have bypassed this need for an embryo to produce the stem cells, we are now on the same side.

CHAIR—Thank you. I have three questions, from Mrs Tighe, Dr Rogers and then Dr Fisher.

Mrs TIGHE—It is perhaps more of a comment and perhaps it is a cynical comment. Earlier, Jennifer Weber asked why you would reject the notion of reproductive cloning. There seems to be a lot of emphasis placed on the need to distinguish between therapeutic cloning and reproductive cloning. I put it to you that, whilst I accept the assurances of the scientists here today – they are probably quite genuine — isn't it perhaps the yuk factor that members of the public feel very uncomfortable at the thought of manufacturing identical human beings and rightly think about where that can lead us? At the same time I say I feel very cynical about your responses, because I well remember back in 1980, after the birth of the first test tube baby, the press conferences conducted by Dr Alan Trounson, Professor Carl Woods and others in which they strenuously denied that they would ever experiment upon embryos, that they would ever freeze them, that they would ever stockpile them or that they would ever discard them et cetera. Little by little and more and more we have seen all of these things occur, and worse, so that now we read that in certain parts of the United States, for example, very attractive models or very clever students can advertise their physical attributes for sale so that their eggs can be sold and, similarly, we have the sale of sperm from clever people. So I think that we have to look at very recent history and see where this path has led us before we embark upon yet another path.

CHAIR—Any comments? Does anyone wish to reply to that? As there is no-one, I will take Dr Rogers.

Dr ROGERS—My matter is also really in the form of a comment. It seems to me at this stage that the use of somatic cell nuclei and an enucleated ovum may come to replace the need for embryonic stem cells. But it would seem – and I would be interested in the comments of other people – that at the moment we are still at a stage where embryonic stem cell research remains critical in this whole scientific endeavour.

Prof. WILLIAMSON—I think that at the moment embryonic stem cells represent the way to study the differentiation of a totipotent cell down these various pathways that are so important. It is possible you could make a case out now that, if all of the human ES lines that are in existence were swapped between all of the labs that have made them, albeit there are only three or four, there might even be enough to do everything you would need to do; I do not know. Certainly, there is no need to create lots more but at this moment in time my personal feeling is that it would be a mistake to say that embryonic stem cell research should not continue and be supported, because it is still the best way to understand what is going on. I personally feel that in another year or two that may have changed. In another year or two, looking at what is happening in the animal systems, that may no longer be necessary, but as of now probably yes.

Prof. TROUNSON—I agree with Dr Rogers. I think it is absolutely crucial that we get on and discover what these cells can actually do and whether they really can provide the potential benefit that we hope that they might. I have been long enough in research to know that all our aspirations for helping very sick people cannot always be met and we are going to have to give up on some of those, but until we do the basic research then we are not going to know.

We are at a very early phase in the research. We think we probably need to regenerate some embryonic stem cells to meet the base line that the NIH has made for working on those cells. I think there are some good reasons, including consent for commercial use and so forth, that probably have not been derived in the first instance. If we then have a benchmark that we all agree to, I do not think we need to generate any more than another four lines ourselves. I think the cells that we currently have we could supply to all the institutes in Australia in the near future for all of the cell research that they would want to do – and I am not suggesting that we maintain a monopoly in that regard, but as a resource for not needing to regenerate them again from embryos. It would just be a very sensible thing to do to have this resource utilised in the fantastic research institutes around this country.

CHAIR—As I understand what you are saying, apart from the need to comply with the draft NIH guidelines there is probably no need to recreate ES cell lines from additional embryos. I know you have given me a copy of the draft document but I have not read it yet. This is not a pun but is there no grandfathering clause in those guidelines?

Prof. TROUNSON—There is none in the guidelines. They are very specific that they would not accept a funding basis from the NIH unless you did meet those guidelines, and that they would audit that very carefully because of the concerns that there are in the United States about deriving cell lines from embryos, so I think we will have to do that. In terms of the current cell lines – and there are only about four or five of them, at the most, in existence – I think we will all have to go back and rederive them. If we want five or six cell lines that will keep hundreds of scientists busy for a very long time. I think we will do that from less than 20 embryos, and probably less than 10.

Prof. PERA—I would just like to make one point very clear to the committee and to other individuals here, and that is that these two lines of research are not competing and they are not exclusive, they are complementary. It is far too early in the developments of this field to predict which one will eventually produce the most important information. They should go together, hand in hand, and we should not in any way restrict or narrow the pathway that we follow at this stage; it would be premature.

Rev. Dr FISHER—I have two questions, one to our several scientific witnesses – and the answer should be able to be very brief so it will not take long – and the other is specifically to Professor Trounson. Following our very interesting discussion this morning, is each of you willing to go on the record that you and the institutions with which you are associated would never take part in so-called reproductive cloning – that is, human cloning with a view to bringing a child to term – no matter how heart wrenching the particular case or how public opinion might be swayed over time?

Prof. TROUNSON—I can be on the record as yes, Anthony. I do not have any problem with that. The only thing I would say is that if humanity was to come to an end unless we did something like that, I might want to take the case up with you again, but, otherwise, no.

CHAIR—Are there any other responses?

Prof. WILLIAMSON—I agree with Alan. I am certainly able to give that undertaking on behalf of the Murdoch and the VCGS. Like all such undertakings, it would be reviewed, but I cannot envisage any conceivable scenario where I personally would wish to review that undertaking.

Prof. SHORT—I speak for myself, not for the Royal Women's Hospital. Certainly I would give that undertaking for myself.

Prof. BECK—I think that applies to me also. Clearly, we do not have a crystal ball and we do not know what the future will bring but, in any conceivable circumstances we can see at the moment, we could give that undertaking without any doubt.

Rev. Dr FISHER—I am appearing for the Catholic Archdiocese of Melbourne. I should mention that I am a member of the Infertility Treatment Authority in Victoria, but I am not here representing that authority today. Professor Trounson, the NIH draft guidelines restrict embryonic stem cell derivation to so-called spare embryos from infertility treatment programs. If the otherwise very liberal NIH guidelines were adopted as a kind of international gold standard, as you hinted at this morning, wouldn't that preclude creating clones specifically for genotype compatibility and, therefore, some of the the therapeutic applications that have been raised this morning as attractive reasons for allowing cloning?

Prof. TROUNSON—You are quite correct. That would be a reasonable interpretation of those guidelines. We also attached our response to those guidelines and we did point out that as they were drafted would make it exceedingly difficult to do therapeutic cloning. We felt that probably they needed to give due consideration to that as a need should you want to transplant tissues in the near future, given our present knowledge base. We have indicated that that might well be a drawback of that draft. I do not think it necessarily overly concerns us at this moment because, as I have said this morning, our discovery pathways do not intend to transplant those tissues in the very near future.

Prof. WILLIAMSON—There is some doubt as to whether the sort of procedure I described would come under the guidelines at all.

Prof. PERA—I am not sure about that. The NIH guidelines specifically rule out some funding of cloned embryos.

Prof. WILLIAMSON—That is because there is no cloning.

CHAIR—Just on the NIH guidelines, Dr Trounson, I note in your response to the NIH that you say that to your knowledge none of the existing stem cell lines meet the requirements. You then go on to say that it would be helpful if existing cell lines could somehow be exempted from these requirements. Presumably the Wisconsin group, which I understand is the other group that has produced the ES lines, would be putting a similar proposition to the NIH. I would be surprised if they did otherwise. Have you had any response to that proposal?

Prof. PERA—I think the last time I spoke to James Thomson the idea was that he would have to produce some novel cell lines to meet the requirements and that there would not be a grandfather clause. John Cerhart, who made the cells from embryonic gonads, expressed the same thing. That was as of about a month ago.

Dr TOBIN—It is very clear to me that the scientists on this side of the table are unanimous in rejecting the proposal from the Australian Health Ethics Committee that a primate research facility ought to be established. What is not clear to me is why that proposal that this be considered is not supported and why people feel so strongly against it. I have heard one reason just towards the end of the discussion from Professor Williamson. That was, as I understood it, something like this: we need to replicate the research that has already been done in humans. Perhaps that is the reason, but I would be interested to know what the reason is. There might be a variety of reasons. Certainly, the scientists at the table would know that some scientists do not share their view, but the unanimous view is very clear. I am interested in the reasons why.

Prof. WILLIAMSON—There are three reasons. The first is that, speaking personally, I am uneasy with primate research. We all have our own particular touchstones of things we are uneasy with. I happen to be uneasy with primate research. I have carried out primate research, unlike most people in this room, and I found it a profoundly unsettling experience. The second reason is that, as you said, we will in any case have to revalidate any research on primates using humans. We actually have an enormous amount of information already as background in other species. It does not seem to me that using primates is important since everything will have to be revalidated in any case before we use it on humans. The third reason is that Australia is not incredibly generous to its biomedical research community in terms of funding. It seems to me that if this is going to cost $3 million – and you can double that by the time you actually get around to doing it – then my personal view is that there would be far more productive and useful ways of spending the money.

Prof. TROUNSON—I would add that the human genome project is about to be completed – it will only be a matter of months rather than years. All the genes in the whole of the human genome – and there are hundreds of thousands of them – will be laid out, completed, accessible to all of us. We absolutely have no knowledge of the genome of the monkeys, the primates, and they will vary dramatically one to another. It is a huge disadvantage for a discovery program to not have access to that database, and that is basically because it is just not there. So we would prefer a scientist to utilise the information that has been generated on the genome through the human, and the mouse, because it is also progressed, and drosophila, rather than go back and hope that we might hit or miss with all of the lack of knowledge that exists in the monkeys.

Secondly, there are perfectly good primate facilities in our neighbourhood, if you really want to do that research, without setting it up here. We have people who are working on other aspects – nothing to do with this work – who work in Indonesia and have access there to properly facilitated NIH agreed facilities. Why would

we want to duplicate all that here? Why wouldn't we want to work with the resources that are in our near neighbour? Why would we want to duplicate all of the high costs of doing it? So there are numerous reasons why you really would not want to do it. Mostly, it is just not good sense to do it.

Prof. SHORT—A final ethical reason, which concerns me, is that most primates are now severely endangered in the wild, and we have wiped them out. Anything that would put further pressure on stocks of wild primates would be morally repugnant.

Mr CADMAN—I just think of myself as a primate. I want to know when Dolly became a sheep? When you zapped her, when the electric charge went through, or when the fusion went in or what? When did Dolly become a sheep?

Prof. WILLIAMSON—We should ask the ethicists.

Mr CADMAN—No, I want a scientific answer, please.

Prof. TROUNSON—I think I can address that: with great surprise. In reality, that was not supposed to work – it was one of the negative control lines that they thought would not work. And when the animal became pregnant and delivered a lamb, when Dolly appeared for that first time, it was with great surprise that they recognised it was a sheep. Prior to that time, they had no idea that it was actually going to be a sheep.

Mr CADMAN—There is some correlation between my question and what Professor Williamson does or is planning to do. I just want to know, if you are building up a whole bunch of cells there that you can use, when that bunch of cells or that somatic cell becomes –

Prof. WILLIAMSON—My definition would be this: if you are creating an embryo by the fertilisation of an egg with a sperm, it is possible to argue that that fertilisation step represents the start of a process which will generate an individual. That is one time, and the advantage of using that time is that it is a definitive moment in time. It is not the only moment –

Mr CADMAN—You have a chart here about Dolly's commencement.

Prof. WILLIAMSON—That is right. If, however, you are using a Dolly process, where you are taking a somatic cell, my personal view would be that it is foolish to say that the stem cell that you create is an embryo. I would prefer to define the time of the creation of the embryo as the time of viability, at least not before implantation and probably not before viability as measured by some physiological or neurological characteristics. That would be my personal view.

Mr CADMAN—Once the egg takes, if you can use that term, you can say that that is the point?

Prof. WILLIAMSON—I think it is bizarre to define it before that point – I think you could argue exactly where after that point it is – because it leads you down a pathway where you are defining a cell in a test tube or a cell in the mother sheep as being the embryo and that leads you down a path that I think is unsustainable.

Mr CADMAN—Does anybody else have any comments?

Prof. SHORT—It is a very important question you are asking. I think we are all going to fudge the answer, because we do not honestly know. I could say to you that I would have thought that something very significant happened when the electric current that passed through the mammary cell which was sitting next to the enucleated egg allowed the two to fuse. So maybe I would say it was the bolt of lightning. But I would have to qualify that by saying that we know that Dolly is the only success out of 291 experiments. We do not know exactly when they failed, except that there were certainly many late foetal deaths.

Mr CADMAN—If full-term gestation is five months in a sheep, was it after three or four months?

Prof. SHORT—Yes, there were late foetal deaths at three to four months of gestation out of the total of five months. This is another reason why I think we all feel that the idea of human reproductive cloning is absolutely not on: because of the enormously high abnormality rate of the foetuses, both in sheep and in mice, produced by the cloning technology. So a flash of lightning in the case of Dolly, but we do not really know the early processes of embryonic development and we do not really even begin to understand this enormously high failure rate.

Prof. BECK—With the greatest respect, I do not think that the question you are putting is a scientific question. It is an ethical question perhaps .

Mr CADMAN—I am asking scientists and I want a scientific response. If you say, 'I cannot answer that,' I do not mind that.

Prof. BECK—Yes, but you are putting a question that is theological or philosophical. It is not one which relates to a specific fact. It is a semantic question, if you like. When does life start? When does a human being start? We have all explained that life is a continuum from the primordial amoeba that was generated billions of years ago. We cannot say that at this point you have a new individual. That may be an ethical question and it

may be a philosophical question, but the simple fact is that science cannot give you an answer to that – in my opinion.

Prof. TROUNSON—I have been at a table so many times, including at a Senate committee hearing on IVF, when all of these discussions have taken place – and some members who are sitting around this table have been there as well. My scientists call cloned embryos cloned embryos. That is what they call them – embryos That does not mean to say that they believe they are the same as a fertilised embryo. They do not believe in any way that they are the same. But if you want to know what we call them, we call them embryos.

I do not have any problems with embryo research in its first phase. I never really did have. I do not think I have ever been on the record as being different to that. I have always weighed up the research on embryos on the benefits. That is why I am prepared to derive human embryonic stem cells. Instead of throwing them away or giving them to someone else or doing something else with them, that is why we derive these cell lines. That is because the benefits of this work are so huge that I think a better outcome than throwing them in the bin or in the sink of leaving them to die is to generate these cell lines. I do not apologise for that because I got that sorted out a long time ago. I am at difference with other people about that, but they are prepared to accept that that is my view. Most of my scientists have that view as well but not all of them. There is some variance in what they think about these things as well.

Mr CADMAN—I guess my question really relates to when that cell started to take on the characteristics of a sheep. We have had a couple of opinions, and I think one was at the start of the process and the other one was when it actually took to the placenta wall. I find both of those to be answers that I can think about as reasonable.

Prof. TROUNSON—My view is that once you start to form a body plan, and that is what embryonic step cells cannot do, that says, 'I have got a head and a tail –

Mr CADMAN—I understand your point of view completely.

Prof. TROUNSON—Then I recognise it as being a sheep and I recognise it as being human in that regard, absolutely.

CHAIR—I think this is probably an appropriate time to bring this morning's discussion to a conclusion. This afternoon we want to go on and look at some of the ethical aspects and also some of the regulatory aspects beyond that. Before concluding, can I thank each of the scientists who have come this morning for their contributions both in terms of the outline and their willingness to participate in the discussion and answer questions generally. That has been something that has been most helpful to us as members of the committee in trying to understand all the aspects and issues involved in that. So thank you for your participation so far and for the submissions.

Proceedings suspended from 12.42 p.m. to 1.34 p.m.

CHAIR—The purpose of this first session this afternoon is to address some of the ethical aspects of the issue. I know a number of participants at the table were not here this morning. There are, as you can see, many here who wish to make a comment. Whilst the committee finds the public hearings invaluable in terms of its process, we still do rely upon the written submissions which are provided. So do not feel that if you have a shorter period of time than you might like that that is the only word from you which is taken into account by the committee. Primarily we look to the written submissions and we use these opportunities to tease out some aspects that are in the written submissions. Given that there are about 19 individuals representing different organisations who wish to comment this afternoon on some ethical aspects, can I ask you to keep your comments to about two or a maximum of three minutes, otherwise we will run over time and will not be able to get through the rest of the program. I think, Dr Tobin, you were listed first. Can I ask you to lead off?

Dr TOBIN—Thank you. I have three points I would like to make. First of all, I would like to draw your attention to the fact that AHEC rejected the idea that the distinction between reproductive cloning and therapeutic cloning should act as the kind of framework for a discussion of the ethics of cloning. AHEC had two reasons, I think, for doing that. One is a sense that what is critical here is whether you are proposing to clone or to conduct research upon a whole human organism or whether you are proposing to clone or to conduct research upon merely a part. The 'whole part' language is rather clumsy, but I think you will get the idea. Under parts, we gave as examples cells, DNA, et cetera. That was our first reason for rejecting the idea that that distinction ought to provide the fundamental framework, because that distinction glosses over what you are really doing.

Secondly, in evaluating the ethics of any proposal, you really need to consider much more than its likely consequences, important though they are. You really need to consider a whole range of other aspects of any proposal, in particular what the proposal involves in itself. So a critical issue is whether or not embryonic stem cell research, somatic cell nuclear transfer and any other technique involves conducting research on embryos. Then, of course, there are further questions about whether or not that research is destructive of the embryo.

The next point is about whether these kinds of technologies involve research on embryos. We have really heard two views. One is, yes, it does – crudely put – and the other is, no, it does not. Some people claim that only embryonic stem cell research involves research on embryos and some people claim that both embryonic stem cell research procedures involve research on embryos – that is, that somatic cell nuclear transfer does also. So people are split on that. The scientists I am referring to are divided on whether that is merely ethically permissible, given that embryos are involved in at least some of the processes. Some want to say that in fact it is ethically required, that this research is so important that it would be unethical not to do it. The other view is that research on embryos would be involved only in embryonic stem cell research and not in somatic cell nuclear transfer. Again, there were differences there. Professor Trounson said that they would need only a few embryos, and I guess that is a matter of real importance. But what I want to draw your attention to is just this simple point: whether or not embryos are involved is obviously a critical issue whichever side of the debate you are on.

On the third point, I want to bring your attention to conducting research on human embryos. I asked the scientists today why they rejected the suggestion from AHEC that research ought to be done on non-human organisms first. They gave five reasons. I want to draw your attention to them very quickly and then tell you what I think is a sixth reason lurking there, because it is important. One is that, even if we do research on non-human tissue or organs, we will have to revalidate that research in humans. A second reason was the resource allocation problem: there are better ways to spend the limited dollar that goes on medical research. A third reason is that it would be silly or unwise not to capitalise on the information that has been generated by the human genome project. A fourth reason was that we ought to use the primate facilities in neighbouring countries and not reduplicate what already exists. A very interesting one was the fifth reason: that was an unease about conducting research on primates.

I want to suggest to you that there is another reason. That is that there is an assumption here that ethically it is all the same whether you conduct research on non-human or human embryos. It does not make a difference to the ethics of the matter whether it is a human embryo or a non-human embryo. I want to suggest to you that there are a couple of lines of philosophy that support that kind of view. Peter Singer would be the most influential exponent of a moral philosophy that would endorse that view. Of course, there is a philosophy that says that what matters is whether you conduct research on persons. Persons are self-conscious organisms aware of having a future and a past. Clearly, a newborn baby is not one of them, so anything earlier than that is clearly not a person too. Whatever the philosophical ingredients which inform that assumption, I think that assumption is there and it is an assumption that really needs to be revealed and then discussed.

Rev. Dr PULLIN—It seems to me we are looking at issues which depend on the definition of what is life and what are the rights and responsibilities we have in both the alteration and use of life processes. Part of that is a subquestion which is emerging of: what does it mean when we have a new human being beginning to emerge? At what point do we change from the parents, the original sources of material, into a new being? I suggest there is a biological answer to part of that.

Most of the definitions that we have heard today of what it means to be human are defined in terms of their function rather than their nature. It seems to me human beings ought to be defined in both. When the genetic material to produce the new being or organ et cetera comes together and begins to reproduce, we have a new entity. That is my answer to those who want to say that, because we do not use sperm and ovum in the enucleated eggs, somehow we avoid that process. The cell that is formed has the standard properties of the cell appropriate for its stage of development. The human embryo committee said a number of years ago that it is an entity which is able to move, given the right environment, to achieve the full potential.

We also have tremendous public, scientific, commercial and even government interest. At this stage we need to be careful that the scenario that has been presented of what the possibilities are has not yet been achieved. In one sense, we are on the first steps of what could be a very long path or ladder. Part of the discussion is driven by the thought that it will inevitably happen. I suggest there is a long way to go before we actually get to there.

We do have a problem with the pluralist society, so the answers I believe need to be put on very clearly enunciated ethical principles to try to take into account the differences in values and belief, as well as seeking to provide the best solutions which promote the most good in our society. That is a very difficult juggling act for people to deal with. The submission that we made outlines a series of principles on which such a system is possible to be constructed.

I would agree, too, that the difference between therapeutic and reproductive cloning is more a semantic argument than it is a reality. Ethically, you cannot define the goodness of a process by the end; you must also consider the means to achieve that end and where you start from, so a full ethical analysis must include all of those areas as well as whether the end itself is good.

At the end of the day science cannot provide answers to the ethical questions, but I believe science should be accountable to the society in which it operates. The questions surrounding the alteration and use of human

life have major implications for the future of all humankind. It is there that this is such an important matter. The decisions we make which will provide the framework for ongoing and future decisions around this area will be decisions which have longlasting effects on the whole of humanity, not simply on our society or on particular groups within it.

Rev. Dr FORD—Thank you, Mr Chairman and members of the committee, for coming to see how Melbourne is. I am waiting for the sheet to be given out because the overheads that are up there you cannot read, so you will have a copy now in your hands. You have a reverse side to that page but I do not think I will have time, if other speakers are to speak, to do the reverse side of that page.

As Dolly is a real sheep derived from a cloned embryo, a cloned child would be a real human being derived from a real embryo. A cloned human child would be a human individual, a person, a subject and not an object to be created or used as a means for the benefit of others – for instance, as a source of tissue. Human cloning deprives children of their genetic fathers and mothers and other family relations. It would be akin to committing a natural injustice against the children. It would be unfair because unreal expectations would be placed on the growing child to mirror the adult somatic cell donor. Cloning human embryos, especially children, is unethical and should be legally banned in all states. It is in some but not all.

Going to the second slide, underpinning all this is our concept of the embryo in an ethical sense. I submit that a human embryo is a cell or group of cells which has or have the inherent active capacity to continue – which means they have started – organised, species specific human development given a suitable environment, that is, normally a special culture for IVF and the intra-uterine environment once they have transferred it.

ES cells are not embryos – I make that point. They lack the inherent active capacity to continue organised species specific human development, including a body plan, as we heard this morning. Human embryos, naturally or artificially formed, should not be damaged to obtain the ES cells. I think that is another ethical principle which may be transcended with developments.

To the final overhead, stem cells may soon – that is, down the track – be able to be formed from ES cells by inserting a somatic cell nucleus inside them. This would be ethical if obtaining the ES cells did not involve harming human embryos in the first place. Information on that has just been published in this year's January issue of the *New Scientist* magazine.

Growing ES cells in culture for valuable medical purposes would not be opposed to human life once you have them. How you get them is the issue. It is akin to the issue of vaccination. Today we all use it. The row was 30 years ago when some vaccines were developed from cells of aborted foetuses. But what is used today is not done in collusion with what happened 30 years ago.

Finally, ES cells may one day be ethically obtained by the partial reversal of differentiation on the nucleus of an adult somatic cell, arresting it before the totipotent stage where it can produce a whole offspring. Professor Trounson hinted at this earlier, but that is down the track. To be able to do this, they need to learn a lot more about differentiation, hence the dilemma. We are in a catch-22. I think that the reverse side of the page of slides could come in during questioning. I have to respect those that follow.

CHAIR—Thank you, Dr Ford.

Mr SIDHU—I would like to also thank the committee for their invitation for us to speak today. We may have a slightly different perspective on the issue of cloning. Our key concern with the AHEC report, and with the cloning issue in general, is the possibility that these cloning techniques might have for the further commodification of human life. People have mentioned certain reproductive technologies and alluded to other inquiries on that issue. With those inquiries there was also this issue of commodification of human life. It is good to pause and think about what these cloning techniques and technologies will have in those areas.

Essentially, we speak of commodification where the status of a human being goes from that of a unique special individual with inherent dignity to that merely of a complex cellular structure and something that can be bought and sold. Some of the scientific members have talked about the buying and selling of certain genetic material. While the report recommends a ban on so-called reproductive cloning, as others have alluded to earlier, the door seems to have been left open with the issue of therapeutic cloning. We understand this can mean a practice where you deliberately create an embryo merely to destroy it and harvest the embryonic stem cells you require for the further research. To us this sounds an even more horrific scenario than reproductive cloning.

We believe that, in treating the most vulnerable of human beings with such disregard for their human rights and dignity, we diminish our own claim to human rights. If the innocent and vulnerable have no inalienable right to life, how can we claim these rights for ourselves? It brings into question the kinds of rights that we can claim when we might not address those rights of these human beings in a very early stage of development. We have not opposed any research that has the potential to save many lives. Obviously, there are aspects of this technology with that potential. We have to stop short where we get to the point where human life needs to be destroyed in order for the research to continue. We are particularly interested that there appears great promise

in this research of transdifferentiation and dedifferentiation of cells and think that maybe this is the way to go and not down the path of somatic cells, cloning and further experimentation on embryos for deriving cell lines.

As young people, we are sick to an extent of seeing human life treated with such disrespect. We are in a society where we speak much of human rights and yet we freely allow the destruction of human life at its most innocent and vulnerable stage. We can see many of the benefits that might arise from these cloning technologies, but there appears to be great harm through any mis-application of this technology.

Miss RANSOM—As the next generation of parents at the point of just entering the work force, we are the ones who are going to have to deal with any public policy decisions you make now that you recommend to the minister. People talk about environmental pollution and how that is going to affect future generations. What we are concerned about is the commodification of human life and how human experimentation will affect society. It may not be immediate but down the line. Many people regard informed consent as the cornerstone of ethical decision making, particularly in the area of human experimentation.

Human experimentation represents a leap from begetting to breeding and from procreation to manufacture. Human rights would be violated by science and medicine anxious for progress. We insist that strict regulations be put into place to help prevent the creation of human embryos for the sole purpose of experimentation and destruction. Self-regulation is not the answer because it would allow individuals to be left to their own devices in deciding whether their decisions are ethical or not. We believe that legislation and not regulation is the way to go. While laws may not put an end to underground experimentation, they will send a clear message to scientists and to the biomedical industry that the government and the electorate will not tolerate destructive research. This would also prevent scientists from attempting to gain public credit for their research. Youth Concerned With Cloning would like to urge the committee to recommend to the minister that human embryos are not used in any form of human experimentation.

Rev. Dr FISHER—Thank you, Mr Chairman. Rather than rehearse my submission, I have four points to make today. We heard this morning that 'a human clone is not a human embryo because there is no union of an egg and a sperm', but the fact is that some embryos happen asexually; that is, other than by the union of an egg and a sperm. For example, in monozygotic twinning (identical twinning) when an embryo at some stage after conception comes off the first embryo; or in laboratory cloning or, possibly in the future, through parthenogenesis or chimeras.

Professor Wilmut naturally called Dolly an embryo from the moment he had a single celled organism with the organised capacity to develop as a sheep. Nothing else was added after the moment of the electrically induced fusion of the enucleated egg and the adult nucleus. If there had not been a lamb embryo at that stage, we never would have had Dolly the sheep. So it is no consolation for Catholics or for anyone else disturbed by the exploitation of human embryos that some today have proposed that we do not call them embryos. The fact is that this organism has the same nature and capacities as any other human embryo. A rose by any other name is still a rose.

The second claim that we have heard today is that 'the experimentation proposed is therapeutic'. The fact is, as several people have already pointed out, that the distinction between reproductive and therapeutic cloning is a distinction without a difference. It is bogus. The language chosen is a form of false advertising, implying the niceness of 'therapy' for some procedures which are actually lethal for those organisms and implying that somehow some cloning is not reproductive, when in fact it is. Not only is it false advertising then on that account, but I think it simply muddies the waters in the present debate because the principal concern of those opposed to this activity is that it involves the destruction of embryos, whatever the goals of those who created them in terms of their future use – bringing them to term or dismembering them and getting products from them.

Thirdly, we have heard today that 'it is ethically unproblematical to clone human embryos with a view to obtaining ES cells'. The fact is that human cloning for the purpose of ES cell collection as presently proposed requires the creation, dismemberment and destruction of embryonic human beings or, at the very least, subjecting them to grave risks and unethical exploitation. Furthermore, despite some comforting promises that we only need to use a few embryos for this purpose, it will in fact likely involve the destruction of many embryos in order to perfect it, and many more if, as has been proposed, there would be benefit in going down the line of producing embryos for each particular patient that would be immunocompatible for the purposes of transplantation of tissue.

Fourthly, we have heard today that, 'however obtained, once we have ES cells, using them is ethically unproblematical'. ES cells may have sufficient totipotency or the inherent organisation to develop as a human being or as a disabled human being. It is therefore the present position of the Catholic Church in Melbourne that it is unethical to create, exploit or destroy ES cells while ever there is a reasonable doubt about whether there is an embryonic human being at stake here. Furthermore, current research using ES cell lines probably

involves unethical collusion in the human embryo destruction that was necessary in order to obtain those ES cells.

We therefore exhort the committee to find that the generation of human embryos by cloning not merely for the purpose of bringing cloned babies to term but also for the purpose of dismembering them to obtain human embryonic stem cells or others products is unethical, inimical to the principles of our democracy and law and should be prohibited throughout this country. Thank you.

Dr PIKE—I wonder if I could begin by highlighting a couple of terms which often get used broadly in this debate. They are used in reference to embryos and to human life in general. It might be useful to unpackage them. The first term, respect, refers to the condition or state of being esteemed or honoured. It is to prize or to value, and furthermore it includes in its meaning to refrain from interfering with or to spare. In this sense, respect is strong. It is not light or without regard. Respect, in this sense, is to acknowledge status or position in the overall context of the place of human beings in the natural order. It is often said by both opponents and proponents of embryo experimentation that embryos must be treated with the highest respect in recognition of that status.

The second term, dignity, is more powerful in the sense that it implies an inherence or value or quality which is intrinsic to, in this case, human beings. This is why those humans who are diminished in their faculties through disease or injury – that is, the disabled – possess this same inherent dignity. It is the dignity attached to humanness per se. It is the dignity that sets humans apart from the rest of the animal kingdom, which is why we tend to recoil when the distinction is breached by an intimate mixing of the two. It is this deep-seated inherent dignity which underscores the human rights documents and various codes of medical ethics which mark all human kind as worthy of the highest respect. It is there for the protection of us all. When some are classed outside that basic human dignity they become subject to minimal protection. If anything, the sciences of embryology and genetics have increased our respect for the remarkable processes occurring in development. They have unveiled a previously mysterious process so that now we can catch a small glimpse of the complex and finely orchestrated events of those early days following conception. In knowing more of the mystery, surely we ought to be more, rather than less awestruck. Surely this stage of human life, even before the appearance of human form emerges, deserves special protection, characteristic as it is of the beginning of the lives of each of us here. Although it has been said that minimal numbers of embryos would be used, having spent about 20 years of my life in science, I am aware of the requirement for repeatability in scientific experimentation and how it actually happens in the lab. The reality is that I find it very hard to believe that only minimal numbers of embryos will be used. If any steps towards transplantation of tissues are under way, there will be a requirement for large numbers of embryos to get the science right. It will not happen without a lot of research. It will not come overnight.

Finally, while the promise of human embryonic stem cells in therapy appears at this time to be so great that destructive embryo experimentation is justified, in reality there can be no guarantee of therapeutic outcome. Indeed, given the unpredictable and often serendipitous nature of scientific research, greater promise may reside elsewhere, perhaps in adult stem cells. The promise of embryonic stem cells may be borne out in part, in full or not at all. In the process, numerous human embryos will have been destroyed. In reference to so-called therapeutic cloning, the words of Lord Alton are rather strong but I will read them here: he said that the process of therapeutic cloning involves a form of technological cannibalism according to which your tiny twin and triplet siblings must pay with their lives on the altar of your medical treatment. He said that this vampiric transfusion of life from the cloned sibling to the original sick patient is a paradigmatic example of using others as a means to an end. He went on to say that it was simply revolting and ethically beyond the pale. It would have been interesting to listen to him say that.

In summary, can we be sure what is being traded here? Are some of the deep values and principles guiding human conduct worth surrendering for possible medical treatment? The promise of therapy seems exciting and full of hope, but if, in the process, something quite fundamental has been exchanged, our humanity may be significantly compromised and diminished and with the risk of further diminishing steps, the consequences of which cannot at this stage be fully known. Thank you.

Mr MUEHLENBERG—The discussion today is something that all Australians eventually will be impacted by. I am aware that much of the – by necessity – technical jargon of today's proceedings will perhaps be lost on the majority of Australians. So I would like, in a very simple manner, to express a major concern that we have, something that perhaps your average Australian could latch onto.

In any of these discussions where there are important issues going on there are what are often known as first principles that need to be appealed to. We heard this morning on one such first principle, the question of when human life begins, that this is an old discussion, it has been around for years, almost passe, if you will. But it seems to me that, in any civilised society in which such crucial issues are being debated, these kinds of questions need to keep cropping up and we need, as best as we can, to try to answer those questions. It is more,

perhaps, than just an esoteric philosophical discussion, as one put it this morning, but it strikes at the heart of where all of us are and what we value in life.

I would like to give a very brief analogy simply to help frame the debate. This is because as long as we still do use human embryos both for experimentation and destructive purposes – for which hopefully one day the need will be taken away, but at the moment we are doing it – it is good to keep in mind some very basic concerns. Wisconsin has been mentioned a few times today, so perhaps I can use that as the basis of my analogy. I come from Wisconsin and hunting, especially deer hunting, is quite popular there, so let me use that as an analogy. Imagine, if you will, a person in the woods of Wisconsin looking for his prize deer. He finds a movement off to the left in the bushes, turns, aims the gun and fires. He goes to inspect what he hopes is a very large deer, but is shocked to find that instead he has actually shot and killed a fellow human being, another hunter. I could imagine that in any court of law probably the first obvious question that would be asked would be something like this: 'If you weren't absolutely certain of what was behind that bush, why did you pull the trigger?'

It seems to me we have heard this morning that, as one person said, your definition of when human life begins is as good as another. It seems to me that if we are not sure when human life begins, then the kind of experimentation and destruction that we have already allowed to take place, if the analogy holds, really would not hold in a court of law. It seems to me, in other words, that these basic principles, these basic questions, if they are not properly dealt with, are going to allow us to go into an ethical no-man's-land, which I think nobody wants to head into. That is my main concern, that we tend to think such questions are either for the realm of the philosopher or the theologian, but in fact they affect all of us and need to be addressed before research further rushes along. Thank you.

Mrs TIGHE—Thank you for the opportunity to address you on an issue which has enormous and frightening implications for the whole of mankind and womankind. As one commentator put it at the time of the birth in Melbourne in 1980 of the first IVF baby: the genie is out of the bottle. Putting it back where it belongs, back in the bottle, has become increasingly difficult. The matter before us today – that is, whether or not we allow cloning of human beings – is a manifestation of the giant ethical blunder which I believe we made when we sanctioned the manufacturing in laboratories of human beings through the IVF programs.

Over the past 20 years we have witnessed a gradual breaking down of the respect for the hapless human embryo conceived in the laboratory. While we marvel at IVF babies and their understandably happy parents, we conveniently ignore the price we have had to pay to achieve these babies. The general attitude abroad today is that human embryos are so tiny as to be of no consequence when it comes to experimentation. The reality is that every human being is a very small but unique human individual possessing all of the attributes of that future man or woman. The irony of reproductive technology is that for infertile couples the presence in the woman's body of a live embryo means that at last a son or a daughter is on the way. An embryo is a very precious thing. It would seem that embryos are of enormous consequence to some people but useful tools for the advancement of science to others.

Given the developments in reproductive technology over the past 20 years, it is not surprising that we are today looking human cloning in the face. If it was not seen as something which is very significant for the whole of society, we would not have a parliamentary committee looking into the matter and holding meetings around the country. It is quite obvious that it is a very serious development. I well recall the strenuous assurances by IVF scientists over the years – I will leave you out of this, Professor Trounson – that they would not permit experimentation with embryos, that they would not freeze them, that they would not store them up. We know now that they do do that, that human embryos have a use-by date and when they have reached that use-by date, if the parents cannot be found or if the parents have decided that they no longer need them, then out they go. We have come a long way since then and now we are in danger of falling for a new set of assurances on the part of medical scientists. 'No reproductive cloning,' they insist. 'We only want to have access to stem cells of embryos so that we can clone tissue to be used to cure diseases.' Who can be opposed to that? You would seem to be heartless if you were going to be opposed to it. Are we going to fall for that line again, to let yet another very dangerous genie out of the bottle?

Ladies and gentlemen of the committee, you have a very important task ahead of you, the outcome of which can either be of great good or great harm to the society. It is imperative that you say no to all types of human cloning and that other means of curing disease must be developed, as I am sure eventually they will, and this has happened over the years. For many diseases that are able to be cured and dealt with today, once this was not the case. This is because of the advances of medical science. Ultimately we cannot demand health for some at the expense of others. I speak here of hapless human embryos.

Dr PALMER—The Royal College of Obstetricians and Gynaecologists of New Zealand and Australia supports a statement issued in March 1998 by the Federation of International Gynaecologists and Obstetricians, FIGO, that cloning for the purpose of implantation into the human uterus for the development of a pregnancy

should be prohibited. That agrees with everything that has been said today. The royal college supports non-reproductive cloning and stem cell research where the primary focus is for transplant or has a tissue graft potential, that is, bone marrow or full organ. This should be permitted in a regulated and accountable manner in licensed facilities. Legislation or regulation of human non-reproductive cloning is needed and should be worded carefully so as not to prohibit the use of cloning techniques in research. The bioethical advisory group of the college agrees that regulation can be achieved by institutional ethics committees acting under the guidance of the Australian Health Ethics Committee and the National Health and Medical Research Council, the so-called two-tier national regulatory approach which we are going to talk about later.

Dr MATTHEWS—Mr Chairman, may I have permission to table the document which I have given to the inquiry secretary today? In the interests of time, I will not read the document but I will read from the summary and will make two other comments. Firstly, human research ethics committees or institutional ethics committees do not appropriately act as policemen. In their decision making, they attempt to reflect community standards and will always welcome information to help achieve this end. In general, they are relatively unfamiliar with the specific processes related to the topic of this inquiry and look forward to the development of Australian guidelines which will facilitate research proposals acceptable to both the investigator and the community. Personally, I am particularly supportive of the advice in the AHEC document being reviewed today that the minister should promote informed discussion in the area of research under consideration, while nevertheless being cognisant of the difficulties of reporting in some areas of the media. Lastly, I would make the comment that the history of science is littered with heretics, both religious and social.

Dr WALSH—I would like to thank you for the opportunity for our organisation to be represented here. On a slightly different angle, perhaps, I am a general medical practitioner and, in my work and in the work of the organisation that I am representing, I work very closely with couples, helping them manage their fertility and dealing very often with the very deep trauma of infertility or of couples who are having recurrent early miscarriages. I would like to remind you – and it is obvious – that there is a very deep psychological and spiritual significance when we are dealing with very early embryonic life. I would remind you that tampering or experimenting with that very early embryonic life may be scientifically exciting but we have to remember that it can be very disturbing and damaging at a deep psychological and spiritual level for individuals and, ultimately, for a society that might condone such tampering and experimentation.

Our organisation has a fundamental belief that an individual begins at the moment of conception and that the individual's rights and dignity begin at that moment as a continuum. Criteria such as appearance, age, size and the ability to speak up for themselves should not be a prerequisite for the survival of that individual or for accordance to it of proper care and respect. As has been mentioned by previous speakers, we believe that individuals have a right to come into being, not as a laboratory product or experiment, not subject to quality control, not to be used as a means to an end and not to be used and discarded as per the proposal under discussion of therapeutic cloning to obtain embryonic stem cells. There is no therapeutic benefit for the discarded embryonic human life. Proposed procedures where the embryo may, perhaps, not be lost but the cells may be gained is experimental in the least and utilitarian, and we believe they should not be allowed.

Reproductive cloning of an individual is an offence against the dignity of that human being, and we believe it should be prohibited. There is much good that is being talked about and it may be foreseen to be possible, but that good should not blind scientists and regulators to the very urgent moral and ethical questions that need to be solved. Achieving this possible good through immoral means is never a satisfactory answer, as there is much more harm, on balance, that could be done, as the one or two cells may be experimented with as embryos or lives may be lost. There is also moral harm to the researchers, the law makers and the community in general that tolerate such practices.

We believe that research on somatic cells, where stem cells may be isolated from ordinary body cells – the pluripotent cells – looks exciting and should be encouraged, and public money should be spent on research practices that will not worry or confuse the community and which do not have the potential for great harm.

Mrs STRNAD—Thank you. The humanists very strongly oppose the reproductive cloning of human beings. We very strongly support research on cell cloning for therapeutic purposes and, given its potential to alleviate human suffering as outlined by Dr Pera this morning, we believe there is a moral and societal obligation to promote it. We regard the stem cell culture technique as akin to autologous graft or transfusion where, for instance, the patient's skin is taken and grown to a larger amount to cover a large area of skin grafting, or transfusion where the patient cannot or will not have donor blood. Their own blood is collected and manipulated by being anticoagulated – very much like the stem cells – and returned to that patient. I have brought some copies of a very recent article in the *New Scientist* that reports on a new technique: cloning without embryos. I brought this to illustrate how necessary it is to have very short sunset clauses in any regulations, because the technology moves so quickly.

I would like to comment on a few expressions and concepts used in this debate. We believe that 'embryo' is an unfortunate term for the early cluster of cells. In the United Kingdom, the Warnock committee mentioned by Professor Short refers to this as pre-embryo so as not to conjure the image of a miniature child. This has been approved by the House of Lords. The same committee approved research on the pre-embryo till day 14 – till the appearance of primitive streak. We believe this should be allowed here.

On the subject of human dignity, we do not believe that it is a genetically based heritable quality. Rather, it is acquired and nurtured and consists of integrity, decency and moral responsibility. It is situational. It is absent in brutalising conditions such as torture, prison and severe illness. Sufferers of leprosy, both actually and proverbially, are not accorded dignity nor are the untouchables in India. It is a cultural construct and in various cultures accorded differently. We do not believe that it is inherent in the 23 pairs of chromosones that define the human species.

On the subject of personal uniqueness which is perceived to be destroyed in manipulation of cells, we believe that it is not a practical construct. Rather it is an abstract, given that most of us seek like-minded people, kindred spirits and common ground. We emulate our idols and the expression 'two peas in a pod' denotes a good relationship. Were I to discuss my uniqueness with my friends I would be told that I take myself too seriously, and probably not in such polite terms. So we dispute both the personal uniqueness and dignity that is perceived to be destroyed in handling of early cells.

We are not experts on matters legal, but we are concerned about the commercial pressures on this technology. We would very much love to see government regulation, if not legislation, and we wish to point out that every new invention, including the wheel, brought with it its own risks. It should not be beyond our combined wit and wisdom and experience to provide barriers to its abuse and to reduce its potential for abuse.

We have a problem accepting that life begins at syngamy, that is, at the fusion of ovum and sperm. It would indicate that nature has very scant regard for human sanctity, given that 50 per cent of embryos conceived in vivo do not implant and are discharged in the next menstrual flow. So we believe that life begins at the 20th week of gestation, when consciousness begins. We do not believe we are just a mass of cells.

Finally, some of the current opposition to therapeutic cell cloning is reminiscent of the opposition that existed not so long ago to the use of analgesia in childbirth. It was perceived that it was unnatural and that we were meant to be born in pain and suffering. I believe cell cloning will be as acceptable in the near future as pain relief is now.

Dr HACKER—Thank you to the committee for permitting the AMA its voice here. The AMA has no views on some of the issues that no doubt have been receiving much attention this morning and will continue to receive it, that is, on issues of when life begins. The primary issue for our organisation is that it supports the view that the cloning of human beings is unethical but also supports a view that using the cloning techniques to therapeutic ends is an ethical procedure which should be permitted to occur in this country under suitable ethical frameworks and that it cannot agree that the prohibition of these activities can be useful for the Australian population or for Australian research. There are a number of concerns about what would occur were the committee to regulate against these procedures. This is a major concern of our organisation.

There are, of course, lots of medical professionals in the country who are involved in the basic research, and those people may be lost to this country. The intellectual capital that these people bring to our nation may go elsewhere because, even if this research is denied to this country, it will continue elsewhere. The concern is that, if it is not given acceptability by the government, the possibility of it then falling into the hands of private enterprise and being patented, which the AMA is also opposed to, will also be a grave risk. We therefore believe it should be open, transparent and in the public arena and should not be prohibited.

The AMA has been participating in the World Medical Association's work into human cloning. It participated in a working group set up by the WMA into cloning and human dignity. Regrettably, that paper has not been finalised and is therefore not available for you at this time. There has been much talk this afternoon about one end of this process. Many members of the medical profession work at the other end, myself included. I work in a heart-lung transplant unit, and there are many others who work in transplantation. There is an enormous shortage of organs in this country. Australia has one of the worst organ donation rates in the Western world. If you go to some other countries, you will hear that people are unprepared to give their corneas because they believe that they will need them in the next world.

We have a dilemma here. The AMA really has a very powerful view that we must continue this work because we have to turn off machines. I have to sit with the young people who are losing their parents and with the parents who are losing their children because we do not have enough organs. The research that can come out of this work clearly has enormous benefit. It will continue elsewhere, regardless of what goes on here. It is important to remember that the committee is faced with an incredible dilemma. I have no doubt that it is aware of that. It seems to me that this afternoon you have heard one end of this work rather than much about the

other. There are huge issues related to the possible outcomes of the work that are equally ethically demanding. I think it is important to state those views here today.

Dr PIERCY—There is international consensus that human cloning should be prohibited because it is an affront to human dignity. Deliberately produced clones are a means to an end and it is treating human beings as commodities. This condemnation of cloning is usually thought of as applying to the use of cloning technology to produce a whole human being who is born and grows to adulthood. Human beings, however, are whole human beings from their single cell beginning, no matter how this cell is created. Any other point chosen for the beginning of this process is just arbitrary. Before this point there is no spontaneous potential for the development of a baby and after the creation of that cell there is.

I disagree with the statement that the results of passing a somatic cell through an egg to produce cells in a culture dish are not equivalent to an embryo. As was said, there is the small possibility of being able to implant these cells and allow development to the birth of a new child. How can there not be a difference between such cells and an ordinary body cell which, without such manipulation, could never become a baby? This manipulation enables the production of an embryo from a somatic cell. It does not indicate that people who believe that life begins from a single cell stage believe that somatic cells are equivalent to embryos.

It is my view that embryos, pre-embryos and embryoid bodies – whatever they are called – should be awarded dignity and protection. Even if these are produced differently to an embryo produced by fertilisation, this human life should not be used as research material or as a source of cell line or tissue. Our pursuit of new medical treatment should never sanction the destruction of human life in order to benefit other humans. Therapeutic and reproductive cloning both begin in the same way with the production of totipotent cells. Therapeutic cloning does necessitate the production of what is ethically equivalent to an embryo, even if it is not called an embryo by some scientists. It requires the sacrifice of this human being.

I am quite concerned about the idea of requiring organ transplants and that this is a good reason for pursuing cloning technology. Whole organs cannot be produced in vitro. They require the implantation of an embryo, growth to a stage where the organ has developed sufficiently in the foetus, and then abortion of the foetus for harvesting of the organ. While amorphous sorts of tissues could be produced in vitro, something like a liver that needs blood supply, ducts and so on would not be able to be produced in vitro.

The semantics that are used in this debate come from researchers in the biotech industry that seeks to profit from the freedom to carry out human cloning research. The industrial production mentality in which human life is used for its tissue is dangerous, reducing the tiniest and most vulnerable members of the human family to new products.

Human beings should not become a commodity. Commercial interest in human cloning should be withstood. If human cloning is permitted for any purpose, even if it is just for very specific purposes, there will be pressure on clinics, and on women to donate eggs and to offer their wombs as incubators. There is some potential for coercion. Allowing the cloning of human embryos, even in very limited numbers and in special circumstances, would inevitably lead to greater numbers and wider circumstances being accepted for cloning research.

I also have concerns about the safety of it being applied to humans even in transplantation of tissue. There is the risk of malignant transformation. I believe, too, that the cost of human cloning research, both financially and in terms of the wastage of human life, would be enormous. The resources necessary to successfully clone and produce healthy babies or to develop useful tissue or organs for transplant would be exorbitant and beyond justification given the other pressing needs of our society and the rest of the world.

Finally, I believe the committee has a duty to support research which has the potential to benefit the lives of many people, but only as long as such research does not do so by harming or destroying other lives. Since human cloning does harm and destroy human life, all such research should be prohibited. Research should focus instead on efforts to culture adult stem cells in order to alter their type for use in tissue transplantation. There have already been some promising results in this area. This would avoid the ethical difficulties of cloning human embryos in order to obtain embryonic stem cells. It is imperative that science be guided and upheld by ethical standards in order to discover new treatments for genetic and degenerative diseases which do not violate the dignity of human life.

Dr ROGERS—The Human Genetics Society of Australasia feels that cloning to produce another individual is certainly unethical. But, when it comes to the question of research, this is a community with different views of the early embryo, and those views are reflected within our society. It is very hard to see that an embryonic stem cell or a somatic cell is actually the equivalent of a human being, as many people have put forward here this afternoon. Whilst there is the remote potential, with great nurture, for some of these cells to be developed in that way, I think this is a very remote potential.

The potential benefits from research in this area in terms of birth defects, malignancy and transplantation, to name a few of them, are enormous. We feel that it is critical that this research be facilitated within Australia, although properly regulated – which we will go on to later this afternoon – and perhaps there is an ethical imperative that this research proceeds. Also, it is important not to close off the possible gains from embryonic stem cell research in the hope that the development from somatic cells will ultimately enable us to get to the same place. One part of the research informs the other and they ethically and critically combine together.

Mr MENEY—The Association of Catholic Families has concerns about cloning in general. Whilst I appreciate the differences that have been put forward about therapeutic and reproductive cloning, we feel that perhaps what is needed is an essential understanding of the human person. Our principal concerns are that we believe that much of what has already been proposed can be achieved in some circumstances without using the cloning of embryos. We are concerned the illusion of the cloning of human organs has continued to mislead people when what in fact is being proposed is the cloning of embryos prior to dismemberment. We are concerned that in the name of health care we are embracing a principle that worth is determined by the extent of development and capacity, and that as such the embryo is worth less than the foetus, the foetus is worth less than the child, the child is worth less than the adult and perhaps the disabled adult is worth less than the able adult.

The next concern relates to the evidence which indicates that it has already become a practice in Australia to avoid local bans on human embryo experimentation and destruction by importing parts of embryos resulting from experiments done overseas, or to export Australian embryos overseas for experiments that are banned here. We are especially concerned that the continued importing and exporting of the products of human cloning involves our country in a moral contradiction whereby we are participants in a process and we have outsourced those aspects over which we have some moral repugnance.

We are greatly concerned that the forced twinning of human embryos to facilitate pre-implantation genetic diagnosis will cause a further distortion of our understanding of the nature of the human person by encouraging the perception that responsible parenting involves shopping for particular types of desirable offspring. Will we continue to abort embryos for ever more superficial reasons, such as sex or limb deformity or deafness, and in the process so distort our understanding of what it is to be human? We will become a society that frowns upon and passively discriminates against those parents who choose not to abort individuals who appear less than perfect. The growing pressure exerted by US health insurers on pregnant women to screen for Down syndrome is a case in point.

Finally, we are concerned about the loss of social connectiveness and the commodification of human reproduction that will result from cloning. Relationships could move from father-son to owner-donor and parenthood could be regarded as elective. We feel that the growing suggestion which views human reproduction as a commodity and women as sources of ova and wombs for gestation is, in the words of UNESCO, an offence against human dignity. Thank you.

Ms WEBER—The Council for Marriage and the Family is concerned with the implications of cloning for the family, familial relationships and the dignity of the human person. The council argued in its submission for prohibition of any form of cloning, whether it be described in terms of the creation of a human identical to another or other asexual reproductive techniques. In the case of the embryonic stem cells, given the two aspects – that of the unknown capacity and the possibility, if placed with the tetracloid cells, it would form placenta and develop normally – we need to give the benefit of the doubt and not permit cloning.

The council submits that, in its opinion, human cloning is contrary to promoting and protecting the human being, whether it be the embryo, the siblings or the parents. Human cloning is unacceptable as it compromises a child's sense of identity as well as compromising the child's relationship with its parents. Human cloning treats the unborn child as a product manufactured to serve consumer demand. If scientists, parents and the community are willing to treat the designed or cloned child in this fashion, this will potentially damage the child's relationship with its parents in knowing that a donor sibling has been sacrificed for the medical benefits of other members of the family.

Human cloning does nothing to protect the individuality of a human being. The principle of the family being a sanctuary of life is at stake. It is this sanctuary which is about protecting the child and family members. The family is the basic community of society which is unique and unrepeatable. It is in this environment that a child experiences a relationship with parents, other family members and with the wider community. The family is where a child will come to experience the meaning of human dignity, care, love and acceptance regardless of their abilities. In circumstances involving cloning this knowledge is distorted. How could a child be expected to cope with the knowledge of what has taken place with these medical procedures? How is a child expected to understand their relationship with their parents in coming to terms with the decisions and cloning processes, whether the treatment has been for reproductive or therapeutic reasons – decisions and processes which would appear to be ultimately determined by the community setting the standards? This is a violation of the child's

right to be protected by the family, and the family – as a sanctuary of life in fulfilling its role in protecting family members – should be protected by the community. This is necessary in order that the family can continue its role in caring and protecting the family members and protecting the child's dignity and sense of worth and ultimately ensuring that a human person is able to fulfil their potential. Thank you.

CHAIR—Can I perhaps lead off in asking some questions on behalf of committee members. It seems to me that there are two issues about which there is some commonality of view. One is the suggestion that reproductive cloning should be prohibited. I do not think there has been a different view expressed all day, so I am not going to waste time in going down that track. It seems to me also that, for a variety of reasons, not all similar, there is a general agreement that some of the terminology that is being used in this area is confusing. Perhaps some clearer distinctions ought to be drawn and we ought to be using terminology that actually describes processes rather than using broad expressions such as 'cloning', which can mean different things to different people in different circumstances. So I am proposing to leave those issues aside at the moment.

It does seem that there is a difference of opinion, however, when it comes to the ethical judgment made about research involving the ES cells. I would like to tease this out a little because, if I look at what Dr Ford stated in one of his overheads, he says, 'ES cells are not embryos; they lack the inherent active capacity to continue organised species-specific human development including a body plan.' As I wrote it down, Dr Fisher said, 'They may have sufficient totipotency to develop,' and there are other comments from other members of the group that, whilst not in those words, were expressing that view. My question is therefore to both Dr Fisher and Dr Ford in trying to tease out the ethics of this particular issue, because it does seem to me to be an issue about which there is some disagreement and debate. Perhaps I can start with you, Dr Fisher. You say that they may have sufficient totipotency to develop and therefore they ought to be recorded – these are my words, but I think this is what you are saying – that involves not researching them. Can you elucidate that position further? I am going to ask Dr Ford the same question from his perspective.

Rev. Dr FISHER—I use the word 'may' because I confess to not being sure about this. This is a prudential judgment ultimately. If there are reasonable grounds to think that these organisms may have the inherent organisation to develop as a human being, or as a disabled human being but still a human being – one perhaps missing a vital organ but otherwise a human being, disabled – then I think, as a matter of prudence, we should accord to them the same respect that we would any other human being. A common parallel that is drawn in moral philosophy is if you see something moving behind a bush while you are out shooting for kangaroos: it may be the farmer's son or it may be a kangaroo. While ever you are not sure whether you are dealing with a human being, but there are some good grounds to think you might be, you ought not to shoot. You should, for present purposes, until you are sure about this matter, accord what is there the respect that you would accord a human being. That is the proposition of the Catholic Church of Melbourne that is being put to you today: while ever there are some reasonable grounds to think this has sufficient totipotency to continue the course of development of a human being, we should treat it with that kind of respect.

Rev. Dr FORD—I have looked into this matter. I have discussed it with some of the scientists and it is my understanding – I will ask Professor Trounson to correct me – that to obtain ES cells a blastocyst is destroyed to take out the inner cell mass. In other words, an embryo is destroyed to obtain the inner cell mass cells. It is my understanding that up to 15 or even 20 ES cells could be obtained from one blastocyst. Is that correct?

Prof. TROUNSON—You are talking about the number of inner cell mass cells?

Rev. Dr FORD—Inside the blastocyst.

Prof. TROUNSON—20, 25, 40.

Rev. Dr FORD—So one embryo is destroyed and we create 25? I find this a little extraordinary. My second point is that there would be a sort of residual potency if the ES cells were to be aggregated with trophoblastic cells – the cells that are on the outside of the blastocyst. The inner cell mass cells from which the ES cells come need the trophoblastic cells in order to continue developing as an embryo. When they are removed from that environment, they lack that potential to continue development. What happens now is that they are put on a feeder cell layer and remain in the undifferentiated state and multiply. To argue that, in that state, they are embryos lacks credibility. I find no reason or grounds to believe that, when you destroy one embryo, you create another 20 embryos.

I go to point 2: an egg has the potential to become an embryo only after it is fused with the sperm. Then you get the new joint life principle from the contribution of the mother and the father – egg and sperm. But you do not have it prior to that fusion. So I also argue that, granted that the ES cells, if they were to be, again, fused with trophoblastic cells either from the one they came from or from another one, you would even then only get your embryos once development resumes. This has been done with the mouse, and I am not sure whether you can extrapolate from the mouse to the human – Professor Beck might comment on that. And there would be no guarantee it would be the same embryo because you might get 15 or 20 of them.

Speaking to this committee in the equivalence of being under oath, I cannot accept the reason or grounds to argue on science and philosophy that you are dealing with another 15 to 25 embryos from the destruction of one embryo. To use an argument to force in our country legislation to ban this sort of work for these reasons is very flimsy. I am prepared to answer questions.

I might add this one case. If I were HIV positive and were morally irresponsible enough to engage in sexual activity with another person – let us say unprotected vaginal sex – I would be putting the woman at risk, and it would be unethical to do so. This has happened in Victoria. Somebody did this where the woman did not know the man was HIV positive and it went to the courts. The risk is something like one in 600 or one in 1,000 – the risk is very minimal – and he was not convicted by the Supreme Court on the grounds that there was too little risk to the life of the woman. In other words, the jury – the law – threw it out on the grounds that there was not sufficient reason to believe that there was a serious risk to the woman from a one-off episode. Here we are talking about legislating to make certain activities with ES cells criminal on the grounds that they 'may, may, may' be embryos. There is an ethical problem for the committee in what recommendations it makes in the name of the Australian people on this particular issue.

Mr CADMAN—Gentlemen, I wonder if I could pursue the Chair's questioning. To distil what you have said, stem cell experimentation is rejected by you, firstly, because of the way in which those stem cells were gained, that is with the destruction of an embryo and, secondly, because once the flashpoint or the take point is reached, somatic adult cells reach a point where you say experimentation should not continue. Is that right?

Rev. Dr FORD—I am not sure what you mean by that take point.

Mr CADMAN—For example, when Dolly stops being a mammary gland cell and turns into a sheep. Let us call that the flashpoint.

Rev. Dr FORD—In other words, a somatic cell is placed inside an enucleated egg, fused with a little bit of electric shock and its nucleus is reprogrammed to imitate an embryo and act like an embryo, and off it takes.

Mr CADMAN—That is right.

Rev. Dr FORD—Then after a few days you will get your blastocyst. But, earlier on, the experimentation we are talking about here is embryonic stem cells or ES cells, which are not the same as stem cells.

Mr CADMAN—I understand that.

Rev. Dr FORD—There is no problem with stem cells. The problem is with the ES cells.

Mr CADMAN—I thought you said that you rejected the destruction of an embryo to obtain it.

Rev. Dr FORD—But what you obtain are the embryonic stem cells. I object to the destruction of the blastocyst to obtain the ES cells. But I also referred in my overheads to the possibility of reprogramming a somatic cell partially back not to the totipotent stage but to the pluripotent stage where you could get your stem cells, and there would be no embryo involved at all. You could even perhaps get to the ES cell stage by that process and it would not come from an embryo. That is where I was saying there would be no offence against life. It is wrong, in my view, to destroy the embryo, to destroy the blastocyst, but once you have got your ES cells, once they are there and you are multiplying them – and there are thousands of them here – I would not accord them the respect due to an embryo. In conscience I just could not.

Mr CADMAN—What is Dr Fisher's view?

CHAIR—Before we come to that, Dr Ford, do I understand your position correctly that, if I could put it this way, Dr Trounson can use what he has got but he cannot go and make some more?

Rev. Dr FORD—If you want to take the ethical argument fully, in what they are going to do afterwards there ought to be no collusion with what you did before. Perhaps someone else who had nothing to do with the production might ethically be able to proceed.

CHAIR—So you are saying that Dr Trounson can give them to someone else but he cannot use them?

Mr CADMAN—He should not be using them.

Rev. Dr FORD—I will not speak for Dr Trounson. But if someone else were to know that there were ES cells available and wanted to do this laudable research for medical purposes, I would not see any collusion with how they came to be in the first place, much the same there are vaccinations that emanated from an abortion 30 years and that does not cause problems today. But if one did it with the purpose of doing it, there would be collusion.

Mr CADMAN—Dr Fisher, could I have your comments on those two points?

Rev. Dr FISHER—Unlike Dr Ford, I do not find it extraordinary that sometimes an embryo can be split into several embryos. This happens in identical twinning, monozygotic twinning. The way people normally reproduce roses is by taking many cuttings from a rose, and you could start with one and end up with his extraordinary 25. Asexual reproduction is one of the ways that reproduction happens naturally in the human,

though rarely, and now we can do it in the laboratory. They are still embryos, even if they are created by splitting them off, by taking one cell or several out of an existing embryo and letting that develop, if that can happen.

That an embryo might not have the ability to develop a placenta means certainly that it is a disabled embryo, just as some human beings are lacking some other vital organ. We have many adults, including possibly some in this room, lacking a vital organ, but they are still a disabled human being. So it is not a clinching argument for me that we could design this process in a way that ensured that the embryo lacked a placenta or lacked brain, as has been proposed in some of the experiments, if in fact it continues development as a human embryo would. So, from my point of view, it is both the destruction of human embryos in order to obtain these cells, but also, having obtained them, the possibility that these cells themselves have the ability to develop as human embryos, that is morally problematical. I have, as it were, two concerns here, whereas I think Father Ford and I would share concern about the first one, which is the destruction of embryos to get these cells.

Mr CADMAN—What about the Dolly situation?

Rev. Dr FISHER—In the case of Dolly the sheep, nothing extra was done to Dolly the sheep after the electrical fusion of the enucleated ovum and the mammary cell from the adult sheep, apart from putting it in the appropriate environment for an embryo – which is, in this case, another sheep's womb – and that embryo developed.

It may have been a surprise to many that it happened in that way, but that is what happened. There was no additional conception process – no additional fertilisation process – that occurred. Quite clearly, if we want to trace Dolly's life history, the only point which we can reasonably give for the beginning of Dolly was the point when the lamb embryo occurred – that is, the fusion of the enucleated egg and the nucleus from the mammary cell of the adult sheep.

Mr MURPHY—Father Fisher, this morning you called for the scientists present in this room to guarantee that in their work they would not assist in the development of a human clone and you were given that guarantee, save for Professor Trounson's prospect of the destruction of humanity. From your submission to the committee earlier this afternoon on behalf of the Catholic community of Melbourne, I took that you do not condone the scientific research currently being undertaken in this city on stem cells. So, in view of this, are you saying that the research on the stem cells being undertaken at Monash Institute should stop forthwith?

Rev. Dr FISHER—Yes, that is what I am saying.

Mr MURPHY—If the research should stop forthwith, what would you suggest be done with the stem cells?

Rev. Dr FISHER—The stem cells, as I have suggested, are potentially or possibly may be human embryos, human embryos that it would seem to me we have no morally practicable way of bringing to term – of allowing them to develop as human beings – and so they should be allowed to succumb. But what I would be proposing more positively than that rather sad way to end this program would be the sorts of things we have suggested in our submission at 4.3: the whole range of positive ways this research could be taken, including a way proposed by Professor Trounson. That is to look at de-differentiating adult cells so that you would never need to create an embryo or an embryonic stem cell as a means to achieving many of the same goals. But I would say we have no morally available means of saving the lives of the ones we have at the moment, and they should be allowed to succumb.

Mr MURPHY—I suspect that the scientists would argue that they are dealing with cells now that in no way impact on live embryos, notwithstanding what work is done at Monash Institute, and against a background that science is looking at ways of manipulating these cells at some future time to provide cures for Alzheimer's, Parkinson's disease, for the growth of new organs, and all that. This is something that is not going to go away from us in our positions in the parliament in the future – and there are certainly a number of us who are Catholics. What advice do you have for us?

Rev. Dr FISHER—I entirely sympathise with the kinds of concerns you have mentioned here, such as: 'What is going to happen with these cells?', 'It seems such a waste just to dispose of them,' 'It is going to happen anyway somewhere else,' and 'Couldn't there be great results that come of this?' But I think the kinds of issues that were raised at the beginning of this session by Dr Tobin have to be very much in our minds. The result is not all that counts. We certainly have to be concerned about results, and that is why I propose that we look for more positive, creative ways of achieving some of these same goals; even if we might not get these results quite as quickly by going down this path, we would get them in a less ethically problematical way. We should still seek these positive ends, but we should always ensure that we do it in ways that are not compromising some of the most fundamental values of this community. I think that includes respect for human life in its origins and throughout its development, respect for human parenthood and the family and some of the other values we have identified in our submission. So my positive proposal is: look for other better ways of achieving these goals. Do not compromise our basic values just because you want to get there more quickly.

Mr MURPHY—I just take it a little bit further and say that they have already been compromised and the cells are there, and my understanding from Professor Trounson and Professor Pera in their submissions today is that they have probably got sufficient stem cells not only to satisfy Australia but the world at large and they seem to be pioneering this research. I am finding it difficult that you, as a spokesperson for the church here in Melbourne, and I respect your point of view on behalf of the church, should say that those cells should be allowed to succumb.

Rev. Dr FISHER—I think this is a similar issue to questions that have arisen many times in the history of medical experimentation, where experiments have occurred which people would regard, at least in retrospect if they did not know at the time they were happening, as profoundly immoral experiments but which have resulted in some benefits of one kind or another. Sometimes we benefit from them years later. But if at the time you know this is happening you would do your best to stop it. My proposition to you is that, given the complicity of this experimentation in the destruction of human embryos, even if it is occurring in Singapore rather than here, and given the at least doubtful status of the cells themselves, we should be saying, 'We are calling a halt to this line of inquiry and looking for less morally problematical ways of seeking the same ends.'

CHAIR—Dr Ford, have you got a comment on this?

Rev. Dr FORD—I agree where there are reasonable doubts fully in line with our traditional principles, but I do not find reasonable grounds either in what Dr Fisher said now nor in what Dr Peter McCullach said in Melbourne when we had a meeting last year. It is not a numbers game, whether it is 25 or one – that is not the argument. Where are the grounds to believe the ES cell has the inherent active potential to go on unless it is added to other trophoblastic cells? An egg cannot become an embryo unless the sperm is added. Even the egg would have the potential, as is demonstrated in the mouse, to be activated by heat, alcohol or a pinprick to start parthenogenetic development, and in a mouse it goes to mid-gestation, so you have got a foetus halfway down the track. Nothing new by way of a genetic addition is added but there is evidence of that foetal mouse. Therefore, every egg has the potential to become an embryo. Are we going to give moral respect to every egg? I am looking for the reasonable grounds for arguing that the ES cell is an embryo, and I find it is parallel to arguing that every egg is an embryo because it could be stimulated with a pinprick, alcohol, heat or electric shock. This is a very important point. Just to say there are reasonable grounds for belief without saying what those reasonable grounds are I do not find acceptable to be put to the Australian people, nor to this committee and the parliament.

Ms ROXON—I am going to change subject completely, because I must say I find the position of Reverend Fisher totally logically inconsistent, that you would be ethically opposed to this research but the consequence of your ethical opposition to the research would be that you, in your own words, kill – I think 'allowed to succumb' is the euphemism – what you believe is human life. I find that inconsistent, but I suspect we are destined to disagree on that.

Rev. Dr FISHER—I think I have been misunderstood if it has been understood that I said we would be killing somebody.

Ms ROXON—I understood that is what you mean, although you would not like to say it in those terms.

Rev. Dr FISHER—I just want to clarify that I certainly would not be proposing that. I think here we are in a parallel situation to dealing with someone at the end of their life for whom there is nothing morally available we can do to extend their life and we accept that. There is nothing morally available we can do. If there was we might do it, but there is not, so in this situation we do other things. We hold their hand, we pray with them, we care for them, but we do not actively aim to kill them either. I think this is the parallel here. If we have embryos or things very like embryos but we have no morally available way of saving their lives, then we allow them to succumb. But what we are certainly not doing is moving in there to kill them and going in with homicidal intent.

Ms ROXON—As I said, I think we are destined to disagree. I think it is an entirely inconsistent view to have, but that is by the by. My question is actually to each witness who has said that they would be opposed to any form of research. So, whether you have chosen to use the words 'therapeutic cloning' or 'research on embryonic stem cells', just for my own perspective could each of you who have said that – I know a number of witnesses have not said that – tell me whether they also opposed, or represent an organisation that opposed, IVF at the time that there was the debate. It would be helpful for me have a perspective on that. Mrs Tighe has already indicated in her submission that Right to Life had strongly opposed that at the time but, for the other organisations that have said no, if we could just quickly go around the table and say yes/no that would be very helpful.

Dr TOBIN—I did not take part in any of those discussions earlier. I am puzzled by your question. The second thing to say is that even IVF is itself a contested term. In order to answer your question I would need to know what you count as IVF and what you do not. There would be some forms of IVF I would think ethically undesirable and others that I would not. It is a matter of what you include and what you do not.

Rev. Dr PULLIN—The question needs teasing out and defining. The Anglican Church has always promoted the values of science, its good for the community and its responsibility back to the community. I have tried to help people understand how knowledge may be advanced in ethically legitimate ways. While I did not state that what our submission said was because this area is so ethically muddy, because there is so little consensus they did not recommend a ban, they recommended a moratorium for five years while we have these debates and arguments before we actually make a decision on what will be the final outcome.

Rev. Dr FORD—I was a member of the St Vincent's Bioethics Centre at the time. There are other people present who can speak for themselves. We were opposed on ethical grounds to IVF. As a Catholic priest I accept those reasons still today to oppose on ethical grounds 'the' extracorporeal conception. That is not to say that I want to use my influence for the law to ban it. Let us say adultery is unethical, but I would not argue to make it a crime if it is consensual.

Mr SIDHU—I was probably too old at that stage when the debate got under way.

Ms ROXON—I think I am in the same position.

Mr SIDHU—As to how we feel about that now, perhaps looking back on the debate, we would be opposed to the experimentation that was involved with it. As to the actual procedure itself, which procedure in IVF technology is it? Could you specify exactly what that is? As a general line, the experimentation that has occurred with those procedures we would be opposed to.

Rev. Dr FISHER—The Catholic Church in Melbourne would have taken a similar position to the one enunciated by Dr Tobin. It depends what you are calling IVF. It would be well known, for instance, that there is a significant reproductive technology program in the Mercy Hospital for Women that offers certain procedures that some people call GIFT. Other people would include them under the umbrella of IVF. There are some things people call IVF that clearly are contrary to the teachings of the Catholic Church and other forms of assisting people to procreate which may not be.

Dr PIKE—At the time the debate was happening I was not with the Southern Cross Bioethics Institute, so I can only speak personally. Yes, I would be primarily, with similar qualifications, against IVF. I suspect that the institute at the time would also have held a similar position, again with qualifications about the detail that you may be alluding to.

Mr MUEHLENBERG—I believe both the Festival of Light and the Australian Family Association were in embryonic development at that point about 20 years ago. However, I believe they both shared concerns about some aspects of IVF, especially as it impacts upon the family.

Mrs TIGHE—If I can explain a bit further, our organisation took that position back in 1980 purely and simply on the basis of the fact that we knew it would involve an inherent lack of respect for human life – no other philosophical reasons. I believe that our position has been proven correct. If you would look at our record of lobbying in the Victorian parliament when there has been IVF legislation, you would see that we have consistently opposed it, not because we lack concern for infertile couples – of course that is not the case at all – but because of a consideration of what is happening to human embryos. I well remember at the time – I am old enough to remember it – there was debate on television in one of those programs that no longer exist and I remember Peter Singer saying – one thing about him is at least he is honest – 'I can't see what all the debate is about; after all it is no different to an abortion, what happens to these embryos.' He was quite honest there. So that is our position.

Dr PALMER—As a college, we did not oppose IVF, more because we were worried about the treatment of infertility patients and knowing the concerns of these patients. It was their only hope really for a cure, if you like, on that basis. So, as a college, we were never against IVF.

Ms ROXON—I think we can skip a few who did not oppose it in their submissions, unless I am misrepresenting anyone. I think it is Dr Piercy —

CHAIR—Has anybody else got anything they want to add?

Ms ROXON—A yes or no is what I have not successfully got from anybody, or not briefly anyway. Dr Piercy, I think you are the next person.

Dr PIERCY—Yes, I was a bit young, I think, at the time. I also oppose the embryo experimentation that goes along with some of the IVF procedures.

Ms WEBER—The IVF debate predates our organisation, but our concern has always been with the implications for any form of reproductive technology on familial relationships, especially the fragmentation of the family structure through surrogacy and donor gametes. That would be our position now too.

Prof. CHALMERS—I just wonder if I might be allowed just a small coda to some of this discussion and direct the committee to the evidence before them in Australian Health Ethics Committee, *Ethical guidelines on Assisted Reproductive Technology*, and perhaps take some layers of the questions which have been asked. First

of all, I hope that I am not misunderstanding the nature of some of the questions which are coming from the panel, but I think there is a distinction between the intentional creation of an embryo for purposes of research – and, according to paragraph 11.1 of the AHEC guidelines, that was classified as a prohibited practice. I think that is a view which is shared in many of the statements throughout the world. I would also direct the committee to the recommendations of the National Bioethics Advisory Commission on the ethical conduct of stem cell research. In recommendation 3, they take a similar view: intentional creation of embryos for the purpose of research is something which is morally different from treating the circumstances as they exist.

I think the second point – when does life begin – has challenged this group for some time. I think what we would say in our document is that there are at the time of conception duties towards the embryo and I think there are ways in which one would organise one's dealings with the embryo which should accord the necessary and, I think, required standards of dignity and respect for the embryo. I am not sure that it is terribly helpful to go along a chain of events and find out, as Professor Williamson said, that nidation is more significant than 14 days or whatever. I think we say that we as a community would like to arrange our treatment of the embryo in ways which advance the dignity and respect for that embryo.

That then, I think, takes us to the third stage, which is: is there, as it were, one position towards the embryo? I think what we tried to say in the short paragraph No. 2 on page 10 is that we encountered in our public submissions a range of views, from those that would say that no research under any circumstances should be permitted to those that would say there may be circumstances in which research may be justified as a benefit from that embryo to another, and to others who would have said in very restricted circumstances some research may be permitted.

We then went on to say – and I think this is really the nature of what we are saying – this: do we say no to every form of research or do we say there may be limited, exceptional circumstances that would allow us to move from the position of the absolute protection of the embryo? I think the view which was accorded in that statement – and I direct you to it at paragraph 6.4 – says that there is a difference between therapeutic research carried out on the embryo for its benefit and non-therapeutic research. Where it is non-therapeutic research, we said it should be grounded in three restrictions: firstly, there should be a likelihood of significant advance in knowledge or an improvement in the technologies for the treatment of particular procedures; secondly, there should be a restricted number of embryos; and, finally, there should be all the necessary consents from those involved. In that sense, with the Very Reverend Fisher – and I hope this is of some assistance in regard to Mr Murphy's question – I think there is a difference there. We would say that they should not be allowed to succumb if an ethics committee, satisfied with the protocol put forward, justified as to the science presented, could show evidence of a likelihood of a significant advance in knowledge – and I think that covers some of the things that have been said in this morning's session – or, alternatively, if it could show it to be improving some technology. There may be a possibility to say yes in those limited and restricted circumstances. I hope that may be of some assistance with respect to the questions which were asked.

CHAIR—Can I ask you a couple of things arising from that, Professor Chalmers. In light of the discussion today, would you add that that ES cell would be unlikely to develop in such a way as to form an embryo as we commonly understand it – a foetus?

Prof. CHALMERS—As I am here representing the Australian Health Ethics Committee, I believe we did not answer that question. But, on a personal level, I think the explanation offered by Dr Ford seems to be quite logical in that respect.

CHAIR—You will have to elucidate, Professor. I am not with what you are saying.

Prof. CHALMERS—In an official sense, that question was not answered.

CHAIR—I understand that part. My question is: if you accept the view that, in some circumstances, this could develop in such a way that a foetus is formed, in terms of the parameters which you would draw around the usage of the ES cells – of which you have given three bases upon which an exception to allow the use could be undertaken – and in light of the discussion we have had and the one-in-whatever possibility that a foetus could develop, would you say that that would be part of the parameters that you would draw? That is to say, if it was done for that purpose that would not be an exception?

Prof. TROUNSON—I think it would be unethical to try to demonstrate for you whether it would, could or could not, because you would have to combine it with another embryo and then demonstrate it had the chimerical properties or, in some way, destroy the carrying embryo cells. That is not the kind of experiment that I could actually work through any ethics committee anywhere in the world.

CHAIR—You do not need to answer that then, Professor Chalmers; it has been answered for you. There is another matter. I had two, and I am trying to remember them because I did not jot them down. I have always thought that one difficulty with this notion of intentionally creating embryos is that, if one looks back at differ-

ent phases of artificial reproduction techniques and discussions, there have been phases where, for other reasons, many embryos have been created, in which case you therefore have spare or excess embryos.

Is there any validity in that distinction drawn in the guidelines about intentionally creating embryos, if it is quite easy to subvert that by saying that the more eggs we fertilise the better chance and, if you implant more, there is a better chance of success? That was a common practice and I do not know whether it is now. I know there have been some revisions of those views over the years and that it may not be the practice now. Does that undermine, to any extent, this notion of intentionally creating embryos?

Prof. CHALMERS—No, I do not think it does. The situation we were envisaging at the time of these guidelines was one in which someone, for commercial reasons, altruistic reasons or whatever, was not intending to create an embryo for the purpose of transplantation and to produce a human being. It was considered less acceptable if somebody was to be involved in deliberately creating them for purposes of research. The second situation I think you are describing is where you have been superovulating under the knowledge that there are going to be spare embryos produced. I think you have answered it yourself, Mr Chairman. There have been procedures that have been followed, with the Fertility Society of Australia and in other jurisdictions, trying to say that is really not an acceptable practice.

Many of the reports produced in this country have suggested that the IVF procedures should be primarily intended for the alleviation of infertility. As such, although it is not mathematically possible to do so, you should be creating embryos sufficient for each of the transplantation cycles. I do not think it is appropriate that I say that we know that some individuals may or may not have been following the strict guidelines. We have to attribute to them that there were circumstances in which the knowledge of the administration of drugs and the connection with the number of eggs that could be harvested afterwards in the creation of those embryos were less precise.

Dr TOBIN—I am not here representing AHEC. Nonetheless, I would like to make two comments about what is in these guidelines on research on assisted reproductive technology. Firstly, they are silent on the matter of research on embryos that have been created unintentionally. I think that is strictly the case. Secondly, these guidelines belong to a phase in which couples were being encouraged to create only those embryos they were really confident of implanting.

Ms ROXON—Could any of the people who have made submissions this afternoon indicate if, in forming the written and oral submissions, any of you work in an ongoing way with disability organisations?

CHAIR—Dr Fisher, Dr Pullen, Mr Tonti-Filippini and Ms Weber indicate so.

Ms ROXON—Thank you.

CHAIR—I am going to draw this session to a close because we are over time. There are aspects arising out of the discussion today that no doubt the committee will continue to pursue as this inquiry continues. I would like to move to the session dealing with the regulatory aspects of the issue. Associate Professor Skene and Mr Tonti-Filippini have been invited to make some comments about that before we proceed to some questions and discussion.

Prof. SKENE—First of all, I apologise that I was not present this morning and also that I have to leave at 4 o'clock. I want to speak to my submission which I submitted in advance and in which I set out responses to the questions in relation to regulatory regimes that were put to me. First if all, I was asked to consider the current regulation. The current regulation at federal and state level consists of legislation in some jurisdictions – for example, the Victorian Infertility Treatment Act prohibits cloning – and the jurisdictions that do not have legislation are regulated by the NHMRC guidelines.

The NHMRC guidelines apply throughout Australia. They are not, of course, law because they are as they are described – guidelines. This does not mean that they do not have legal effect. With regard to guidelines, they are a statement of accepted practice. If an issue should come up as to whether a researcher had been negligent, for example, and a court had to decide whether this person had failed to take reasonable care, one of the things that might be considered is whether the person or institution had followed the recommended practice set out in the guidelines. Similarly, the guidelines can be enforced by the withdrawal of funding, if it is a project that is funded by the NHMRC; by peer pressure, which may prevent the publication of research that is undertaken that does not follow the guidelines; and the NHMRC has power to name somebody who offends against the guidelines in federal parliament. So although we talk about guidelines as if they are quite contradistinct from law, in fact they provide a standard that can be taken account of in applying the law, and there are many inducements to compliance. However, they are not directly enforceable, so somebody who fails to comply with the NHMRC guidelines cannot, on that account alone, be prosecuted or sued. They may be fired by their organisation if the guidelines are part of a contract of employment, but nobody can initiate that from the public directly.

I was also asked to consider whether it is desirable and practicable to implement a national legal regime. First of all, there are a lot of advantages in having a national system. One of the main advantages is equity. It seems unfair that people should be subjected to different legal regimes if they live in different states or territories. We have forum shopping, so someone will move from one jurisdiction to another in order to avail themselves of a more favourable legislative or other regulatory regime. This seems basically unjust if we live in a country in which we think that people should be treated alike. So there are many advantages in a national regime but, of course, there are also disadvantages. It is part of our legislative structure that people's values in each jurisdiction should be reflected in the legislation of the jurisdiction in which they live. For this reason, Victoria has different views on assisted reproductive technology from New South Wales, and so Victoria has legislation and New South Wales does not. We see it as the right of the people who live respectively in Victoria and New South Wales to decide what the law should be within their jurisdiction.

I want to talk specifically about different ways of regulation and the advantages of different types of regulation. If we have a legislative regime, there are advantages in legislation over guidelines. First of all, legislation is the clearest statement possible in our system for stating people's values and having those reflected in laws. Legislation is clear and conclusive. It is prospective – it does not apply retrospectively like the common law does. It is systematic – you cannot establish bodies without having legislation, so if you have a body that is going to oversee and enforce rules on this sort of technology, then those need to be established by legislation.

On the other hand, legislation is seen as being set in concrete. It is often difficult to change, although I was interested in Mrs Strnad's point about having a sunset clause, so this is one way you can make your legislation more flexible with changing technology. Biotechnology does change rapidly, and I think that creates particular problems for legislation, and that is one way we may be able to deal with that.

If we do not legislate, it does not mean that there is no law. When people say there should be a law on it, they are really thinking, 'Do we need legislation on it?' But if there is no legislation there is always the common law, the judge-made law, which expands to fill in the gaps in which there does not seem to be legislation. There are many advantages in leaving legal change to the common law. It is slow, it proceeds by one issue at a time according to the issues that come up before the courts and it tends to be conservative, but it can develop very gradually. As issues come up then the law can be fitted into the whole complex of the rest of the law, so you are not making law on one issue, as legislation tends to do, without thinking about the impact that is going to have on the whole web of the rest of law. However, you can see as I described it that a disadvantage of the common law is that it is piecemeal, it depends on the issues that come up before the courts, it is not structured, it is not subjected to broad community consultation, though judges are expected to take account of community values, and it is often uncertain because the common law depends on standards like 'reasonable'. In relation to reasonable care, how do you know in advance what is reasonable? On the other hand, legislation tends also to be framed in very general terms because it is necessary for the purposes of flexibility, and even if you have legislation it is sometimes difficult to see how that is going to operate in a specific fact situation.

If we were to have national legislation, how could that be achieved? I think that we would need to consider the relevant international instruments because there is no Commonwealth head of power that immediately lends itself to the enactment of legislation in relation to cloning. If we could find a relevant international instrument, the Constitution would enable the federal parliament to use the external affairs power for the purpose of enacting legislation.

Looking at the international instruments, perhaps the most appropriate one to look at is the UNESCO universal declaration on the human genome and human rights of 1997. Article 11 of that declaration states that practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. Other articles protect individuals from discrimination, abuse or harm on the basis of genetic factors. Article 2 says that everyone has a right to respect for their dignity and for their human rights regardless of their genetic characteristics. Article 6 bans discrimination based on genetic characteristics where the discrimination is intended to infringe or has the effect of infringing on human rights, fundamental freedoms and human dignity. Of these articles, I think only the first is clearly adequate to found legislation under the external affairs power. That states that practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. We have heard from Mr Andrews that throughout the day people have been saying that reproductive cloning of human beings is not permissible. I think under that article the Commonwealth parliament might use the external affairs power to pass legislation prohibiting reproductive cloning of human beings.

If you want to go further than that under the external affairs power, it seems to me to be more problematic. You would have to say practices which are contrary to human dignity shall not be permitted and take out the example they give, such as reproductive cloning, and think about whether the other sorts of procedures that have been discussed earlier are contrary to human dignity. Personally, I have grave reservations about this. I know what Mr Tonti-Filippini is likely to say, although we have not discussed this in advance, on what he understands by human dignity. Human dignity is a term that is used commonly in international instruments with-

out any definition or expansion of what is meant. One of the things that the committee will have to consider is whether it is contrary to human dignity to undertake cloning on human stem cells for therapeutic purposes – is this contrary to human dignity?

With regard to the international instruments, they do not form part of Australian law in themselves. If, however, an issue was to arise in the High Court of Australia, in particular, on which there was no clear precedent, the High Court could take account of what is said in an international instrument for the purposes of saying what the law is or should be. Again, it seems to me that the High Court will not be greatly persuaded, guided or aided by that type of instrument which is in such vague terms. The High Court would be looking at those words of what is contrary to human dignity and should not be permitted. But, until there is legislation putting into force one of these international instruments directly in municipal law, the international instrument has no direct effect.

I want to say something with regard to patent law, which has probably come up through the day, and to point out that patents do not constitute ownership, nor do they encourage secrecy with regard to an invention. I do not know if people have been talking about this earlier in the day, but I do want to refute these things in case they are relevant to the current discussion. Patent law gives the person who holds the patent a limited period during which he or she can exploit their monopoly and be paid for anybody else using it. As a condition of getting a patent, they have to make their invention known to other people and allow other people to use the invention. It encourages disclosure and it encourages research and development because, if people cannot patent over the short period of time, there will be less incentive for research and development, which obviously involves great costs. Once the patent period is over, anybody can use the invention. Anybody can use the invention initially, provided that they pay the patent holder. If the patent holder tries to prevent people using the invention, there is a procedure under the Patents Act which enables the invention to be brought into the public arena and used.

My last point is a summary of my views. I do not think that we should rush into legislation. If there is to be legislation, I think it should be limited to preventing cloning for reproductive purposes. With regard to other aspects of cloning research and development, it seems to me that there is great potential. It is an area for research and treatment and it is an area that is very rapidly developing. Legislation is always difficult to form in a way that is both flexible and clear. If you make a mistake, it is difficult to change the legislation and it is an inflexible form of regulation.

I think that the Australian Health Ethics Committee guidelines and procedures have worked well. If we have a body of that kind, which has power to oversee the development of new technology, I think that that is the most flexible way to go. It would be possible to establish another body overseas for cloning research generally but I think that the Australian Health Ethics Committee, with expanded powers and expanded resources, would be an appropriate body to undertake this role.

Mr TONTI-FILIPPINI—Thank you, Mr Chairman, for the opportunity to give evidence to this committee. I would like to do the same thing and go through the points that the committee has indicated in its discussion paper are important things to discuss. In a sense I am building on the submission that I made. As for the development of legal regimes at federal and state levels, no-one has indicated the existing system of law in some states and then the NHMRC across the board. The law in some states is actually proving to be inadequate in relation to cloning, because the way in which cloning has developed has outstripped the definitions in the state law, so none of the states actually has definitions of cloning that are adequate for the task of covering all the possibilities for cloning, even if you are talking about the cloning of adult people only. So there is a need for them to be revised. In relation to the National Health and Medical Research Council and that kind of regulation in Australia, because it really only applies to public institutions we are really creating a pressure for this work to go into the private institutions and private companies.

It should be borne in mind that, if you take it down that track – and so you are looking at things that are not government funded and are privately funded – you are going to drive the developments, given that much of the pressure for scientific research is commercial, into an area that is unregulated and which will be looking largely at the development of pharmaceutical products. That raises some grave concerns about where exactly it would all head, especially in the circumstances where you are talking about virtually the free flow of human embryonic stem cells and what might be developed from them. There is at least a concern that there be an adjustment that would somehow bring the whole private sector under some form of regulation. Of course, it is partly regulated in the states that have laws but it is not in the other states. Only a minority of states have laws.

The other question concerns the adequacy of the ethics committees themselves even in relation to public research, which is the only research they really have jurisdiction over. They only cover that research which receives public funding, and so it is on an application process for funding that you then go through an ethics committee. These are of course committees that are appointed by the institutions themselves. Since 1972, the trend has increasingly been to bring in more and more people who would be considered to be lay people rather

than medical people, bringing in lawyers and clergypeople, for example. But the basic structure is that the institution still appoints them and I think that still remains problematic, that here we have a body that is quasi-judicial and is exercising a great deal of power. In fact, it is an essential element under the Therapeutic Goods Act, the Commonwealth act, so it actually has a status in that respect and there are numerous other uses that are made of it and there are references made to it in regulation. So ethics committees have a very important role to perform, but they are appointed by the institution to whom they apply.

A major thing that could be tackled on a national basis would be to try to establish them on a more impartial basis and their composition could be better constructed to ensure that there is a majority of people who are not involved with the particular institution itself. They are not funded of course. By and large, people who sit on ethics committees do it on a purely voluntary basis, so that very much limits the kind of work that they can do, and they have really no great capacity to monitor, so a particular ethics committee only knows about what is going on in the laboratories from the point of view of what is reported to it. Very often they do not have much of a function in relation to even following up the approvals that they have given. So there are inadequacies in that structure. They are improving and the new guidelines of the NHMRC go to address some of the problems that used to be there, like conflict of interest and so on, but there is not really a structure that you would see as adequately regulatory. If you look at the second question of the desirability and practicability of implementing a national regime, the question here is really to do with what kind of a regime. We tend to immediately think of criminal law and creating offences of one kind or other.

But there are options like setting up a licensing system, so that you set conditions for people holding a licence, which has worked in lots of other areas than in medicine. You can also do it in a way that was recommended by, in a sense, your predecessor committee, the Senate Select Committee on the Human Embryo Experimentation Bill 1985. Its recommendations were in relation to setting up a national body which operated according to a set of guidelines or principles established by the parliament, so that is another model.

One other thing to say about the desirability is that, if this is all left to ethics committees and common law process, in fact that is more dangerous for people doing the research. Legislation actually enables, so when you make a statute that says that this is lawful, you then remove many of the obstacles that would have been there in terms of risk of litigation that could have been taken in a common law process. You can in fact, by creating legislation, enable the work in the directions that it should go while, at the same time, limiting it in those areas where there is likely to be danger of somebody being harmed.

There are many options for the Commonwealth to do this. I thought I would run through some options for kinds of legislation in terms of the constitutional basis. You could have a bill using the corporations, patents, finance and Customs and excise powers, so you could have several different powers that you could use other than the external affairs powers. It would be limited in its scope and it would not be able to regulate the state funded or the private companies undertaking human cloning. But it is important to bear in mind that there are areas in this that are regulated only by the Commonwealth. Those areas are, for instance, the import and export of cloning products – and we have seen how that is used in a way that manages to avoid, perhaps, state legislation where you import the product that you want to use that was devised by a means that would have been illegal in the state where you come from.

There is the question of patenting, which is a Commonwealth matter and not a state matter. And there is the question of patenting human organisms, which is a problem that has arisen very recently and certainly in the Italian jurisdiction, where they suddenly discovered, as the patent body said itself, they inadvertently put out a patent on a human organism. And then there is the question of the use of Commonwealth funds and Commonwealth institutions, so the corporations and the finance powers of the Commonwealth obviously come to bear. The Commonwealth could make sure at least that Commonwealth funds did not go to things that were improperly conducted in the community. That is one option: using those powers.

Another would be to use the external affairs powers. But my guess is that the external affairs powers are currently not favoured by the government and a bill using the external affairs powers probably would not get up. Loane referred to the use of the Universal Declaration on the Human Genome and Human Rights, which I was part of developing with UNESCO, but that has not been ratified by Australia. It has no place in Australia at the moment until Australia ratifies it. But there are powers that you could use under the International Covenant on Civil and Political Rights, which is already scheduled to the Human Rights and Equal Opportunity Act. There is also the Convention on the Rights of the Child, which is also scheduled to the Human Rights and Equal Opportunity Act. So you could use those powers – and there is a lot in them. This is the subject of my doctoral thesis, so I do not want to go on too long. There is a lot in those things to do with family formation as well as the points that Loane made about dignity but there are some specific things about respect for human life, family formation, the rights of the child to identity and security, access to its natural parents and all those sorts of issues which are harmed or diminished by cloning. So you could use them in a much broader way than Loane suggested.

A third option would be to have a bill using the first option – the corporations, patents, finance and Customs and excise powers – but you could then go further, in doing that, to establish a set of principles. The model I would suggest for this is the model that we have for our censorship laws, where the Commonwealth establishes through its agency – and its agency determines them – the classifications of film and so on and then the states legislate to apply those classifications, so there could be that kind of a regime. So we would have a national basis established by the Commonwealth parliament and then the states would opt into it and they would actually determine at what level they would plug into the classifications that you make.

There is the preparation of legislation as a fourth option for them to adopt uniformly, and that happened with the Human Tissue Act in 1981-82. That was developed by the Australian Law Reform Commission and it went through the states and all of them bar Western Australia and Tasmania adopted it uniformly, and then they came in, in part, later. So that is a possibility.

The other would be the model that is established by the Family Law Act, or the family law jurisdiction. That is actually ceded to the Commonwealth as a power by the states and so the Commonwealth could ask them, in discussion with the states, to cede the power to regulate this cloning area to the Commonwealth. So there are actually five options, I think, where there is a constitutional basis for the Commonwealth to act.

The appropriateness of the Commonwealth acting, I think, is really a question of the desirability of it being uniform, given that much of this work, 25 per cent, will be funded by the Commonwealth, so there is a good idea to have a uniform set of regulations applied. Then there is the question of the available options for non-legislative responses, and again it is possible for the Commonwealth, via an agency like the National Health and Medical Research Council, to establish a stronger sense of regulation than currently exists. It could certainly direct the NHMRC to tighten up the formation of the ethics committees and it could also give some direction about basic principles to use.

Finally, there is the ownership and control of cloning technology. One of the things I think we missed today in our discussion is that no form of producing a human embryo by human cloning can occur unless a woman gives her egg. So there is a question there as to who controls, who owns, who consents. If you are using material from somebody else, the UNESCO declaration refers to nobody having ownership of the human genome. There is a question here as to what you talk about in terms of what can and cannot be owned, what kind of a thing can be owned. Then there are questions to do with the elements of control in that respect, patent things, one minimal form of control, but there are numerous issues that arise there in relation to once these things are in the laboratory as to who has control and who owns them which is only partially answered by those states that have law and it is not answered at all by those states that do not have law.

CHAIR—Can I take up something with Professor Chalmers arising out of this? This comes back to your recommendations in your report, which in a sense we are reviewing. The first two recommendations in fact I want to ask you about. In the first one you urged the Commonwealth government, through the Minister for Health and Aged Care, to reaffirm its support for the UNESCO Declaration on the Human Genome and Human Rights. Is there any reason that we could not do more than that? Why did AHEC choose that form of recommendation rather than something stronger, I suppose, is my question?

Prof. CHALMERS—I think the reason has been outlined by Nicholas Tonti-Filippini and Professor Skene. We are aware that that was a declaration, it was not a treaty. It was not a treaty which was to have an activating municipal law closed, such as the International Covenant on Civil and Political Rights, which has a clause which says that the signatory, having ratified at stage 2, shall introduce municipal legislation. I do not believe – and I think I have some difference with Professor Skene, though I think I would be in agreement with Nicholas Tonti-Filippini – that because it is a declaration it gives a head of power to the Commonwealth under the external affairs power to introduce municipal legislation. So we felt that at least the effect of that declaration, the fact that Australia was in agreement with it, was at least a way of the federal minister publicising what we believe to be a fairly agreed stand from a number of organisations and a number of those that were consulted, that that was at it were saying we should not be going down that track. It was, as I said earlier, a real statement and I think of great symbolic force. We recognised there were limitations on being able to use that as the basis for introducing municipal legislation.

CHAIR—My second question relates to your second recommendation, that is, where you have in effect urged those states that have not legislated to do so. Elsewhere in your report you make the comment that that urging had occurred in the past and had not been taken up with positive action by the states. I am interested in your comments as to why you think those states have not taken steps to introduce some form of legislation.

Prof. CHALMERS—You are quite correct. As a matter of record, once we produced the report on ethical guidelines in relation to assisted reproductive technology, we followed that up with a letter to the minister suggesting that beyond the research implications, which are the powers of AHEC in that document, there were really quite considerable social and ethical effects, that there were responsibilities about record keeping and monitoring which we thought were important in being able to generate the data. That was not the function or

powers of AHEC. We referred it to the minister to consider developing some either uniform, complementary or integrated legislative framework, because we felt quite strongly at that time, and certainly as we looked at the cloning, that accidents of our geography should not have the effect of the consequential legal regime. It seemed in this particular area, where it is perfectly possible for the work to be carried out in a number of places which do not have legislation, that it would desirable to move towards a legislative framework.

On the other part of your questions, Chair, I am quite conscious of the work which you did in this in your earlier career. We probably realised that there were circumstances in this state of Victoria which at the time was one of the leading research centres in the world and that there was a particular series of debates which led that jurisdiction to take legislation. There was less of the research being done in other places and I think that was why they did not carry on, and then, when we eventually moved to the other two states, an entirely different form of legal regime, preferring reproductive councils, was established. Now, as we start to realise how the science is moving in areas such as this, there really is a case for reflecting and wondering whether this is not a case for a national response rather than a regional response.

This country has decided that it sees its future in biotechnology. There have been a number of initiatives, with the appointment and production of the report by Mr Peter Wills entitled *The virtuous cycle*, trying to encourage private and public investment in research and, hopefully, leading to what this country sometimes is not as competent at – namely, the commercial exploitation of our research. A similar thing is happening in Biotechnology Australia. In that sense we now have – I believe the scientists would tell us – very promising research. Yet we may in fact have the possibility of a piecemeal development of this research, depending on what jurisdiction applies, and we may even find that it may be done outside of this country. If we are to take a responsible position, the working party and the comments which we received as we looked at this report suggested that we may have reached a time when regional, state and territory legislation is not the way to go. There is quite enough difficulty, the resources which we have are finite, and I think they are better directed towards the research than large amounts of bureaucracies, legislation and regulation.

Dr TOBIN—Two or three years ago when the guidelines on research in the area of assisted reproductive technology were completed by AHEC, one of the things that followed that was that the minister for health set up a working party to determine what were the contents of a minimum data set that ought to be kept by all units engaged in that kind of activity throughout Australia and what were the kinds of research that ought to be conducted in this area. That working party met over a couple of years and it has finalised its recommendations to the minister. In those recommendations was what I think was a quite substantial minimum data set which, if adopted, would go some way towards the goals that were being expressed when AHEC said there ought to be complementary legislation in all states and territories. Personally, I do not know what has happened to the results of the recommendations of that working party.

Prof. SKENE—I apologise for my absence from the meeting, which was because of the car parking situation. I just want to comment on the regulation of genetic technology in relation to genetically manipulated organisms. I have been a member of the Genetic Manipulation Advisory Committee for some years, so I am able to comment on this. This is one area in which, after a great deal of effort, legislation has gradually been developed at federal level by cooperation between the states and territories. Going on from what Professor Chalmers was saying, if it was not possible to find an aspect of an international instrument that could be used as the basis for the exercise of the external affairs power, the Commonwealth government might think of trying to get the states together, perhaps through a standing committee of ministers, to try and get complementary legislation, either with a transfer of powers to the Commonwealth to legislate itself or to have similar legislation in all states. We do not have a great track record with this in Australia. The human tissue legislation is one of the few areas in the health field which have been regulated in this way. However, with the creation of the Office of the Gene Technology Regulator, it shows that if there is the will between the states and territories it is possible to establish a federal regulatory structure.

Mr TONTI-FILIPPINI—One of the things that I discussed while you were out of the room was several different models for legislating. It is possible that the Commonwealth could have a kind of boots and braces approach to this. One of the models you could use would be the censorship laws, where the Commonwealth actually sets a set of classifications and then the states come in with legislation that picks up on those classifications, which is what happens with censorship.

Prof. SKENE—What would the head of power be?

Mr TONTI-FILIPPINI—For censorship, the head of power is for the Commonwealth to legislate for the ACT and then the states come in and simply pick up and adopt what the Commonwealth has done for the ACT. That is my understanding. You people are lawyers.

Prof. SKENE—I just wondered what you had in mind. But that is the model, because obviously the federal government has power to legislate for the ACT.

Mr TONTI-FILIPPINI—There were several other powers that I did not think you mentioned which could have been used. They are the corporations power, the patents power, the finance power and the customs and excise power, all of which the Commonwealth could use in different ways to apply to this area. For instance, it could legislate under those powers, which would have an impact on public institutions and an impact on what the Commonwealth funds, have an impact on what could be imported and exported and have an impact on what could be patented. When you have got all that set together and so you are applying a set of principles to all those areas and so you have got the set of principles which the states could then tap into, the states could very simply then adopt a licensing system, like Western Australia and Victoria and partly South Australia, where scientists working in this area have to be licensed and the states specify that a condition of the licence is that they abide by a set of principles and have been established in the Commonwealth legislation. That way you bring in the whole private sector, which is now not regulated, under regulation and you have one uniform set that is determined by the Commonwealth parliament.

Prof. SKENE—It sounds immensely complicated but it is possible.

Mr TONTI-FILIPPINI—No more complicated than censorship. I should not have said that.

CHAIR—Given the reluctance, for whatever reason of –

Prof. CHALMERS—Of the states, previously.

CHAIR—the states to do anything – we will ask those states. Whether we get an answer as to their reasons for not accepting your urgings remains to be seen. Given that reluctance, for whatever reason, and given the doubts about whether or not we could rely on the external affairs power to do something in this area, what is your comment about Mr Tonti-Filippini's suggestion that we rely on a collection of powers such as the corporate power, the customs power, the finance powers, the patent power and anything else you can wind up into it? I am interested in your views about that.

Prof. CHALMERS—One of the major principles, as you know, is that we all take joint responsibility for a report and we should never then attribute any parts of the report to individuals. But it would be fair to say that the council of the NHMRC asked Dame Margaret Guilfoyle to join our committee. I think she is a person of considerable experience and I think she gave wise counsel to us. As you looked through recommendation 2, you would be wondering what the Delphic innuendo and underlying assumptions were. Yes, we did not believe we could find a direct head of power on which we could clearly hang the capacity of the Commonwealth to legislate. I think it would be really quite tenuous to follow through the corporations power, although I am sure there is much wise counsel from the High Court about that head of power as there has been with the external affairs power in a number of cases, quite a number of which, of course, affected the building of a certain dam in the state in which I reside. We felt that it was something which was really the responsibility of the minister, to try to get the necessary urging.

I believe we were thinking of two ways. One, which I think has been addressed by Nick, is that you actually decide that you want to try and follow the uniform complementary route. That would really require some agreement. It may be that legislation of one of the states would serve as a model. Alternatively, there is a referral of power. In these times of, as I understand, the cooperative relation between the federal government and the states, I do not think that you would want to be saying, 'We have got the power,' unless you can definitively say so. I am sure you will be getting advice from the Attorney-General's Department. I am not sure that I could point unequivocably to that head of power. That was the reason that I believe the recommendation was to 'urge'.

I would hope now that your committee may be assisted in the difficulties of the deliberation. But I think this particular advice which you will be giving to the parliament does impinge on other developments of the Office of Gene Technology Regulator. I think it does impinge on the general movement of research funding and, as it were, the direction this country has decided to move towards biotechnology and knowledge based technology. I would hope that that may, in fact, be something which the states, territories and federal government would see as a being unifying reason for looking at sensible regulation so that we do not end up with fights between the states and territories and arguments for more and more state based inquiries. We might be able to reflect and come to some wise judgments about how best to move forward. As I said, our feeling was that it would be best if there was some form of regulation in the form of legislation. Perhaps, since I have the floor, I would not feel that AHEC is necessarily it. I think it is a reasonable way of going at the moment but eventually, as with the Office of Gene Technology Regulator, you will probably find that some legislation will be required.

Ms ROXON—We obviously have to deal with the process that we would use for any type of regulation, if the committee was to recommend that track. However, it seems we are a long way from knowing what it is that we want to put in that regulation, whatever form it is going to take. I am following up from some comments that Professor Trounson made earlier, that their organisation, for example, was wanting to look at complying with the guidelines that exist in the US, for funding reasons, I suppose, but also for a whole lot of reasons

about wanting to be seen to be complying with what, at least, are regarded in some parts of the world as being suitable guidelines.

Mr Tonti-Filippini and Professor Skene, and also Professor Chalmers, could you comment on whether there would be some value in having those guidelines, acknowledging that the difficult part is actually agreeing on what those guidelines should be and whether they have some legislative force or regulatory force initially? Do you have a view that they would provide any assistance to people working in the area and the public in this ongoing debate and then, perhaps, in the development of whether or not the states would refer their power or we would go down some other course? My question really is: is there any use in that, if the committee were to decide that that was one way that we could go?

Prof. SKENE—One advantage of legislation is that it states quite specifically what is prohibited and then it assuages community concern. It would be possible to take something like reproductive cloning and say that you have found, from overwhelming submissions, that people do not support it and, to make sure that nobody tries to do it, you will make it an offence throughout Australia. With regard to other things which may change from time to time or on which there may be more doubts about whether they should be permitted, you could either establish a new body or confer powers on an existing body, like AHEC or the Office of the Gene Technology Regulator, to make decisions on a basis from time to time. That body could put out guidelines which would be much more flexible because they could be changed by the body without having to go back to parliament. The researchers in the field could seek advice from that body, as they do with the Genetic Manipulation Advisory Committee, on what is permissible and what is not – although the Genetic Manipulation Advisory Committee is directed more to safety issues rather than giving legal advice on what is lawful and what is not.

To answer your question, I think there would be some advantages, for the people in the field wanting to know what they can and cannot do and also for the community as a whole, in knowing that there are some things that they do not think should ever be allowed that are not allowed in legislation.

Mr TONTI-FILIPPINI—I would make a couple of extra points. One is that, when you legislate, you also make an expression of permission as well as excluding things. So one of the effects of legislation is to enable and to reduce the chances of litigation against the people who are engaging in that work. Legislation can be an important tool from that point of view. I think that is the case in Victoria, fairly largely.

The second thing is, in the history of inquiries and committees reviewing aspects of medicine, there have been some strong differences between a parliamentary committee inquiring and a parliament making decisions and a committee making decisions. There always seems to be a very strong distance between an appointed committee investigating something and a parliamentary inquiry or a parliamentary committee. I suspect you get something much closer to community attitudes and concerns when you go through a parliamentary committee than you would if you set up a body of some kind. That makes me wary of the idea of setting up some kind of expert committee to make these decisions and draw up guidelines unchecked. I think that is a description that really applied to the NHMRC in 1982 when it drafted the first IVF guidelines – contrast that with all the state inquiries with that were appointed by parliaments and so on that produced different results.

So the check would be simply that, when these committees draft these guidelines, the guidelines do not pass into use until they have been to the parliament. They go to the parliament as disallowable instruments, so the parliament has the opportunity to vote – to approve or not – on the particular instrument. If the parliament disapproves, it goes back to be amended before it comes back to the parliament, so that at some point the community can have the confidence that its representatives are having some say here and that it is not just some body of elite people – not that parliamentarians are not elite – who are making judgments that do not reflect the community.

Prof. CHALMERS—As I understand your question, Deputy Chair, what I think we are discussing at the moment is the future. I note that during the day we seemed to have moved from research into trying to look at the future. If we look at what was described this morning as research, we note Professor Trounson, I think it was, saying we are at a very early phase of the research. I found that a very important thing for us to say because quite often in our discussion we were moving from research into actually thinking things were about to happen. Traditionally, research has stayed within self regulation, and I think this country decided to move one stage further than that by bringing in enabling umbrella legislation with the National Health and Medical Research Council and with a specific body called the Australian Health Ethics Committee. So I think what Professor Loane Skene is suggesting actually has some merit, in that you say you are reasonably satisfied with the initial review by an ethics committee and there is, as it were, oversight by the Australian Health Ethics Committee.

I think what you are now asking is whether we can actually jig that system along by, instead of having the current guidelines in relation to embryo research, which are rather limited – they may have been as a response to conditions of IVF – now trying to get NIH ones. I think the answer is yes, because I believe you do have power through the minister to make a recommendation that the minister recommend to the AHEC the intro-

duction of those guidelines. And I believe there is an avenue for you to decide to use the prevailing legislation and to say that is what you would like to try to jig. I would have to say that I agree with Nick very strongly there. There is a change of emphasis because it is in a regulatory framework, because those guidelines will in fact come back before the parliament and your committee gets reports from the NHMRC and you, if you wish, can interrogate the NHMRC about what is going on. I would only say that at this stage there are one or two things that we would be concerned about if you simply were to try, as it were, a rejigging of the existing structure. One would have to hope that you would also recommend that the monitoring and record keeping, which was an extension of the work that we did on reproductory technology, would in fact be activated, because I do think that, with all the worries that parliaments have, you are not going to be concerned with the day to day detail; you really have to make sure not that just the guidelines are there but also that some other framework about monitoring, review, checks and balances is there so that there is an accumulation of the information that will inform you if you want to look afterwards.

The second thing that I am not sure about is that you are going to be able to cover the private area: That was one of the reasons we talked about in terms of legislation. You may have to find some ways of approaching the private side and asking them to voluntarily comply – or there is a model that I think you are using with your private sector privacy, which is to use the light touch legislation. So you use your heads of power for privacy, which might be one of the heads that I noticed we have not used but which now might be easier to use, you set up some legislation which says that in the business of that research you want to have that information for privacy purposes and to make sure they are complying with some guidelines. So I think you would have to find some way of teasing in the private sector, otherwise you may feel that it will be well covered in the public area but the private one is outside.

The third thing you may have to have a think about is that under that model you are now really saying that AHEC is not developing guidelines and monitoring the IEC system. It is, as it were, really applying a second stage, a two-tier system. If that is the case, you may want to look at the composition of the AHEC. At the moment, very wisely, the parliament has chosen a particular composition, but I think you are asking it to do something slightly more. You may want to ensure that, for particular purposes, there is a little better science, perhaps better ethical review, than is currently there.

Finally, if you are going to do all that, as it were playing at the edges, you may eventually come to the conclusion that it is just simply to look, as with the Office of Gene Technology Regulator, and you may in fact find it sensible to set up a body. It would have to be governed by a sunset clause, because it is perfectly possible that in a few years you may find that you do not need to look at it. One of the things that the body would do, importantly, is licence certain people to do be doing this research. I really do feel this. It is a point which Nick has just made and I have heard it from a number of people who are here. This is not the kind of research where we want anyone who finds a commercial company to back them to be saying, 'Well, I'll see if I can go off.' There is tremendous pressure nowadays in the universities and in our research to get the money.

There are some types of research where we want to see reputation, track record, expertise and responsibility, where we would like to see some restriction – in that respect, the model that the Office of Gene Technology Regulator is setting up. It is supposed to be a licensing and an accreditation body – a definition of the type of work which it is doing. I believe it is covered with a sunset clause. There is the controversy of whether it should be self-funding; I think there are some debates about that. But it is not an enormous investment and a high cost, and it may be one of the ways in which you can achieve coverage of the private sector and ensure the involvement of responsible scientists in this work and the necessary reporting and monitoring and so on. I am very sorry for giving such a longwinded reply. The answer is, yes, I believe you can activate the NIH.

Prof. TROUNSON—I believe it would be down to the patchwork quilt of the different states' non-legislation or legislation in IVF to know what huge disadvantages there are in that. The points and the barbs about what we do or do not do there are sometimes unkind, and it is basically because there is a patchwork quilt there. I have actually been involved in discussion in setting up the Office of the Gene Technology Regulator, and I am impressed with the way that has been gone about. I think that also represents a concern in the community that is being dealt with in a fashion that will actually get uniform agreement across the states. I think that might be a very good idea, and I think I suggested that this morning. As scientists, we have concerns about AHEC and our capacity to talk to them. They are not an easy body to talk to. NHMRC is in fact not an easy body to talk to. But I think, in terms of getting things done on a reasonably efficient basis, the Office of the Gene Technology Regulator is going to provide that.

The other really important part to understand in this area is that there is going to be entry of a lot of commercial or industry related money because it is biotechnology and it will in fact relate to pharmaceutical industries. The factors that we discover in these programs will have medical value, they will be used for treating patients and so they will be very valuable. It is absolutely certain that the balance of funding that will come in there will be a minor amount of public money and a major amount of commercial money. I think you have to have a regulatory system that can actually absorb that—bring it in and treat it in an appropriate way. Other-

wise, if it is made too difficult, all you have done is create a non-compete clause for Australia to be involved in these biotechnologies. If you make it too difficult, private industry will not put the money into the area; they will put it in where there is less difficulty.

So I think the parallels of what has had to be considered for the genetically modified organisms is well worth looking at. There needs to be some input into that to see whether there are some parallels that can be linked into what you might make as a recommendation. We would strongly support that kind of instrument as a regulatory body – something which is responsive and that has good quality people who not only represent the community's interest but also understand what we are on about. Sometimes it is very difficult to communicate with some of the bodies that are created in some places. That creates its own particular problems.

Mr TONTI-FILIPPINI—With the Office of the Gene Technology Regulator, it is too early to assess how that is going to work yet and whether its constitutional legislative basis is strong enough to regulate the private area. One of the concerns I have is that there will be another huge disaster in regulation, which we had in Australia in recent history. In spite of the evidence presented to the Human Gonadotrophic Advisory Committee about Creutzfeldt-Jakob disease in as early as the 1960s, it did not take notice of that until the 1980s. As a result of that, we have people who were infected – or who were at risk of infection – with the disease.

There are several problems with that committee in terms of structure that we should bear in mind. Firstly, it was almost entirely composed of people who were clinicians or researchers in the area. It lacked expertise in the areas where it should have had expertise, such as in biology and so on. It was not responsive at all to the community. The community would not have known it existed or what functions it had. It also existed in parallel to the National Health and Medical Research Council, so there was some question of who had jurisdiction over what.

I am concerned with the Office of the Gene Technology Regulator – where the divisions fall; how strong its legislative base is to regulate; how responsive it is to the community; how open it is in terms of making public the decisions that it is making. That, of course, is a general criticism of our existing structure with the institutional ethics committees which do not publish and which the community has no access to in terms of finding out what sorts of things they are approving. I would be very concerned about a structure being set up that, in fact, repeated the mistakes of old in relation to the 1982 NHMRC, the Human Gonadotrophic Advisory Committee and the existing structure of institutional ethics committees – none of which satisfy any standards of being responsive to the community or being adequately public or having sufficient powers to adequately regulate.

CHAIR—There was something on that which I was going to ask earlier. Professor Williamson is not here but I recall, and I made a note at the time, that committee hearings in the US are held in public. I was not sure which committee hearings he was referring to at that stage and whether this is relevant to the discussion we are having at the present time.

Prof. CHALMERS—As far as I know, he was referring to the general principles under their legislation, which requires all of the hearings in relation to research, regulation and FDA to be in open session.

CHAIR—Is that the equivalent to our institutional ethics committees?

Prof. CHALMERS—I do not think IRBs are held in public.

Prof. TROUNSON—No, they are not.

Prof. CHALMERS—It would be a body such as this.

CHAIR—Equivalent to AHEC?

Prof. CHALMERS—Yes. The AHEC has to be held in public.

Prof. SKENE—Could I respond to one of the comments that Mr Tonti-Filippini made and also make one other point. I want to respond in relation to GMAC, of which I have been a member for a number of years, though I am not now. With regard to publicity, GMAC has a web site which can be accessed by any researchers and also by members of the public. It regularly publishes newsletters which state in user-friendly language what is being proposed. It has an annual report which does the same. The meetings of GMAC are not open to the public and the applications are protected by commercial-in-confidence agreements. To that extent, the meetings are not public. But there is quite a lot of information that is made available to the public.

My second comment was with regard to the Gene Therapy Research Advisory Panel of the National Health and Medical Research Council. I do not know if that has been raised earlier in the day or earlier in your hearings. Taking Professor Chalmers' approach to research, if it was decided that the best way to regulate research is to continue with oversight by the human research ethics committees backed by an NHMRC committee, the Gene Therapy Research Advisory Panel, of which I am also a member, might be an appropriate committee to consider at this stage. Its role is to provide advice to researchers. It is not very well funded and it does not meet very regularly but, given more resources and given broader terms of reference, it would be possible for it to

provide some sorts of monitoring facilities in relation to people wanting to do research involving cloning techniques.

ACTING CHAIR (Ms Roxon)—We did say we would have an opportunity for you to be able to ask each other questions, too. Could I ask if there any other witnesses at the table who had questions either for Professor Skene or Mr Tonti-Filippini?

Mr MENEY—I have a question for Professor Skene. Given that we now live in an economy where people are always talking about globalisation and different economies dovetailing in with another, if as a country the parliament decides to pass legislation to allow certain sorts of things to happen and not other things – it might be steps A and B in a technology but not step C – what would be the situation where we might derive the benefits of a technology which we had regarded as illegal within our own country but was conducted offshore elsewhere? In other words, we outsource those bits that we have some discomfort with and then we do stage D in Australia. Is it possible to actually legislate for something like that? Is it possible to control what happens in terms of our involvement with things, which we regard to be illegal were they to be conducted within Australia, that happen to be conducted elsewhere?

Prof. SKENE—Obviously Australia can only legislate for things within its own boundaries. It can, however, legislate with regard to things going in and out of its boundaries. So, in Victoria under the Infertility Treatment Act, it is prohibited to take embryos, for example, in and out of Victoria without the consent of the monitoring committee. With regard to using a technology that has developed in another country, we can certainly do that subject to the patent protection that that other inventor has. The patent extends to Australia only if the patent is registered here. But if an American company or a company in a Third World country, for example, uses procedures that would not be permitted in Australia and then they produce a product or a method which they patent and then they register their patent here, we could pay the patent holder and use their product or their process here. It could be done. Are you saying: could we prevent that happening?

Mr MENEY—Yes.

Prof. SKENE—You are saying: could we prevent the use of a new product? It is difficult to think in advance what it is. It would be possible to pass legislation saying that we will not use a particular medical procedure in Australia. You would have to know what it is that you are legislating against. You could not do it just in your imagination.

Mr MENEY—Could I suggest the scenario that perhaps a clone is allowed to grow to a certain stage within Australia but elsewhere other countries decide that there are advantages in allowing a clone to progress to further stages so that the liver or whatever would be much more efficiently harvested and used for the benefit of somebody else.

Prof. SKENE—And they then develop the cells that are used for liver damage.

Mr MENEY—That is right.

Prof. SKENE—Can we use those cells? Yes.

Mr TONTI-FILIPPINI—I think there is a way to handle this. If you set up a licensing system of Australian researchers, you can deny or remove their licences if they become involved with procedures overseas that would be illegal in Australia. It is very simple to put it in a licensing system. You could set any conditions that you like in a licensing system. We could have a licensing system pretty much like we have got in Victoria, South Australia and Western Australia. There are problems with each of them, particularly in relation to complicating the licence system with offences. If you set up a licensing system and then you add to it an offence system, because the offence system works on the basis of being subject to the rules of evidence, especially in relation to criminal law, then you have got a much weaker system because you have to prove your case. Whereas, with a licensing system, you can make licences depend on reputation and all sorts of things so that you only have to follow a due process. You do not actually have to establish that somebody broke the law in order to review their licence or limit their licence.

CHAIR—I think Dr Ford had a comment.

Rev. Dr FORD—This committee hearing was set up at the request of the health minister; is that correct?

CHAIR—Yes.

Rev. Dr FORD—And this committee reports back to the health minister?

CHAIR—No, to the parliament. To the House of Representatives.

Rev. Dr FORD—Via this mechanism of reporting back – and the minister is also a member of the parliament – has the minister got any say or power or influence over NHMRC or AHEC in recommending what they ought to do? Attached to that would be the control of funding. Is funding a mechanism for controlling what people do?

Mr TONTI-FILIPPINI—The only trouble is the NHMRC is a statutory authority. It is independent of the minister.

Rev. Dr FORD—So there is no power?

Mr TONTI-FILIPPINI—But it is funded by the minister.

CHAIR—I am reminded of that old saying, Dr Ford, that you only get to the top by not asking any questions and only stay there by not answering any. But in this case I will answer. Yes, there is power which flows from funding because a lot of what government does is administrative rather than legislative. Administrative powers flow from the funding that is tied to administration. So, to answer your question, yes, there are possibilities for regulation in the broad sense which involves powers relating to funding. But there are difficulties also with that in that there is less transparency, I suppose you could say, in the sense that the process of review is the process of review adopted by the parliament. So you have to rely on parliamentary committees – for example, estimates committees and the like – to provide the process of review. But it is a model.

Rev. Dr FORD—So where there is a will, at least there is a little way?

CHAIR—Yes. Anyway, on the basis that I am not here to answer questions, I will move on.

Mrs STRNAD—May I ask Professor Skene a question? Is there not a basic and established human right to the benefits of new technology and should it be outlawed in Australia and available elsewhere? People will have a justifiable grievance here.

Prof. SKENE—It is sadly a feature of our human rights law that the human rights which have received most emphasis and have been implemented are negative rights. They are rights not to have something done to you. We have very few rights to actually take advantage of something. So, although we sometimes talk vaguely about the right to health care, you in fact have no right that you can enforce, except possibly in emergency circumstances. If you go to the doctor and say, 'I want this particular new treatment,' it is an exercise of clinical judgment for the doctor to decide whether he or she will give it to you. Although one might say that we have a fundamental human right to take advantage of new technology, it is a right in discourse and not one that you can enforce.

CHAIR—Are there any other questions from participants?

Dr MATTHEWS—Not so much a question but, although I applaud the idea of having uniform legislation to a degree, I was a little surprised at what I thought Professor Chalmers was doing in proposing considerable legislation to control the situation to whatever was finally desired. To add to that, on the other hand I was somewhat appalled at the rather toothless, powerless tiger phenomenon that Mr Tonti-Filippini ascribed to institutional ethics committees. Firstly, just prior to his discussion, we heard that there are many ways in which institutional ethics committees can ensure that projects that are put before them can be carried out according to reasonable community standards. Now they may not all be up to the same level but, with Professor Chalmers's help, they are all getting that way. They all certainly would not receive projects involving the type of discussions which are the subject of our discussions today. And there are negative aspects, as we have heard from Professor Skene, about legislation – namely, how difficult it is to change and therefore how careful we must be if it ever comes into force. I just make those observations. I am not sure they require any comment, apart from perhaps for my own benefit from Mr Tonti-Filippini because I think he should not tar all institutional ethics committees with the same brush. I am not sure which ones he has experienced.

Mr TONTI-FILIPPINI—I am not sure which comments exactly you are talking about. I will go back over what I said. Firstly, there is the fact that institutional ethics committees basically operate in secret. There is not access to them by the general public so what is being approved or not being approved, the type of research that is being done or not being done, is not known to the general public. Really, the only way it becomes known as a rule is when there is a positive breakthrough announcement that a researcher decides to make. So whatever else happens that the researcher decides not to publish does not get published, so the failures do not get published and the impact of the failures does not get published.

The next thing is their composition. They are appointed by the hospitals or the universities, the institutions themselves, and that has to raise questions about their impartiality in the way they operate, and there is some good research that has been done—not current research but research that was done six or seven years ago, funded by the NHMRC—into the function of them. So those are two major elements that are of concern. The more important they become, the more important it is that they be properly structured.

The final thing to say about them is to say that they fit within a structure that really only regulates research which is publicly funded. If somebody wants to fund research in a private institution, there is no compulsion on that research to be taken to an institutional ethics committee to get approval. More than that, practically anybody can set up an institutional ethics committee, and we have seen that happen in our history where a body that was not normally a research institution set itself up with an ethics committee to approve some particular research and pointed to the very fact that the whole structure—while many of the ethics committees

may be very good committees—was basically flawed in the manner in which these things could be set up and operate.

Dr MATTHEWS—If I could respond briefly to two points, some of which I agree with Mr Tonti-Filippini on, certainly the ethics committees meet in private. They do publish a report every year of what projects come before them, or of what are approved and require ongoing reports. Such has been the advice from AHEC. The reports are the property of the institutions, and certainly in the public institutions I am sure they would be available, although I stand corrected there.

Mr TONTI-FILIPPINI—They are not even available under a freedom of information application.

Dr MATTHEWS—There certainly is a limitation from the funding point of view that all projects do not have to come through these institutional ethics committees. For example, on the committee on which I sit there is a considerable amount of privately funded research which goes before that committee. Also, there are requests from outside of the institution for independently funded research projects to be approved according to the standard that the institution would apply to their own projects.

Dr McPHATE—Dr Martin Pera this morning referred to the need to increase government funding for research. The present government appears to philosophically prefer private enterprise funding over government funding. Would the scientists give their opinion regarding the disadvantages of entrepreneurial funding of medical research compared with government funding. Banting and Best discovered insulin. Florey and Fleming discovered penicillin. They received no monetary gain for their discoveries. Their aim and reward was to share the knowledge and gain with all mankind. Under entrepreneurial rules we have commercial-in-confidence information and no sharing, with a predicted slow-down of scientific knowledge. Would the scientists comment, please.

Prof. TROUNSON—I do not think I know of any scientists who have actually got rich, although maybe they have those thoughts. Medical research done in Australia is done in institutions where you are salaried. That does not mean to say that in the future, if you make a major advance that becomes a patent that can be used as an enabling technology, you may not be able to share with the institution if that was able to make a lot of money in the future. That is a possibility and that has always to some extent been available.

What you are saying now is that it is more available. Having just sent a key research scientist from our institutes to go to pharmaceutical industries in the US at a very, very high salary, I think there are opportunities for very good scientists to move into the commercial sector. I think there are opportunities in the biotechnologies to spin off, if you like, commercial opportunities for Australia in introducing factors that might be of importance for the pharmaceutical industry or for medicine. We do not have very many examples of this, but AMRAD, for example, would be a relatively good example. The key scientists and business members of AMRAD, I am sure, are well paid and they probably have shares in the company. I do not know that either, but that would be a normal process.

I think this is part of the evolution of our medical research. If there has been a criticism of Australian medical research, it is that we have done it for nothing. That is, we have taken the money, we have published the data and let everybody else benefit—pharmaceutical industries and monoliths overseas. We are told by the community that this is no longer really acceptable. We have heard this message. To a large extent that was the message that was delivered by the Wills report, which had very strong government approval. So I think you have to look at all of this in the framework of an evolving biotechnology in Australia.

The things that we told you about this morning may or may not be part of it. I think they are very likely to be a part of our evolving biotechnology industries—not in my view at all for cloning. If you think about therapeutic cloning, it is not going to be to be done by multinationals; it is going to be done by the ethics committees and the small hospitals where the patients are going to be. So it is going to come right the way back to your very doorstep for the institutional ethics committees.

I think the discovery of key molecules for the treatment of very severe diseases and cancers may well flow from this, and I actually cannot see any problem. In fact, I think the Australian community and the Australian government is telling us to get our act in order and show that we can actually benefit the Australian community from the very large amount of money that has been invested in medical research. I think in the sense of therapeutic cloning, if it ever does come—and I have given my reasons this morning for not knowing whether that will be the case—that will be a case for every hospital ethics committee to decide whether it is appropriate, in a case of a special patient who is about to die, to try to set up a cloned set of cells that might save that individual's life. To be honest, I think that is where it is going to go, and I do not think the multinationals or the biotechnology companies will be involved one iota in that.

Mr MURPHY—I would like to make a quick comment in view of the discussion. I support more public funding for medical and scientific research, and I exhort everyone to read—if you have not already—an article adjacent to the leader in today's *Age* written by a Melbourne academic which certainly highlights the dangers

of those who are reporting on medical and scientific research who are funded by the private sector. And the theme, of course, all through the article, deals with the requirement of those involved in this field to be at all times truthful to themselves and, in fact, obviously, honest.

Rev. Dr FORD—I have a comment, not a question. Professor Pera earlier mentioned that testing of drugs would be one of the benefits. I can see big drug companies, pharmaceutical companies, having great profits, and they will want to test their drugs for toxicity on stem cells that are produced by cloning technology—not embryonic stem cells, by the way—to find out what cures, what effects they could have, in order to market a drug not for the few who are sick but for the mass of populations. That is where we have to think in terms of control.

CHAIR—If there are no further questions or comments, I propose to draw these proceedings to a conclusion. There is one more, by the look of it.

Mrs DUFFY-KROHN—This question is to both Professor Skene and Mr Tonti-Filippini. What mechanism is in place that ensures that women from whom the ova are collected give consent that is 'informed' and free, et cetera? How is this monitored?

Prof. SKENE—The law requires, before any tissue or any invasive procedure is undertaken on a person, that they be informed about what is proposed and any material risks associated with that, and in the light of that information they make a choice whether to undertake that procedure. If an embryo was being created specifically for the purpose of research, quite apart from whether it is lawful to do the research, the creation of an embryo or the removal of any tissue like an ovum for the purpose of creating the embryo would require what used to be the full 'informed consent'. The High Court of Australia has now said that we should not use that term because it is apt to mislead, but that whole process would be attracted by the law of negligence and the law of contract.

If, however, the ovum had been taken with the woman's consent and was being stored somewhere, another issue arises as to whether there are any property rights in that stored tissue that would prevent the research being undertaken. The law on that in fact is very unclear as to whether you have to go back to that person and ask them for permission again, telling them what you want to do on this occasion, or whether you can go to them at the beginning and say, 'If we want to use any tissue that we have taken in our research, do you approve its use in research'—without stating exactly what it is. So I think the law on 'informed consent' is adequate to protect the taking of the tissue in the first place, but the use of tissue that has been taken with consent for purposes other than the original purposes for which it was taken is quite unclear.

Mr TONTI-FILIPPINI—UNESCO had a protracted discussion on this in the drafting of the Universal Declaration on the Human Genome and Human Rights. A variety of problems crop up in this context. One of them is deciding what kinds of things can be owned and what kinds of things are in fact better described as being in a custodianship relationship and then applying that to this area in deciding who has to be applied to for consent to use something. If you look at it in terms of the woman giving the egg, that has been addressed in the first instance. But once the egg is separated, what is an egg in terms of its status? Is it something that is owned, is it something that somebody has custodianship of or is it something that no longer has a relationship to the person from whom it came? That is with regard to the egg.

When you talk about human cloning, it is not just the eggs you are talking about. You are talking about the use of genomic material, somebody's genome. UNESCO addressed this in terms of saying that there could not be ownership of the human genome in the sense that you could not sell your human genome to somebody and you could not patent the human genome. But there are still problems with the UNESCO declaration in relation to exactly whether you in fact have custodianship of your own genome. For instance, if somebody obtains your genome perhaps in an unidentified way – either by picking up samples from the laboratory bench or the pathologist or even, more obtusely, by collecting it from the sewerage system – who owns it, who has custodianship of it and who has to give consent to its use?

If you move into the area of producing another human being using genomic material, if a sibling of mine is produced by somebody obtaining genomic material from me – you would call it a sibling perhaps; I am not sure what you call the person who is cloned; you have the clonee, but as yet nobody has come up with a word for the person who is cloned – there is no clarity in this area. This is one of the things you would hope that an inquiry like this would face. If we are going to be talking about using genomic material from somebody, then it is going to have to be very clear as to what exactly the relationship is. The Senate Select Committee on the Human Embryo Experimentation Bill said that the proper relationship to an embryo is one of custodianship. This invokes the sort of relationship you have to a child or to somebody who is mentally incompetent, which means that you have to act in their interests and you cannot exploit them for somebody else. So custodianship is an important notion.

Then there is the question of who gives consent. If somebody has custodianship then they can give consent, but only in that limited way of acting in the interests of what it is they have custodianship of. If they own it

outright, then unless there is some law to the contrary they can do what they like with it. If they possess it and it is de-identified, it seems that there would be no restriction on what they could do with it unless a law is passed to restrict what they could do with it. So it is possible that if somebody could obtain discarded tissues from me and use them for cloning, then they could produce an identical sibling of me without reference to me.

Mrs GAWLER—My question is a result of attending the 1998 Asia Pacific Genecom conference, which was held in Adelaide The conference was interesting to me in that there seemed to be a predominance of patent attorneys and a goodly number of Americans. One of the American speakers at that conference actually raised the matter: would Australia actually permit gene technology to advance to the stage using embryos of a gestational date that would not be permitted in America? She said: 'Surely your Right to Life groups would object.' Someone commented: 'No, not here.' It just made me wonder whether this money that Australia would receive from other countries to invest in biotechnology here is because we would perhaps have less stringent regulations than some other countries, namely America. Is this the sort of money that we would wish to receive from for our economy?

Dr PHELPS—I am from the Gene Ethics Network. I want to ask two questions. The first one concerns the scope of the Office of the Gene Technology Regulator. I would like the lawyers present to comment regarding the failure of the OGTR to have any coverage of drugs in clinical trials. The OGTR is to be set up in the Therapeutic Goods Administration. I wonder if Professor Trounson could wait one micro second because the question is for him. I would like them to comment on the appropriateness of a body which is specifically being put in the Therapeutic Goods Administration excluding from its coverage those things which the Therapeutic Goods Administration actually administers and should regulate.

Secondly, I have a question about the IVF program that your colleague on the panel Ms Roxon asked concerning everyone's attitude to the IVF at the time that it was a matter of public discussion. I want to get Professor Trounson now to give that some context. It is our view that this is important for the transition from an experimental phase of a new technology into clinical practice. We regard IVF still as experimental. As I understand it, it still has a success rate of around 10 per cent. It is still uses superovulation of women and, as far as I know, does not follow those women up to determine the long-term impacts on their health.

I would like to know from him too whether his program actually follows up the children who are born of the program, the general health status of all the children born and what the long-term prognosis for their health and quality of life is. With all new technologies this kind of long-term monitoring we see as essential and very often it is not a thing that is given very much priority.

Prof. TROUNSON—If I may be very brief about it, they do follow up all the women, particularly for those things that have been raised as a concern, that is, breast cancer, ovarian cancer – various cancers. That has been published in the scientific journal, the *Lancet*, now on a number of occasions. The children have been followed up also for childhood abnormalities. That is all published by the Perinatal Statistics Unit. Then in addition there has been further follow-up of the children on behavioural problems and particularly for any childhood cancers. That has been published in the *Lancet*. I think the childhood cancers situation has also been published, although I cannot exactly remember where. So Australia has an incredibly good follow-up of these patients who have been treated with fertility drugs and the children who have come from it. At the present time we have no resident concerns about those treatments. There does not appear to be anything of substantial concern about their health or their wellbeing. I do not believe in this day and age that the IVF treatment is now considered experimental. A very large proportion of the community utilises IVF. The success rates, depending on what country you are in, and what procedures they use are a lot higher than 10 per cent, but in Australia it is around 20 to 25 per cent overall and again, that is published by the Perinatal Statistics Unit each year.

So I do not think we are in any way in the same kind of phase. I think with what we are talking about here for embryonic stem cells we are in very much the initiation stage of the research. I think I have made that point very strongly and I think we have all accepted that it is very difficult to predict the outcomes, but we have tried to outline some of the opportunities to everybody here.

CHAIR—As to the first question, I do not know whether Professor Chalmers or Professor Skene want to comment.

Prof. CHALMERS—To respond very quickly to Dr Matthews, when I was suggesting that we move to considerable legislation I think one of the requirements of any legislation arising from the recommendations of your committee is there has to be a financial-human rights-environment impact, and I think what we have been doing is looking at options – firstly, either banning the procedure, leaving the status quo with the knowledge that there has been considerable reform of the IAC system and, secondly, perhaps bringing in a specific two tier. The Deputy Chair I think was investigating a fourth option which was using the AHEC and, as it were, amending through NIH, and then finally some options of legislation building on the OGTR.

The specific question you have asked me to address, Chair, I think is really beyond the competence of this committee at the moment because I think there is a separate inquiry going on into the Office of the Gene Tech-

nology Regulator. It has been subject to quite extensive public comment. The AHEC had an opportunity to comment. I think it is probably sufficient to say that at one stage there was the possibility of following the full FDA model where the Gene Technology Regulator would have had all matters within one office. I think there was then a second view, which was that the Office of the Gene Technology Regulator was the front door for all gene manipulations, technology and so on. Instead, I think, the model which this legislation is following is to say that there are existing regulations within food, drug technology and so on – the five major regulators – and that the OGTR will now be looking at genetic manipulation and will in fact be regulating as a sweeper, almost. I think that makes an assumption about the way in which the TGA operates. I think it is suggesting that there is sufficient confidence that the new generations of biological drugs, the way in which the clinical trials are operating through the IAC system, is adequate at this stage. I think it is not saying that it is perfect. Throughout the debates before the public and in the discussions it is suggesting, I think, that there will be a responsibility on us all as a nation to keep looking at our regulatory systems and in bodies such as this asking, 'Are these still answering the questions?' May I say, Dr Phelps, I have no doubt whatsoever, if you look to what is happening in the states, what is happening in developing countries, I think the need to maintain the highest possible ethical standards in clinical trials is incumbent on us all.

CHAIR—Ladies and gentlemen, I am going to draw these proceedings to a close. Before I do, may I thank all of those who have participated today for your contributions, your interest and your patience as the day has worn on. Can I say that this process of having evidence given not simply by one person or body at a time but in the process of a roundtable format has been pioneered by this committee from a parliamentary point of view over the last 12 months. I think it is one which has been quite successful as it does enable a range of opinions to be given and for the committee members to hear a variety of views about subjects. I thank you for your participation in it today. The matters which have arisen today will give us food for further thought and reflection and, no doubt, further evidence and hearings as time moves on in the consideration of the matters before the committee.

Resolved (on motion by **Mrs Vale**):

That this committee authorises publication of the proof transcript of the evidence given before it at public hearing this day.

CHAIR—I thank you all for your attendance. I thank *Hansard* and the secretariat staff.

Committee adjourned at 5.16 p.m.