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HOUSE OF REPRESENTATIVES

STANDING COMMITTEE ON LEGAL AND CONSTITUTIONAL AFFAIRS

Reference: Human cloning

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HOUSE OF REPRESENTATIVES

STANDING COMMITTEE ON LEGAL AND CONSTITUTIONAL AFFAIRS

Wednesday, 29 March 2000

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

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

Terms of reference for the inquiry:

To review the 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

ARMSTRONG, Mrs Verona, Catholic Women's League Australia

ATWOOD, Mr John, Acting Assistant Secretary, Public International Law Branch, Office of International Law, Attorney-General's Department

BLACKMORE, Mr Matthew, Executive Director, Consumers Health Forum of Australia Inc.

CAIN, Mr Paul, National Caucus of Disability Consumer Organisations

CAMPBELL, Mr Raymond Paul, Director, Queensland Bioethics Centre

EDDINGTON, Mr Peter (Private capacity)

HEARN, Ms Jane Elizabeth, Senior Legal Officer, Attorney-General's Department

HICKEY, Archbishop Barry, Australian Catholic Bishops Conference

HOFFMAN, Mr Earle Samuel, Canberra Representative, Executive Council of Australian Jewry

LOBLAY, Dr Robert Henry, Senior Lecturer in Immunology and Representative of College of Health Sciences, University of Sydney

MACAULAY, Mrs Jill, Member of Study and Investigation Committee, Country Women's Association of New South Wales

McCULLAGH, Dr Peter (Private capacity)

MAYO, Dr Oliver, Fellow, Member of Academy's Working Party on Cloning, Australian Academy of Science

MORRIS, Ms Christine Faye, Research Fellow, Australian Key Centre for Cultural and Media Policy

NEVILLE, Dr Warwick John, Head of Research Department, Australian Catholic Bishops Conference

NORMAN, Professor Robert John, Council Member, South Australian Council on Reproductive Technology

NORTH, Mr John Frederick Stuart, President, Law Society of New South Wales

PATTISON, Mr Mark, Executive Officer, National Council on Intellectual Disability

PETTIT, Professor Philip Noel (Private capacity)

RATHJEN, Professor Peter David, Professor of Biochemistry, Head of Department, Department of Biochemistry, University of Adelaide

SAVULESCU, Professor Julian, Director, Ethics Program, The Murdoch Children's Research Institute

SERJEANTSON, Professor Sue, Consultant, Australian Academy of Science

SWANTON, Dr David John (Private capacity)

TUDEHOPE, Mr Damien Francis, Spokesperson, Australian Family Association

UHLMANN, Mrs Mary, President, Catholic Women's League, Canberra-Goulburn Catholic Archdiocese

VANCE, Mrs Barbara Joan, Chair, Study and Investigation Committee, Country Women's Association of New South Wales

WOOLF, Mrs Kathleen, Vice President, Australian Federation of Right to Life Associations and the Right to Life Association, New South Wales

CHAIR—Ladies and gentlemen, I open this public meeting of the committee as part of the inquiry into the scientific, ethical and regulatory considerations relevant to cloning of human beings, and on behalf of the House of Representatives Standing Committee on Legal and Constitutional Affairs. May I welcome all the witnesses here present today, and also any other members of the public who are present.

In August 1999, the Minister for Health and Aged Care, the Hon. Michael Wooldridge, asked the committee to undertake this inquiry. As you will know, the terms of reference are 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.* For this meeting, the committee is operating in a public forum format. We plan to take evidence in relation to the major issues on the inquiry's terms of reference. This will cover, obviously, the scientific and ethical concerns and also the legal response that the issues raised. We also propose to have some time to allow any members of the public to put their questions and concerns forward for consideration by the committee and by our witnesses.

Because this is not only a public forum but also a formal hearing of the committee, can I note some procedural rules and ask you to observe them. Firstly, if this is to constitute formal proceedings of the parliament, and therefore to attract parliamentary privilege, then questions and comments need to be directed through me, as the chair. If there are any questions you have of other members of the panel or any comments that you wish to make, I ask you to direct them through me and, similarly, later in the proceedings, if there are members of the public who wish to make comments or ask questions, I ask them to do likewise.

Secondly, can I advise you 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 is regarded as a contempt of the parliament. The evidence today will be recorded by Hansard and, provided that the proceedings are conducted in the way in which I have outlined, they will then attract parliamentary privilege.

The first session is on the scientific aspects of the subject. What we propose to do is to begin with a brief statement from each of those witnesses identified under this issue, namely, Professor Serjeantson, Dr Mayo, Professor Norman, Professor Rathjen and Dr McCullagh. Could I ask you, because of time restraints, to limit your statements to four minutes or to a maximum of five minutes.

Can I say to all the participants that the committee primarily relies upon the written submissions which are made to the committee, so if you have a feeling that you have not covered what may be the voluminous material in your submissions today, do not be concerned. We still look, in fact, primarily at the written submissions. The purpose of today is to allow you to highlight those issues which you think are the most important and the most crucial, and for us to discuss those. We can and will refer back to the written submissions themselves. So it is not a matter of having to cover everything that you have covered in your written submissions and feel that if you do not do so, then somehow the committee will not take that into account. This is more an opportunity for us to tease out some of the most important points which you consider to be relevant to the subject. I invite Professor Serjeantson to begin.

Prof. SERJEANTSON—The Australian Academy of Science produced a statement on human cloning in February 1999. I would like to confirm to the committee that this statement still remains the position of the Australian Academy of Science. The council of the academy considers that reproductive cloning to produce human foetuses is unethical and unsafe and should be prohibited. However, human cells, whether derived from cloning techniques or from embryonic stem cell lines should not be precluded from use in approved research activities in cellular and developmental biology.

The council of the academy does strongly support the recommendation of the Australian Health Ethics Committee that community discussion on this matter could be encouraged and, for that reason, we welcome this inquiry. But the academy feels that if Australia is to capitalise on its undoubted strength in medical research then it is important that research on human therapeutic cloning is not inhibited by withholding federal research funds or prevented by unduly restrictive legislation in some states.

The academy believes it is essential to maintain peer review and public scrutiny of all research involving human embryos and human embryonic stem cell lines undertaken in Australia. The council, for this reason, supports a national regulatory, two-tier, approval process. Approval to undertake any research involving human embryos and human embryonic stem cell lines would need to be obtained from a duly constituted institutional ethics committee, prior to assessment by a national panel of experts who would have national overview of activity in this area.

I have mentioned the terms 'reproductive cloning' and 'therapeutic cloning' which, I think, have been a matter of discussion in some of the submissions. The academy would like to stand by the use of that terminology because we found it very useful in terms of communicating with the lay public. We have used these as a working definition because we want to remind people that therapeutic cloning does not only apply to embryonic stem cell lines or to the cloning technique in that sense. It has much broader application. It includes, for example, the growth of skin cells for grafting, and that has been practised as a reality in this country for some time. Reproductive cloning represents the manipulation of embryos or germ line tissues in order to produce new individuals. Human application of such research has been stated by the academy to be unacceptable. From the academy's point of view, the distinction between therapeutic and reproductive cloning is not a matter of semantics. It is an important issue relating to the intent of research and the application of that research.

Dr MAYO—I simply want to address the question of research on cloning for non-human applications. For some time, the academy and the Australian Health Ethics Committee had slightly different views on stem cell and related research in non-human primates, as against research in humans where the views are very similar. Positions appear to have converged in that neither body is now in favour of establishment of substantial facilities for non-human primate research in Australia.

In some submissions, some witnesses appear to have stated that there is no need for non-human embryonic stem cell and other research of this kind in Australia. I think we need to determine very clearly whether these opinions relate to non-human primates, where the research is primarily directed towards improvements in human reproductive medicine, or whether we are talking about research in other mammals that is primarily directed either to the advancement of human understanding or to the improvement of Australia's livestock industries. It is our view that research in mammals other than primates is very important to the future competitiveness of our leading livestock industries. The regulation that comes out of the inquiry that is directed towards human reproductive research should very clearly distinguish non-human research of the type I have mentioned in order that the regulation does not cover research, for example, on livestock where the intent is simply the improvement of those livestock industries. Reproductive cloning of experimental animals and domestic livestock will be of great benefit in several fundamental matters in biology, namely in understanding the relationship between the ordinary genes in the cell nucleus and the non-nuclear genetic material, in understanding ageing in mammals and, most particularly, in the application of gene technology to livestock improvement. For those reasons, as I say, the academy is concerned that such research is very clearly not covered by any regulation that is recommended by the inquiry.

Prof. NORMAN—I represent the South Australian Council on Reproductive Technology. We are the regulatory body responsible for implementing the act that covers reproductive technology in South Australia, the Reproductive Technology Act 1988. Similar acts and bodies are constituted in Western Australia and Victoria but not in other states and territories. We comprise members of the community—theologians, doctors, lawyers, civil servants and other interested members. I think we are widely acclaimed to be the best model of regulation of assisted reproduction in Australia.

The act is interpreted through a code of ethical practice and this is where cloning is covered in our regulations. There are definitions of cloning which have been quickly superseded by advances in medical and scientific technology. The council was concerned that the current definition of cloning that we had was going to be inadequate for the future. We have therefore constituted a working body in which we included most of the scientists who are involved in animal cloning and those who are interested in potential therapeutic stem cell cloning as part of the group. In my submission, I have given our new definition which I would commend to the committee. That definition is: cloning is the practice of forming an embryo or entity capable of embryogenesis, which is genetically identical to or substantially identical to another human being living or deceased. Whatever definition we come up with is, unfortunately, going to be rapidly superseded by scientific advances.

There are three things I would like to note to the committee. First of all, the council, by law, is only concerned about the use of human gametes and human embryos. If therapeutic cloning or the production of pluripotential cells was to occur using methods other than human gametes or human embryos, the council and the Reproductive Technology Act of South Australia have no jurisdiction over that. Indeed, the council considers that therapeutic cloning is something that scientifically is going to be very important. We are only concerned that we do not use human gametes and human embryos to get these cells. Secondly, the council has no authority over therapeutic cloning of embryonic stem cells with methods that may involve animal cells and human somatic cells. Thirdly, South Australia has a very non-confrontational approach to the regulation of assisted reproductive technology and, indeed, issues of cloning. We would wish to commend to the Australian community the value of collaboration, accommodation and discussion among interested members of the community and scientists involved.

Prof. RATHJEN—My personal area of research expertise for the last 12 or 13 years has been in the area of embryonic stem cell differentiation and de-differentiation. To date, we have used solely mouse cells for that work. That work has obvious implications for therapeutic cloning, as it is being termed here. I would like to make three points which I think might be of relevance to today's discussion.

The first is to bring people's focus to bear on why these sorts of strategies may be important. The idea that they will give new opportunities to research and the understanding of the human condition has already been flagged. But what has not really been enunciated clearly is why there is such excitement about the possibilities of this technology for human therapy. In a nutshell, using embryonic stem cells potentially gives us the ability to produce any kind of cell in any number with any genetic modification, and that potentially opens the opportunity to treat diseases which are currently inaccessible to us. I suppose, as a corollary to that, it is fair to say that Australian scientists are leaders in certain aspects of these technologies and that the country stands to reap benefits from prosecution of some of these endeavours.

The second point, which I want to just flag, is an area where I think there is some confusion in some of the literature. To my mind, there is a very clear distinction between a pluripotent cell or an embryonic stem cell and an embryo. It is very important to recognise that an ES cell is not an embryo and does not have the capacity to give rise to an embryo in any sensible definition. In particular, it cannot form extraembryonic tissues which are critical to survival of the embryo.

The final thing I would like to flag is that the big issue for scientists working in this area at the moment is where they might source their human embryonic stem cells from. Currently many of the methodologies involve embryo destruction and are controversial. It is the case that there are many teams working on strategies to obtain human embryonic stem cells by techniques that do not involve embryo destruction at all and which are consistent with the maintenance of embryonic life.

Dr McCULLAGH—I would like to address three points. One is the question of scientific communication; the second is the question of the position of non-primate research in this; and the third is the context in which it is being placed, not only looking at alternative technologies.

Scientific communication, basically, is about truth. Reading the *Hansard* from the Melbourne hearings, I must say I kept wondering when does hyperbole stray out of truth. In relation to the repeated assertions that one could derive embryonic stem cell lines without destruction of embryos, in particular, there is a mishmash of tenses, terms and species.

The second point relates to non-human primate research. I think it is clear from literature that there is a very substantial difference between embryonic stem cells derived from primates and those derived from rodents. I think this is of relevance to your committee from two aspects: first of all, the primarily medical and, secondly, the primarily ethical, I guess—although they both include elements of the other. Primarily, in the medical sense, there is a strong tradition that any procedure or a therapy which is to be used in humans and patients must be tested in animals. This is subscribed to by the NHMRC, the vice-chancellors, the assorted academies and the ARC, and is, I think, beyond dispute.

In the case of ES cells, the proposals range from transplantation of cells to using them as vectors to taking various genes into the patient. It should be pointed out that all of the ES cell lines which have been derived and which it is proposed to transplant to people are deriving have been derived from potentially very defective embryos. In fact, an IVF clinic only has people who have infertility. Compare this with the mouse work, which is based primarily on one strain, the 129 strain derived by Roy Stevens at the Jackson Lab. These were brother-sister mated for yonks. For generations, the lethal alleles have been totally removed from these. Compare this with not just the normal population of human embryos but a population derived from people who either have no history of producing, so progeny testing—if we get into an animal husbandry term—has not been possible or, alternatively, there is no visible reason for the infertility. The likelihood is that, in a number of cases, if not many cases, you will have lethal or deleterious alleles contained in these. To use this as a source of material to be transplanted into the population at large seems to me to be looking at a rerun of the CJD fiasco. In the animal situations such as Dr Mayo was talking about, I suspect that, for example, the Hereford breed society would not agree to using as vectors cells derived from a bull which had been down the back paddock and never produced a calf. I think this should be taken into account.

That could be overcome in primate research by the use of a species such as the marmoset, for example, which takes 18 months to become sexually mature. It would be possible to look at vertical transmission—to look at a number of generations derived from animals which had been subject to experimentation. This is a sine qua non, if one is proposing to use any of these things as human therapy as distinct from just adding to basic knowledge. From the ethical point of

view, I would suggest that what is known about primate ES cells indicates that they are very different from mouse ones. There are papers published by Thomson—I will give the secretary a list of the papers I am referring to later—in *Proceedings of the National Academy of Science* 1995 describing a rhesus monkey line which, again, had the capacity to produce trophoectoderm and equivalent to inner cell mass, in which Thomson raised the question that this appeared to resemble totipotency.

Even more persuasive is an article in *Biology of Reproduction* in 1996, again published by Thomson's group. This was with marmosets. Looking at marmoset cells, again they found that marmoset cells allowed to aggregate into embryoi bodies—and these were cultured in vitro—formed amnion, embryonic plate with primitive streak, and yolk sac. In fact, they noted that they proceeded as far in vitro as normal marmoset embryos did. The word 'totipotent' was used on a number of occasions—that these cells resembled totipotency. I think one should get rid of the delusion that the embryonic stem cells produced from the Roy Stevens's 129 strain of mice are equivalent to embryonic stem cells produced from primates.

Putting it into context in relation to therapy, embryonic stem cells provide one way of solving the transplantable tissue problem. There are at least two or three others—for example, xenotransplantation, which has many problems of its own, but also derivation of stem cells from specific tissues. The journal *Science* in its last issue of last year identified the production of stem cells specific for particular tissues as being the 'breakthrough of the year'. These stem cells fulfilled the requirements of being self-renewing. For example, one study by Pittenger et al from Osiris Therapeutics and from Johns Hopkins took bone marrow cells from healthy humans—not mice, not marmosets—and cultured these bone marrow cells and were able to produce adipocytes, that is, fat cells, chrondrocytes, that is, cartilage, and osteocytes at will in pure populations of these individual lines by manipulating the culture conditions. They were also able to derive all three lines from a single cell. I would suggest that there is a very substantial alternative technology there and, in fact, the *Science* editorial made the point—I can get you the reference for that—that this seemed to be a resolution of the considerable ethical difficulties which the Americans and the NIH were having about this.

Finally, any of these technologies have the limitations applied to them which are yet to be solved which I referred to in my submission. Firstly, rejection by the immune system of the recipient remains a very real obstacle. Forty years after immunological tolerance was discovered, it is still not solved and does not look like being solved in the near future, I believe. Secondly, in many cases the diseases for which these tissues will be transplanted will not stop at attacking the tissues themselves. It has been very much the case with the early research on type 1 diabetes, which is an auto-immune disease—I think beyond dispute now—that the transplanted tissue is destroyed very rapidly. I suspect it will be the case with spontaneous Parkinson's and with some of the other conditions.

CHAIR—Can I lead off with some questions. One is immediately raised, in a sense, by what Dr McCullagh said, and I would like the other scientists to respond to that. Why shouldn't this area be the same as other areas of medical research, where primate research is primarily undertaken before moving on to human research?

Prof. NORMAN—One of the problems with getting embryos from non-human primates is that it is more difficult, in many ways, than getting those embryos from humans. Monkeys are expensive, they are very difficult to get large numbers of eggs and embryos from and it is fairly difficult to get the sorts of cells that scientists would necessarily want. As you will know, human IVF occurs all over the world now under various regulatory restrictions. There are many, many times more human embryos being produced than there are non-human primate embryos. So the first thing is that it is much more difficult and expensive to get monkey embryos. The second thing is that human embryonic stem cells already exist in various parts of the world, as you will be aware. These are available under various conditions to researchers and to non-government bodies in the United States. Therefore, they exist and people may want to use things that already exist rather than make new embryonic stem cells.

Prof. SERJEANTSON—I would like to endorse those remarks. There are about 700,000 children born worldwide from IVF, but from primates the figure is less than a dozen. I think that is indicative of where the effort and the expense are being directed. There is another element with respect to using non-humans for experimental work. A lot of the experimental work has, of course, been done in other animal models and we would expect that that very important work must continue prior to experimentation in humans. But the reality is that the commercial interests are focused on humans because that is where their patents can be placed.

Dr MAYO—There is the question of resource limitation within Australia. Although we are seeing a very welcome increase in NHMRC funding over the next few years, the fact is that funds in Australia for research have not, in general, been increasing in recent years. The academy was concerned that diversion of funds into establishing a major primate research facility, which at one stage was being proposed by AHEC, would be a diversion of effort that this country could not afford.

Ms ROXON—We had some evidence in Melbourne in relation to this question of undertaking primate research first. I understood a number of the scientists to be saying to us not that their concerns were driven by limited health funding or commercial interests, particularly, but that there was a concern that a lot of the lessons that will be learnt from primate research would not necessarily be easily transferable into human research, so that they would not necessarily be saving, if you like, any time in doing that research first. I am very much paraphrasing; those are my words. I would like any of the scientists to comment on whether that is right or not. It seems that that is quite a different position from the factors that you have responded to the chair's questions on. Would anyone like to comment on that?

Prof. RATHJEN—There are two issues that I would like to address. One of the things that Dr McCullagh referred to was that experiments are often done on animal models to establish efficacy or safety before they are carried out on humans, and that is standard practice. I do not think that people are advocating that we eliminate that from this procedure. It is just that the animal models in this case may not be primate models. There is no doubt that people are working hard to try and use cell type therapies to cure disease conditions in appropriate animal models, although not as closely related to humans as primates.

I have some sympathy with the point that you raised about the Victorian scientists. We do not understand yet a great deal about the origin and derivation of embryonic stem cells nor about

how we might differentiate them and use them. One of the things we can suffer from in this discussion is assuming that we have the technological pieces of the puzzle in place. We do not. A lot of things need development. To my way of thinking, Dr McCullagh is correct that, at present, there appear to be significant differences between some mouse ES cells and other ES cells. Whether that reflects a true biological difference or some technical difference that we do not understand yet I do not know. But if that argument is correct, then it does seem to me that there is an argument that time spent trying to solve those mysteries for primates might not necessarily be directly transferable into improvements with human therapies.

CHAIR—Dr McCullagh, do you wish to add something?

Dr McCULLAGH—I will respond to the questions that were raised. Dr Mayo's question was about the monkeys being difficult to obtain material from. This is correct with some monkey strains, and Thomson makes this point very eloquently in some of his papers from the Wisconsin Primate Centre. With rhesus monkeys it is very hard to regularise their cycles, they have single monkettes—whatever a monkey child is called—and they are expensive and all the other things; they are precious. The case with marmosets is rather different. With marmosets one can regularise the cycle as well as one can with IVF patients. They usually have twins, sometimes three, but often more than one offspring, and they have sexual maturity at 18 months which enables you to do long-term studies. Incidentally, marmosets have shown some use now in studying CJD. In fact, had some of the gung-ho research that was done as therapy in using very impure pituitary extracts on human patients been done first in marmosets, it may well have been that we would not have had some of the catastrophes we have had.

Secondly, on Professor Serjeantson's point, to put it bluntly, primates do not attract 'Vebibank'. The 700,000 women have had IVF because there is financial provision made for giving IVF. There are very few veterinary procedures that are funded so adequately. There has, nevertheless, been substantial work done with primates. Thomson—who, just to remind people of his status, is the first person and certainly the most advanced person in the world to have produced human ES cell lines—maintains quite vigorously that there is a substantial place for primate work. Mind you, he was the first to produce primate lines too, but he has not abandoned those and said, 'We are into the humans, let's go ahead.'

Thirdly, in relation to marmosets, I understand that there was a marmoset colony in Adelaide. I do not know if it is still going, but there used to be one established a few years ago. They were trying to palm it off onto people, but apparently there were no funds available. The AHEC suggestion was, I believe, very explicitly made that there should be extra funds, and they were looking at something in the order of $4 million or $5 million, like the cost of painting a Collins class submarine perhaps.

The point made from the Melbourne hearing which was raised was that the results are not readily transferable from primates to humans. They are much more readily transferable from primates than they are from strain 129 mice. The point that should also be brought out about mouse ES cell lines is that, until very recently, it was impossible to produce mouse ES cell lines other than from one strain of mice which was produced by Leroy Stevens at the Jackson Lab by extensive back-crossing of a mutation onto another strain of mice and then brother-sister mating for many years. This was terrific research; I have great admiration for it and for him. Unfortu-

nately, he worked before the electronic records have traced things back, so a lot of his work is not known to people working nowadays, which is sad. But that is very far removed from human application.

As I have indicated, and as Professor Rathjen indicated also, there are very strong indications that primate ES cell lines are a very different entity from strain 129 mouse ES cell lines. In fact, they resemble Thomson's human cell lines in that the human ES cell lines Thomson produced also have a trophectoderm capacity because they produce human chorionic gonadotrophin. This is noted in Thomson's first description of these cell lines in 1998 in the proceedings of the National Academy of Science in the US. So, in that respect, there is similarity between the marmoset, the Rh 278.5 rhesus monkey line and the human cell lines that Thomson has produced. Thomson has not grown the human cells on to produce embryoid bodies and see what happens with them then. Fairly obviously, the reason for this is that there are ethical constraints, something along the lines referred to by Harold Varmus, testifying before the US Congress on 26 January 1999, when he was asked the specific question: could these human ES cells, which could reassemble into embryoid bodies, then go on and reorganise into an embryo form?

He said quite clearly—this is the outgoing director of NIH, although not outgoing for that reason—that he did not know and, of course, he could not try because it would be ethically impossible to do this sort of experiment. I think we have got to look at where the onus or the balance of proof falls in drawing some of these conclusions.

CHAIR—Can I explore that a bit further with the panel because it seems to me, from what I have heard not only today but in Melbourne and elsewhere, that our state of knowledge about the ES cells and their possible potential for development, which you have alluded to, is still somewhat lacking. I would be interested in the views of the various scientists here about whether there is anything we can say with certainty at this stage, rather than speculation about what may or may not happen.

Prof. RATHJEN—Would you like to clarify your question?

CHAIR—I am picking up on the point that Dr McCullagh made about the work of Professor Thomson in the US and the reference he made to the testimony before the US Congress by the former director of the National Institute of Health. With the ES cell, it seems to me that, on one hand, there is a case being put that the ES cell is something which is distinct from an embryo. I think that was your point, Professor Rathjen: we are talking about two different entities, so to speak, although obviously there is something in common. I draw from that a suggestion that therefore it is not an embryo and they cannot develop in the way in which an embryo would and that we are talking about something different. Somewhere down the line of this argument the ethical, moral and legal considerations are necessarily different.

There is some suggestion from what has been said, particularly by Dr McCullagh this morning, that we are not so clear about that. Obviously it would be extremely useful if we could be clear about that. It may be that we cannot be, so my question therefore comes back to: is there any agreement about what we do know? What is in the realm of possibility or speculation, well founded or otherwise? I am not commenting on that but I am just trying to understand, given that there are some differences of opinion, what we do know at the present time.

Prof. RATHJEN—We get to an important qualification here. It is very difficult for scientists to be definite about anything. That is not the way science works. You do experiments—

CHAIR—That is meant to be reserved for politicians!

Prof. RATHJEN—What it means is that you go with what you know, with your experience, with your judgment and with the experimental data. In that regard, I think the statement that an ES cell is quite obviously distinct from an embryo is a fair judgment. The major difference, to my way of thinking, is that an embryo has a property that an ES cell cannot have: it has organisation. That organisation is inherent in the process of development from the fertilised egg to the blastocyst and the blastocyst is the structure which contains the embryonic stem cells. The embryonic stem cells cultured by themselves do not, in my experience, or in that of the other scientists that I have talked to in this area, have the ability to reform that kind of structure which is critical to ongoing development.

I am confident when I say that in 20 years of looking at mouse embryonic stem cells that has not occurred and we can be quite clear that it would not happen with those. Dr McCullagh has made the reasonable point that we have far less experience with primate or human embryonic stem cells. However, the scientists that I have talked to that have worked with human embryonic stem cells report the same sort of thing. These cells do not appear—and 'appear' in a scientific sense there is being used as quite a strong term—in their culture systems to form anything that remotely looks like the organised structure of an embryo; therefore, something that they might expect to have the capacity to go on and participate in embryogenesis.

Prof. NORMAN—I think we need to qualify Peter Rathjen's comments, and I hope I am correct in this, that the culture conditions under which ES cells are held are deliberately there to keep them pluripotent. In mouse systems you can take an embryonic stem cell and put it into a mouse egg that has had its nucleus removed and then get development to an embryo from there. So I think, Peter, it would be true to qualify that. Embryonic stem cells have the potential under certain conditions to develop into an embryo. Would that be a correct interpretation?

Prof. RATHJEN—Those conditions require experimental manipulation and in fact to my knowledge are not different from the conditions under which any other cell or any other nucleus could give rise to an organism. So a skin cell and an embryonic stem cell in that sense—though skin cells is a bad example—a somatic cell in that sense also can have its nucleus removed, put into an egg and give rise to an organism. That is shown by Dolly the sheep.

The other thing I should say is that Rob Norman referred to the fact that embryonic stem cells are traditionally cultured in such a manner as to prevent their differentiation. That is true while you are trying to grow more embryonic stem cells, but the experiments I was referring to are experiments where these scientists are trying to differentiate the cells and see what other kinds of cells they can get from them, so they are directly pertinent to the question you were asking.

Dr McCULLAGH—To follow up on Professor Norman's comments, I think to put it in a single sentence, you only see what you set out to try and get. To produce the changes I described in the marmoset, or Thomson described in the marmoset which I quoted, which were structures like yolk sac, amnion and primitive streak, you have to get embryoid bodies to form.

Embryoid body formation is the last thing that you want if you are trying to maintain your line. In fact, in the case of a human cell line I would suspect that is the last thing that people are likely to want to do. I do not know if any of the researchers have actually set out to produce human embryoid cell bodies and then put them into conditions which would be conducive to maintaining the human embryo in-vitro, as was done with marmosets by Thomson.

Very clearly the aim, in the case of non-human species if you are aiming to keep the cells going, as has been said already, is to avoid this, and in the case of human species or human cells or human material I would suggest that for ethical reasons the last thing one would want to do would be to undertake the experiment when one deliberately said, 'We will look and see if we can get ES cells to form embryoid bodies that form amnion, primitive streak, et cetera.' Until someone does that, and it would be totally unethical to do it I suggest with human cells, one really does not have an answer. You could say that if Ian Wilmut and the people from the Roslin Institute had knocked off after 250 tries there would never have been a Dolly, so the first 276 were bummers; they produced either nothing or foetuses which were deformed, had liver deformities and this sort of thing. It is all a question of how confident would you like to be, and of course the bind with humans is that, I suspect, it would be very hard to find any scientist—apart perhaps from Richard Seed in Chicago and he is hardly a scientist—who would be prepared to devote the next two or three years to take in human ES cell lines to see if they can first of all get them to develop in-vitro and then perhaps go on to the extent that Harold Varmus said would be totally out of the question, of implanting what you had there into the uterus. So I think there has to be a lot of uncertainty there. But I revert to saying that I think the primates may well provide both a clue, perhaps a way around some of these difficulties, and also a very significant safety valve at a very low cost to the government.

CHAIR—Other members of the panel may have questions, but can I just raise this question. If there is some uncertainty in this area, and regardless of what decisions are made about the research with the human ES cells, it would seem to me to be reasonable nonetheless that we should continue primate research. I would be interested in your comments on that.

Prof. NORMAN—In the field of human reproductive technology the trend has always been to do animal work before human work. There is one major exception, and that was a technique that was introduced in 1992 called intra-cytoplasmic sperm injection—we call that ICSI—and this is a technique that is used for couples where the male has very low sperm counts. In Australia now this technique constitutes between 40 and 50 per cent of all IVF cycles that currently occur.

There have been ongoing concerns about this technique in terms of the genetic normality of some of the embryos. I think overall people are reasonably happy that ICSI is a safe procedure for the vast majority of people, but there is ongoing scientific evidence that makes us less happy with ICSI as a procedure as to straight IVF where the sperm and the eggs are just added in the test tube without any injection. I think most scientists would have liked to have seen non-human work occur first.

Mr CADMAN—Could you describe it a little.

Prof. NORMAN—All right. Where we need to get fertilisation in a test tube for IVF, one normally adds, for each egg, over 100,000 sperm, and the sperm and the eggs intermingle in the test tube to form an embryo. Anything less than that number of sperm is associated with a very poor fertilisation rate. Some men have probably less than 50,000 sperm available total, and it is known that these men, if they and their partner go through IVF, have very poor fertilisation and, indeed, often failed IVF. So the technique of ICSI, as I will call it, is a technique where, with a glass needle, one sperm is picked up and injected into the egg, so there is mechanical insertion of the sperm into the egg as opposed to allowing natural selection to occur, and this has been one of the concerns about ICSI.

I do not want to raise issues that people going through ICSI are going to have genetically abnormal children; that is not true. But there is ongoing concern that a technique was introduced into human reproductive medicine before adequate animal studies were done. It is too late to change that now—the horse has bolted. But, I think in terms of embryonic stem cell technology, it would be wise to have primate research going on, but there should be the potential to move through into human work once adequate, safe experimental work has occurred in subhuman primates.

Mr CADMAN—So you are saying that the exception you have identified does not change the rule?

Prof. NORMAN—If we had good models for human IVF, we should always do subhuman primate work first. But, as I proposed in one of my statements, doing the IVF work in subhuman primates is more difficult than it is doing it in humans, and that is why there has been very little subhuman primate work done before the human IVF work occurs.

Mr CADMAN—Mr Chairman, if I could, I wonder whether it might be possible for Dr Mayo to offer comments on primate research?

Dr MAYO—First of all, on the question of primate research, I should make it clear that the Academy of Science was not saying that this should not go ahead. It was simply saying that, given Australia's resource limitations and other priorities, to establish a substantial primate research facility here when there are such facilities overseas and when we have extremely tight ethics of animal experimentation regulations which, in many cases, preclude types of work here that are done in other countries, did not seem to be a good use of resources. As to what happens in other animals, we are using—and many other groups are using the technique that Professor Norman just mentioned—ICSI as one of the things that we are looking at in attempting genetic modification of domestic livestock. But there you are using normal sperm that you have treated in the hope that they will take up new genes. For us it is, therefore, a case that you are trying to use the best sperm available and the best eggs available to produce a new organism. So we have not done any work that would bear on ICSI, and I am not aware of the work that is done to test the sort of possibility that Professor Norman was alluding to there, and that is the possibility of things going wrong later, so to speak, from use of sperm that were in some way inadequate.

CHAIR—Could I take up the point you made, Dr Mayo? Is there any concern that this area is being largely driven by commercial considerations and that they are predominant?

Dr MAYO—Of course, all of our research in CSIRO where I work is directed at the national benefit. Eventually we would expect it to be taken up commercially by livestock industries. I cannot comment on the medical area except in the same way as anybody who reads the literature. There is enormous investment, particularly in the United States, in this area because infertility is a huge problem and even more so organ transplantation has virtually unlimited demand for organ replacement. That is where a lot of the work is directed. The reason for using human tissues is that the application will be in human medicine, but the reservations that Professor Norman and Dr McCullagh have both made about direct application certainly are real reservations that have to be taken into consideration.

Ms ROXON—I have a question for Professor Rathjen. It was in relation to the third point that you raised which was a comment that there is concern obviously about where embryonic stem cells are obtained from and that there are techniques being worked on that did not involve embryonic destruction. I know in Melbourne we also had evidence about a lot of work that was being done in de-differentiating the cells and being able to work backwards rather than forwards and how that may avoid a lot of the ethical concerns that many people have. Clearly we are in the position where we ultimately have to make a recommendation about how we believe this area should be regulated now and into the future. Is it really realistic that that sort of research is going to provide some method for obtaining embryonic stem cells without using embryos in some way in the near future? What sort of time frame is there for that? I know that is probably the $40,000, $40 million—

CHAIR—Probably $40 billion question.

Prof. RATHJEN—The question is unanswerable for the reasons that you just pointed out. The experiments are being done. They are not necessarily avoiding the use of embryos; they are avoiding destruction of embryos. I am aware of three different approaches which are being taken worldwide to try and solve this problem. Two of them do not involve embryos at all and they involve some kind of de-differentiation, either by directly telling the cells to revert to a more primitive state or by nuclear transfer as was done with Dolly the sheep. There is a third mechanism which would use cells from an embryo but without destroying the embryo or compromising its embryonic ability. The potential outcomes of those experiments are not clear. They have not been done. There are precedents in the literature which provide hope that they will be successful, but the time frame over which they will be successful I do not think can be usefully speculated upon.

Ms ROXON—Thank you.

Prof. RATHJEN—Could I make one distinction which is important in terms of what we were hearing about primate research. There is a difference between the sorts of clinical trials you would want to do before you apply a therapy to a human and the sorts of experimentation you need to do before you know whether the sorts of things you are doing are even going to be relevant. I can give you an example from my own research which might help to clarify that.

We have developed the ability to take embryonic stem cells and turn them into neurons in a very efficient manner. We are at a position now where we can transplant those neurons into rodents to see whether they can, for example, cure diseases in rodents. The question we have now

is: where would we usefully go with our research? We would like to know whether the sorts of conditions we use to make neurons in rodents are also applicable to humans. If they are not then obviously we have got to either tweak the system or do something different. That is the sort of experiment that you would do in a laboratory. It is not the same question as: can we put those neurons back into a human to cure them?—which is a question that you might usefully answer via primates. But for us at least it is less attractive to try and do the early experimentation on primate cells because it may well be that we get an intermediate answer that either gives us the wrong direction or says, 'This is what you have got to do to get it working in primates but it is different again in humans.' It seems that there is a human specific question there which we would like to answer in humans first, but in terms of clinical efficacy we would still expect at some stage to have to go through an appropriate model.

Mr MURPHY—Professor Rathjen, I am just asking you an opinion here. In view of the research that is being undertaken at the moment on stem cells and against the background that they do not have the benefit of the organisational structure of an embryo, in your opinion, do you think that at some time in the future science will be able to create organs for the purposes of transplants?

Prof. RATHJEN—It is not my area of expertise but I am aware that there is significant interest in this area particularly in the United States. If I were asked to make a professional judgment, my view would be that that is a likely outcome but over quite a long time frame. The two questions that you need to answer to try and make organs are, firstly, where do you get the cells from that will give rise to the organs? The embryonic stem cell technology potentially provides you with a source of those cells. Then, secondly, there is a very difficult question: having those cells, how would you organise them into something which functionally resembles an organ?

Mr MURPHY—My understanding is that the number of stem cells that science is using currently for this sort of research is sufficient not to need to procure further cells from existing embryos. Would that be your judgment?

Prof. RATHJEN—Are you referring to embryonic stem cell lines?

Mr MURPHY—Yes.

Prof. RATHJEN—There are some lines in America and a small number of lines in Australia currently that I am aware of. Again, the question becomes: to what purpose do you wish to put those lines? Are you talking about using them therapeutically to cure human disease? In which case, no, I do not think we have the right number of lines because those lines that we have will suffer from the problem of immune rejection, as Dr McCullagh pointed out.

If you are asking whether we have enough lines now to start doing basic investigation to ask the questions: do these things differentiate or behave in similar manners to mouse cells, then the answer I think is maybe. It is clear that those human lines and those primate lines have different properties from the mouse lines that people are accustomed to dealing with. What I do not know and no-one else knows is whether that is because there is something inherently different about human lines or whether it is just because, technically, we are not very good at isolating human lines yet and we might be able to get something which is more similar to a mouse line using a

different methodology. Again, I would like to come back to the fact that I do not think the existing methodologies are very robust or necessarily the ones we want to use in the future. There is still a large amount of room for the development of new kinds of embryonic stem cell lines that might be of different use.

Mr MURPHY—Thank you, Professor.

CHAIR—Dr McCullagh, do you want to comment?

Dr McCULLAGH—The last question was getting on to my concern which is about working on developing organogenesis in vitro with foetal cells from lambs, not from humans. The big difficulty, of course, is growing something that is the size of an organ. We can get three cell types together and grow structures, the normal gut from foetus, and they will coalesce. But we call them mini guts because they get to about three millimetres in size and then they have to have a vascular supply after that. In tissue culture the material can diffuse in, but not otherwise. What the solution may be, regardless of where the cells come from, is to try to inject cells that will repopulate existing organs.

For example, Yandava et al, from Harvard, published one of the articles which attracted the science editorial, a report on shiverer mice. These are not shivering for fear of the experimentation; these are mice which have a tremor because they are lacking in myelin and in some ways they resemble multiple sclerosis lesions. Yandava and his group were able to take a stem cell derived from a mouse cerebellum—the brain of a mouse—inject these cells into the ventricles of the shiverer mice and the cells spread out quite remarkably. These are after birth mice. The cells migrated to the brains of the mice and established themselves and started to produce myelin basic protein. Oligodendroglia are the cells that produce the myelin sheath around nerves which is lacking in demyelinating diseases. The cells migrated out through the brain and restored some of the function and certainly restored the myelin protein. So I think it may be a possibility that you can use the scaffolding of the existing organ and repopulate it. As to growing an organ larger than a mini gut, larger than two or three millimetres, until you find some way of growing a vascular supply in vitro, I think that is going to be well beyond the lifetime of any of us here, if not forever unattainable. I think you have to look at other ways.

Mr CADMAN—I would like to come back to the submission from the Academy of Science and draw out some of the factors you have raised there. It appears under your four dot points. Let us deal with the last two. You say that Australia is capable of capitalising on its strength in medical research and that research on human therapeutic cloning is not inhibited by withholding federal research funding. On the one hand, you appear to be saying, 'There are limitations to where our research could go but take the brakes off and let it rip.' I do not quite understand where you draw the lines of responsibility and accountability and the funding processes. Governments will apply funds but rely on others to make value judgments of this sort. You develop in your fourth dot point what I can only feel is a mixed process: you have an institutional ethics committee but then you have the NHMRC also having some ethical factors as well. I do not understand any of that.

Prof. SERJEANTSON—You are quoting, of course, from the covering letter, which covers the submission where some of these items are fleshed out a little more. With respect to the last

point you raised about the regulatory arrangement, we are suggesting a model that follows two examples in this country already where this mechanism has worked pretty well. One of them is GMAC, the Genetic Manipulation Advisory Committee, and the other one is the Gene Therapy Committee. In these two models, there are institutional ethics committees that have the first opportunity to look at any research proposal and to give advice and feedback to the researchers. These are properly constituted institutional ethics committees with membership following NHMRC guidelines. They have to have representation by various members of the community and so on.

However, in the case of GMAC and in the case of the Gene Therapy Committee, it is important that there is a national overview for all sorts of reasons. We might want to know that there is no duplication of activities, for example. This is the sort of thing that we are proposing here—that there would be a national committee that would have the final word in the approval process but there would be an initial screening of research proposals at the local level. That is on that point.

Mr CADMAN—When you say 'at the local level', do you mean at the institute or at the state level?

Prof. SERJEANTSON—No. At the institution. There are around 200 institutional ethics committees in existence at the moment. They are set up at the level of a university or at the level of a large teaching hospital, for example.

Mr CADMAN—What is the consistency between their ethical statements that those various bodies apply?

Prof. SERJEANTSON—That is why we thought it was important to have a national committee.

Mr CADMAN—Has anybody examined them?

Prof. SERJEANTSON—In the case of GMAC, there are proposals that must come to the national committee depending on the category that they fall into. So that provides some uniformity in terms of feedback to the local committees.

Mr CADMAN—But there is no mandatory or professional requirement that that occur. Does it occur automatically and does it occur thoroughly?

Prof. SERJEANTSON—In my limited experience, it does. I did, for four years, chair the institutional ethics committee for the Australian National University with respect to genetic manipulation and I believe that our researchers gained very much in understanding what was required of them from having some local-level monitoring with feedback to them—local inspections and an educative element as well as a policing element—in that committee.

Dr MAYO—Further to that, all of these committees are set up under regulations under legislation and they all report on a regular basis. So there is information. For example, if it is animal experimentation which requires ethical approval, there is reporting on animals used in that ex-

perimentation and what types of work were done and so on and there are regular visitations to see that institutions are meeting the required standards and so on. So there is reporting upwards and inspection or investigation down in those mechanisms. I believe that a fair degree of consistency is achieved.

Prof. NORMAN—Perhaps I could just mention how research on human sperm eggs and embryos may occur in South Australia. That is along the model of going through a recognised institutional ethics committee, and that is usually—almost always—a body that is getting NHMRC funding. As you know, any breach of NHMRC regulations leads to total removal of funding from that institution. So any project that is put in has to go before the institutional ethics committee. If they then pass it it goes to the South Australian Council on Reproductive Technology, which has a working party on research, and that working party then goes through everything again and then makes a recommendation to the main council. And, as I have implied before, that council has a very wide representation of government and many other interested bodies. Over the years that the council has been in existence, this has worked exceptionally well for handling the issues of dealing with human reproductive material.

Prof. SERJEANTSON—Can I just answer the other part of the question—the issue that if Australia is going to capitalise on its strength in medical research, it is important not to withhold federal research funds, et cetera. The point we are making here is that it is fairly rare these days where Australia actually has got a competitive edge on the rest of the world in our research. This is one instance where we have truly a competitive edge on our research in the work that is being done at the University of Adelaide and at Monash University and some work elsewhere. By 'elsewhere' I mean the Australian National University.

So at the academy we recognised that undoubted strength in medical research. If we are going to capitalise on it, then it is important that we do not take the route that has been taken in America and that has been, 'Okay, we will regulate it by withholding federal funds.' What we see in America is that the private sector is virtually unregulated, and there has been an element of secrecy for some years and the information that they are gaining is not in the public domain. We see it as important at this stage that we put in place a framework that will be binding on both the private and the public sector. We do not think that the right tool is simply withholding public funds from that research.

Mr CADMAN—That is an interesting comment. Dr Mayo, you deal with the result of your work partially in the commercial sector. It would seem to me that what is being proposed is a limitation that applies to the public and private sector, but generally the impact of such regulation is to hamper the private sector. Do you see it in that way?

Dr MAYO—In Australia, that should not happen. What the academy is seeking really is uniform national legislation but not necessarily modelled on the earliest or the most restrictive existing legislation. Of course, in Australia it would apply equally to both the public and private sector so that the private sector should not be hampered in taking up public sector results, provided that all of the work has complied with existing legislative requirements.

CHAIR—Dr Mayo, in your initial comments you made reference to some agreement between the Academy of Science and AHEC. I want to ask you to elaborate on that. There have

been, obviously, some differences of view between the two bodies and I know there have been some further thoughts and discussion. I wonder if you or Professor Serjeantson could outline for the committee what currently the areas of agreement and disagreement are between the Academy of Science and the Health Ethics Committee?

Dr MAYO—If I could elaborate on what I said before, that was simply on the one issue of the place of primate research in this whole area. We have worked through that one now, I hope, to a reasonable understanding. I ask Professor Serjeantson to comment on the other issues.

Prof. SERJEANTSON—The reports from the Academy of Science and from AHEC had several commonalities. First of all, the academy and AHEC agree it is very important to promote informed community discussion in this area. Science cannot go forward unless it has the support of the community. We have already seen how public reluctance to take up GMOs, for example, may seriously impair research in that area. So we genuinely believe it is incredibly important that the community is taken forward on this debate.

The other point of agreement concerned reproductive cloning. The academy made the distinction between reproductive cloning to produce a human foetus and therapeutic cloning, and the academy and AHEC believed that reproductive cloning to produce human foetuses was unethical and unsafe and should be prohibited.

A third point of agreement between the academy and AHEC is that both groups believe that cloning technology is an exciting advance in medical research and that we should all be working to try to facilitate research by our talented scientists in this area and enable them to go forward in a way that is acceptable to the community, that is ethical and that recognises the merit of the research. And we would like to see that regulated in some way.

The main area of disagreement is really the way in which this work might be regulated. The academy believes that scientific progress is proceeding at such a rapid rate that, if we put in place restrictive legislation, it is quite possible that, inadvertently, we are left in an environment where we have inadvertently hindered some of the research that might go forward. That is why the academy is recommending this two-tiered approval process where we had informed people at the national level of experts that included people who were in touch with community attitudes and community standards and who would be able to assess properly the scientific merits of any proposed research, the safety issues and, of course, the ethical acceptability of that work. We feel that we have a good record in Australia of operating under these types of systems. We have heard some examples from the panel this morning where we have had a national regulatory body that has behind it legislation that determines the membership—or the composition, at least—of these various committees. We believe that, in an uncertain world as all scientific worlds are, it may be more sensible, rather than to take a model from one of the states that has existing legislation that was actually put in place for quite different purposes—for ensuring clinical practices were ethical with respect to in-vitro fertilisation—rather than take that state legislation and impose it on other states, it would be sensible to have a more flexible regulatory arrangement that was national. Otherwise, we may well see differing legislative frameworks in different states. The feeling of the academy was that whatever was done should be national. This is an area in which states legislate, so it may be more sensible to go down the regulatory framework road.

Ms ROXON—I am not sure if you want to continue afterwards if there are other areas where you want to highlight differences or similarities, but I have a question which I think should be directed to Professor Norman on the point that has just been raised by Professor Serjeantson. In your position as a state representative, and without wanting to invite the usual arguments on states rights, in practical terms, if there was national regulation in this area, how would you see that affecting the sort of work that you have been doing? How would you envisage the council working as part of some national regulatory system, whether it is legislative or other guidelines as are being proposed?

Prof. NORMAN—The only model that we really have to look at at the moment in the human area is regulation of IVF. We have three states that have regulation of IVF at a state level. My Victorian colleagues tell me that from a medical point of view they are extremely unhappy with the way the system works, but that is only one perspective. The Western Australian regulation appears to be perhaps more harmonious between the practitioners and the regulatory bodies. The South Australian community feel fairly happy about the way things operate.

One of the problems that people have been struggling with is national regulation for IVF, and it appears as if that is a very long way away from actually occurring. There has been much discussion about it. I am not aware that it has progressed in any way at all. There are many different perspectives and feelings across the states and territories as to how this should happen. So in terms of human IVF, which is clearly something that has gone on for 20 years in Australia, we still have not got to any sort of consensus on a national regulatory body. I would suspect that the clinicians and practitioners would be opposed to that, although I accept the fact that many in the community would be much happier with that than the current situation.

When we come to the issue under consideration now, I think it would be easier to institute a national control rather than a state control, largely because most of the researchers working in the area are not using private funds but are using federal funds and therefore would be much more amenable to follow a national body. How that national group would be constituted would be extremely important. Obviously the community would want a big input into that, but I think it is extremely important that the scientists have an input as well. I am sorry I have taken a long time to answer that. I think a national body would work, but there needs to be widespread consultation among the scientific and also the non-scientific community.

Ms ROXON—Thank you. I am sorry to have interrupted—I think Mr Cadman wanted to ask some more questions.

CHAIR—Just before you continue, Alan, I am not sure if Professor Serjeantson had finished talking about whether there are any other areas of disagreement.

Prof. SERJEANTSON—I think we have reached agreement on the primate research facility. We agree that it is important that some research be done in non-human primates, but that does not necessarily have to be done in Australia and it does not necessarily mean the construction of an expensive primate facility.

Mr CADMAN—Okay. Could you just develop a little more the one area of agreement which is outlined in one of your first points of agreement: that any cell of an embryo, foetus, child or

adult, not destined to become a sperm or egg cell shall not be precluded from approved research. That seems very broad to me. I would like to know precisely the points of demarcation in that, because it is saying any cell from those sources—foetus, child or adult—not destined for a particular purpose shall be open to any sort of experimentation. I would like to see some sort of practical guidelines as to how that may in fact be used or abused.

Prof. SERJEANTSON—The academy has been fairly strongly of the view that it is essential to maintain peer review and public scrutiny of all research involving human embryonic stem cell lines, so it is not suggesting open slather. It is suggesting that they should not automatically be—

Mr CADMAN—No, I am not even trying to guess what it may mean in my own head. I am trying to find out what it does mean in a practical sense.

Prof. SERJEANTSON—In a practical sense, cloning, in the sense of cloning DNA, cloning skin cells, cloning cells, is going on.

Mr CADMAN—So the production of stem cells would be a satisfactory process? The use of embryos for the production of new lines of stem cells would be acceptable?

Prof. SERJEANTSON—If they were approved by a properly constituted ethics committee and overseen at the national level.

Mr CADMAN—You have just said that Australia has a very high standard and an enviable standard, but in fact we have got stem cells because somebody had to go offshore and bring in material that was illegal to produce in Australia.

Prof. SERJEANTSON—Illegal to produce in Victoria.

Mr CADMAN—And it could have been produced anywhere else, in South Australia for instance?

Prof. SERJEANTSON—The National Health and Medical Research Council guidelines refer to exceptional circumstances under which that could be done.

Mr CADMAN—But this is for experimental purposes and for further experimentation. There was no specific goal, as I understand it.

Prof. SERJEANTSON—The research in this area in those states without legislation is governed by the National Health and Medical Research Council guidelines on assisted reproductive technologies. They are guidelines in the sense that institutional ethics committees need to interpret those guidelines. What I am suggesting is that in those guidelines there is a reference to exceptional circumstances.

Mr CADMAN—I find it difficult to placate my conscience by saying that, if we grab something that is illegal to produce in Australia except under special circumstances—none of which has been tested, to my knowledge—we can placate ourselves by saying we have a high record.

We appear to be breaking our own rules by a backdoor process. That is a layman's interpretation. My background is a science background, so I am happy for any of you to have a say in how you see that. It is like knocking off plant material from the United States, bringing it home in your pocket and saying, 'Oh, look what I found, I have a new variety of peach or plum tree.'

Dr MAYO—Without knowing all the details of the particular example that Mr Cadman has mentioned, and without wanting to defend the actions of any particular scientist, we should make it very clear that the Australian Academy of Science is advocating that, at all times, all scientists obey the law of the land as it applies where they are. If, in this particular circumstance, that did not happen then we certainly would not be advocating such an action. In the other example given, the person bringing plant material in without declaring it would be committing an offence, and that is certainly something that we would be completely against. If it was legal to import the stem cells from another country and if it was legal to work on them when they got here and if the work was approved by a properly constituted ethics committee set up under the act applying in that particular place, then that work would be complying with what the community requires in that particular place. Again, the academy would obviously wish that all work was complying in that manner.

Mr CADMAN—I wonder whether Professor Norman or Professor Rathjen might have any comments on the availability of material and how we might use material and also, perhaps, on that definition used by the academy?

Prof. NORMAN—In South Australia we would certainly not be able to do the sort of research that has occurred in Singapore and then has been brought back to Australia. I think what the committee needs to understand is that there is an enormous transport of reproductive material, both animal and human, across the world. People will have IVF in Australia and transport their embryos to the United States, and people will have IVF in Europe and bring their frozen embryos to Australia. In the animal field this occurs frequently in all sorts of areas. There is an enormous transport of reproductive material across the world every day through our airports and other areas. This is all regulated and is quite appropriate.

The problems that we have in human work is that, for instance, surrogacy is not legal in most areas in Australia. We certainly would not create embryos to be used by a surrogate in the United States. But, for instance, should we be bringing in sperm from America under conditions that are not those found in Australia? You are raising enormous issues in the human area that we have not really got on top of yet. I believe that the bringing into Australia of preformed embryonic stem cells is an issue that we need an answer on very rapidly.

Prof. RATHJEN—Just to add to that, you may be aware that human embryonic stem cell lines from the University of Wisconsin are now available commercially.

Mr CADMAN—On the open market?

Prof. RATHJEN—On the open market.

Mr CADMAN—Can you get them on the web site?

Prof. RATHJEN—I suspect so.

CHAIR—Professor Rathjen, let me just take up something which arose in the Melbourne hearings. If I understood him correctly, Professor Trounson in Melbourne was suggesting that, given they have ES stem cells and are reproducing them—he took us out to show them to us in culture—it was possible to continue to reproduce the ES stem cell lines and therefore there was no need to produce any more. I heard you say earlier that there might be reason to do that. Professor Trounson, if I understood him correctly, was saying that the only reason they would need to obtain more stem cell lines would be if the national institutes of health in the United States demanded that for future research the production of the ES cells were done according to some new protocols put in place in the US and therefore it would not be acceptable to use the existing ones whether they were produced in Wisconsin or Singapore. I am interested in your comment about this because obviously this is an issue of some concern. If on one hand there are sufficient stem cells around using what is available, that raises some different issues to saying that there are not enough and we need to go on reproducing more of them.

Prof. RATHJEN—You keep asking probing questions.

CHAIR—That is what we are here for.

Prof. RATHJEN—To which there are no answers, of course. There is a major issue here and it comes down to how science works. Science works by people doing experiments, reporting their results in open forum, and then distributing materials so that others can find out whether what they said originally is correct and whether they can maybe build on the results that those people have reported. With Alan's cell lines, which I have not seen, that has not been possible yet. They have not been published to my knowledge and they have not been made freely available to other researchers. For me to make a comment about how useful those cells might be is not possible. In fact, much the same is true of the lines that have been isolated in the United States of America. They are not commonly available and it is not possible for me to tell you now that, yes, they will do everything we need them to do or that, no, they are not satisfactory.

Looking at the literature that is available and talking to the scientists involved, I think it is unlikely that we have in our possession the gold standard embryonic stem cell line that will solve all the problems that we want to solve in the future. What we have is an early stage resource which will enable us to undertake some useful experiments to see whether the sorts of things that control cellular decisions in humans are similar to the sorts of things that control cellular decisions in mice, which is the system which is being used most.

I envisage that in the future, firstly, there will be much more robust and useful embryonic stem cell lines produced and, secondly, those cell lines will be produced by methodologies which we do not currently have in our possession. All we have is the first part of the story. We will improve on that over the years. I come back to what I said in my opening address: it is also my belief that those more useful embryonic stem cell lines will ultimately be produced by technologies which do not require embryo destruction. I think what we are seeking here is permission to be allowed to start to develop those sorts of methodologies.

Dr McCULLAGH—Can I ask you a question, Mr Chairman?

CHAIR—You can ask it—whether I can answer it is another question!

Dr McCULLAGH—It follows up on Professor Trounson's comment that it may be necessary to rederive the lines to comply with NIH standards. I have gone carefully through the NIH standards. I cannot discern what there is that is wrong with the cell lines from Singapore. As Peter says, it is not published, so it is very hard to tell much about them at all. I wondered whether Professor Trounson had indicated what it was. Were they contaminated? Were they derived by mouth pipetting? Was there something done about them which was unacceptable? What is it about them that may require them to be rederived? If you do not know that, I would suggest that it would be very useful information for you to find out. If you could tell me now that would be very interesting.

CHAIR—We will take that as a question on notice, to look at what the NIH has said and, if necessary, to ask Professor Trounson about it. Other members of the committee may be able to correct me if their recollection is better than mine. I do not have the transcript of the Melbourne hearings in front of me, but I had understood that Professor Trounson had written to the NIH asking that they be able to continue with the cell lines which had already been reproduced. His concern, as I understood it, was that if these protocols were put in place in the US, he and those in a similar situation would be precluded from obtaining research funding from the US unless they met the protocols that had been established. If those protocols meant that the cell lines had to be established in a certain way and the ones that they have got have not been, then obviously they would not meet the research criteria. That is how I understood it, but we will pursue the question.

Ms ROXON—I know that Professor Trounson said in the public hearings in Melbourne that the concerns were in relation to the way that the cells had originally been obtained, not in there being anything defective in relation to the cells that were being used. There were questions of permission, what was explained at the time and what was intended for the further research, et cetera. I think he raised simply as a query that if, at some point in the future either in America or Australia, there were guidelines put in place as to how any embryos should be obtained and what sort of consent procedures were needed to go through, he may then not be able to use the cells that were there. I hope that that assists.

CHAIR—Part of this forum was to give other members of the panel an opportunity if they wished to ask questions of the scientists. I note that Archbishop Hickey has joined the panel since we began. If there is any member of the panel who would like to ask a question on science matters I will take any questions and direct them through me to the panel members. I would like to define it to scientific matters because we will go on to discuss ethical, legal and regulatory issues later.

Dr NEVILLE—I have a question for Professor Rathjen. If I understood you correctly, in your comments concerning the distinction between ES cells and embryos, you said one of the reasons for the distinction was that ES cells did not have the capacity to develop in the way that an embryo did. Could ES cells have the capacity to develop as a disabled embryo?

Prof. RATHJEN—What ES cells have the capacity to do is to differentiate into the cell types that make up an animal. They also have the capacity to differentiate into all of those cell types.

If you were to take all the cell types that make up an animal and put them in a dish, to me that is not a disabled animal in the sense that you would be referring to. You would be talking about something that has a sense of animalness to it, something which is recognisably an animal. To my understanding, that is not something an embryonic stem cell could do because it cannot approach that level of organisation that is found in an animal. It can just make the cells that would comprise the animal.

Dr SWANTON—I note that the NHMRC has guidelines that prohibit experimentation on embryos older than 14 days. Do the scientists see any need for experimentation on embryos or embryonic stem cells older than 14 days?

Prof. NORMAN—Certainly not for embryos. For embryonic stem cells, their nature is that they grow potentially forever, and therefore a restriction on the time limit that embryonic stem cells would be looked at would be inappropriate at a 14-day level.

Mrs UHLMANN—I noted that Professor Serjeantson spoke about the importance of community consultation and about GMOs. There is a great fear mounting in the community, an alarmism. Cloning does that; people immediately become afraid. I wonder how you intend to do this, because to have an informed discussion you have to be informed.

Prof. SERJEANTSON—The academy has taken the first small steps in encouraging debate, first of all by making public its statement on its position on human cloning. It has held two forums for discussion of this matter. It has also gained quite a bit of interest in the media that has brought into the community the topic at least. The academy is only one of those with some responsibility in this area for encouraging community discussion. Following the publication of the statement, there was a lot of media interest and we made specialists available who could talk in those forums. It is also important for the Australian Health Ethics Committee to be encouraging that. I think the fact that this inquiry is set up is another encouraging sign that gradually there is an increase in awareness in the community that will lead to debates.

Prof. PETTIT—I have a question for Professor Rathjen. In discussion with Professor Norman, the question was raised about the relationship between the ES stem cell, the embryonic stem cell, and its capacity to develop into an embryo. You said that, yes, in certain conditions it could. But then you went on to say that, well, yes, in those conditions, any cell could—that is what Dolly has taught us, so to speak. So are you saying that the embryonic stem cell and an ordinary adult somatic cell, such as I might take from the lining of my mouth, relate in just the same way and only in the same way to the potential development of an embryo?

Prof. RATHJEN—I was trying to clarify a comment that Professor Norman made along those lines—that you would be able to form an embryo from an embryonic stem cell by removing the nucleus and putting it back onto another site. That has now been published. We know that is possible. But I was making the point, which I believe you have understood correctly, that in that regard a somatic cell could substitute for an embryonic stem cell because all you are looking for is a donor cell for the nucleus. It is the cytoplasm of the egg that reprograms that nucleus such that it can form an animal.

Prof. PETTIT—So that the distance between an embryonic stem cell and an embryo is exactly the distance between a somatic cell and an embryo?

Prof. RATHJEN—In that regard, I believe that they would need active reprogramming by the oocyte cytoplasm—that is correct.

Mr TUDEHOPE—I have a question for Professor Norman. It is a practical question, in a sense, because we made lots of references to ethics committees overseeing the activity of science. In plain English, can you outline for us the sort of experimentation which perhaps has ever been submitted to an ethics committee and which has in fact been rejected by that ethics committee as being unsuitable?

Prof. NORMAN—I cannot give you many situations in South Australia. I know many of the other states, particularly in the Melbourne submission, would give you much more vivid examples. I think the sorts of things that would get rejected are anything against the legal requirements in South Australia. For instance, no embryo destruction is permitted. We could not, for instance, take a human embryo donated by a client and extract DNA from that embryo and do research on that DNA. That is the sort of thing that we would not even bother to put to the human ethics committee because we know that would be rejected. So the fact that there is not a lot of rejection of things by the human ethics committee does not imply that they are not good gating bodies. People do not go through all the work involved in putting things to committees if they do not believe there is a very high chance of it going through that committee.

Mr TUDEHOPE—I have a supplementary question. There was an experiment done under an IVF program in Victoria where a human embryo was implanted in an animal. Is that the sort of activity that you would have envisaged would have been the subject of a review by an ethics committee and either accepted or rejected by that ethics committee?

Prof. NORMAN—That is the sort of experiment we would never even contemplate. We know the way that our ethics committee works. We understand the law in South Australia. It would not even cross our mind to put that sort of thing to an ethics committee because we know what the answer is. To put anything to the ethics committee would take you a minimum of two to three hours of writing, and most scientists do not want to go to that amount of effort.

Mrs WOOLF—I would like to inject some note of scepticism on the part of a non-scientific witness. I think it was Professor Serjeantson who said ‘scientists cannot go forward without community support’. But, indeed, they do exactly that because we were told by Professor Norman that practitioners and clinicians in the field of IVF have proved extremely difficult to bring to some sort of national regulation. In fact, they will do precisely what they want to resist such national regulation. We know, in our experience, that this is true. Genetically modified foods have landed on our shelves. We were not asked beforehand. So I think it is just cant to say that scientists cannot go forward without community support. On the matter of communication with the community, we are told, contradictorily, that scientific progress is going forward so rapidly that it really is not even amenable to parliamentary legislation or regulation and that, in fact, you might put in place restrictive legislation which would inadvertently restrict development—in other words, ‘Back off. Don’t do it.’

It may be that the best expression of community opinion at any particularly time is best put in place by the parliament, and the last answer indicated that certain things would not even be put to the South Australian ethics committee because they were not legal under South Australian law. One of the foundation things that we should have in place is some legislation within which regulations such as the Australian Academy of Science talks about: the setting up of committees under regulations, under legislation. The legislation should limit, of course, the reach of the regulations, and I really wonder why it is that somehow a duly constituted—it is begging the question—institutional ethics committee will sit upon the scientific merits. Okay, there are safety issues and ethical acceptability, but I do not see why a duly constituted institutional ethics committee has some superior insight into what is ethically acceptable about the very work in which their peers are engaged. I would prefer it to be a parliamentary decision.

Prof. SAVULESCU—My question is to Dr Mayo. Ultimately I am a strong supporter of primate research and, in fact, I spent one year of my life doing primate research, but it was enough to actually drive me away from scientific research altogether. When people suggest that rather than using the 1,000 embryos that are frozen and must be destroyed by law in Victoria as a source of stem cells we should use primates, one relevant fact that I would like to know is: what is the current scientific view of the cognitive capacities of those primates? How will those primates be obtained and how will they be treated currently in Australia?

Dr MAYO—In my earlier remarks I commented that certain kinds of research cannot be done in Australia because of the restrictions imposed by our animal welfare legislation in the various states and territories and that, I think, is what we have to consider in this particular case: whether, indeed, research might be unacceptable ethically in terms of what it does to the animals. Therefore, certain kinds of work that people might want to do would not be possible. I am not a cognitive scientist and I could not comment in the slightest on the cognition or otherwise of non-human primates.

Ms ROXON—Does that mean, firstly, that we actually have better regulation or protection for animals than we do for humans? Secondly, does it really go more to the fact that we can actually obtain consent from humans, but we obviously have difficulties in doing that from non-human primates?

Dr MAYO—I cannot comment any longer on the situation with ethics of human experimentation. I was involved with the establishment of some of the committees under the legislation in South Australia many years ago. As I understand it, each institution that does experimental work involving humans has an ethics committee which has to approve all experimentation. When I was on the committee of the then Children's Hospital in Adelaide, it was a very tight committee and it frequently sent the applications back for change because they were not acceptable in their original form. And this is what happens with animal ethics committees that I am familiar with at the moment. I cannot really comment on the contrast between them. All I can say is that in the institutions I have worked in—the University of Adelaide, some universities and hospitals overseas and then CSIRO—this mechanism has been taken very seriously as long as I have had anything to do with it.

Mr CAMPBELL—I have a follow-up question to Professor Rathjen, again on the ES cells. In light of the statement by Harold Varmus, the director of NIH, that he did not know the poten-

tial of ES cells—whether they could recongregate—and we have some evidence through Dr McCullagh's evidence that in some animals they appear to recongregate, what is the evidential basis for your opinion that human embryonic stem cells cannot recongregate?

Prof. RATHJEN—I should probably clarify a little Harold Varmus's comment—I have not seen the actual comment. You need to be aware that Harold Varmus's professional expertise does not lie in this area at all. He is a virologist and works on retroviruses and so he could not be expected to have an opinion of any kind. I am not quite certain what you mean by 'recongregate'. Could you expand on that?

Mr CAMPBELL—I am actually using his language, which I presume meant that they could, as a cell mass, start to show those signs of organisation that you say they do not have.

Prof. RATHJEN—They can show some limited signs of reorganisation, and this comes to something which I wondered about explaining a little earlier. It is a concept called embryoid body formation. The term was used by Dr McCullagh, and it is a standard route used for differentiation of embryonic stem cells. In effect, what you do is to make an aggregate or a congregate of some tens of embryonic stem cells, and they then commence a process of cell differentiation which is quite reminiscent of the process that occurs in the animal. When I say it is reminiscent, what I mean is that you finish up producing the same sorts of cells that are found in an animal and you produce them in much the same way—you go through the same sorts of intermediate cells en route to, for example, production of a muscle cell.

You also within that embryoid body have a very limited level of organisation—you can pick up certain kinds of cells which have come together because they are similar sorts of cells, but you do not have any structure that in any way could be construed as looking like a mouse if they are mouse cells, or looking like a human if they are human cells. The reason for that is that what you are starting off with is a blob of embryonic stem cells and that is not what an embryo starts off with. It starts off with a ball of embryonic stem cells which are surrounded by a sophisticated population of trifectoderm cells which are extra-embryonic in nature. It appears that it is both the presence of those trifectoderm cells and the structure of the embryo at that stage which are important.

Dr McCULLAGH—I will just comment on Professor Savulescu's question. I think it is a bit misleading to group under primate research something involving research in and restraint on a silverback gorilla and what Thomson et al do in the case of marmosets. It is looking at a non-surgical collection of oocytes from an animal which has had its cycle regulated, so it is exactly the same as a lady going into an IVF clinic—except for the paperwork. In effect, thereafter the experimentation is done entirely in-vitro so I guess that unless one thinks that a marmoset embryo has more sentience than the human embryo I do not believe there is a lot of maltreatment of the marmosets involved in that sort of experiment.

Mr HOFFMAN—I am a former senior public servant in the Commonwealth Department of Primary Industry. In that department, among other duties, I was chairman of a series of Commonwealth industry research grant bodies. I would like to support the remarks made quite early in the discussion by Dr Mayo. It is clearly advantageous for Australia to encourage work on mammalian cloning. These techniques offer the prospect of more rapid productivity gains for

our animal industries than the slower selection processes that have led, for example, to twin lambing. If there were to be any regulations introduced, it would be particularly important in Australia's case to ensure that that did not impede in any way the advances that Dr Mayo was referring to.

Archbishop HICKEY—I would like to ask the scientists if anyone would like to comment on the potential of adult cells—their pluripotential, their ability to be cultured into different forms of cells—for repair work on organs and tissues, particularly as an alternative technology to the use of the ES cells.

Prof. SERJEANTSON—The Academy of Science held a forum towards the end of last year, where this issue was discussed in some detail. Those present at the forum were divided in their opinion about the answer to that question. Some of the forum participants believed that the problem of adult de-differentiation could be overcome with a bit of hard work—if the scientists only put their noses to the grindstone and really worked at it that they could achieve de-differentiation of adult cells. Another view expressed was that, without a keen understanding of the molecular and functional properties of the factors that control early embryonic cell differentiation, reprogramming of adult cells would be hit and miss and would have serious technical difficulties, so the scientific community itself I think was divided on this.

Dr McCULLAGH—My suggestion to that probably would be that, when and if one can do that, it would be possible to get so-called syngeneic cells—cells that are histocompatible with the individual—for example, where you take cells from the bone marrow and get these to grow into liver cells, as has been done with rats. Cells have been taken from muscle and have been grown into bone marrow cells and in fact have been shown to renew themselves, so they clearly are stem cells. There are advantages if you can do this, in that you overcome the histocompatibility problems. You do not overcome the problem that the original disease which destroyed the cells may have a go at the new ones, but at least it adds that different slant to it.

Certainly towards the end of the millennium journalists tended to get into a bit of a hype but, as I mentioned, the last issue of *Science* for the year identified this type of activity as their breakthrough of 1999. The *Proceedings of the National Academy of Science* at the same time published an article on this, and I think their reference was that this was about to happen. Someone here may be able to remember it more accurately, but I think the phrase they used was that 'the table is set and dinner is ready'—that this was an area that was really about to go. That was the perception as at December 1999, but, as everyone recognises, the perception changed very rapidly.

CHAIR—Thank you, Dr McCullagh.

Proceedings suspended from 11.06 a.m. to 11.22 a.m.

CHAIR—Ladies and gentlemen, before moving to the ethical considerations, can I say to the scientific panel that if any of them have any material by way of articles, papers or references which they think would be of use to the committee in informing ourselves, we invite you to provide them to us.

I now move to some of the ethical aspects. Again, we will ask each of the people listed if they would like to make a statement. Given the time, I would ask if you could limit it to perhaps three to four minutes. I reiterate that your statement here today is not taken as the totality of your evidence before the committee. We rely primarily on the submissions to the committee, but this allows you to highlight the key points which you wish to make and allows us to tease out some of the issues, as we were attempting to do this morning, so we will approach it in the same manner. I would like to allow a little time before this second session concludes to ask if there are any questions from members of the public who may be here and to give them the opportunity to ask them, so can we keep matters succinct and comments as brief as possible, without limiting the important things you want to say. We will start with Archbishop Hickey.

Archbishop HICKEY—I am accompanied on this occasion by Dr Warwick Neville, who is from the research office of the Australian Catholic Bishops Conference. I have copies of this opening statement should the panel wish to have them.

The Australian Catholic Bishops Conference is grateful for this opportunity to appear before the committee concerning its inquiry into cloning. On behalf of the conference, which is presenting the official view of the Catholic Church in Australia, I wish to make the following points. First, may I express to all members of the committee and, in turn, to all members of parliament and senators our appreciation of the important responsibility that you and they carry in deliberating on laws and regulations which ultimately relate to the protection of human life in its earliest and most vulnerable stages.

Secondly, laws enacted by this parliament only a few years ago that prohibited euthanasia sent important messages to the sick, aged and frail members of our community that they are important, that they are not disposable and that our laws will protect the infirm as well as the hale and hearty. That same law also sent a no less important message to the medical community and many others to extend their significant efforts to find new and better ways to relieve pain and suffering. In a similar way, laws to prohibit cloning will send messages to our community about the dignity of human life. Such laws will send messages to medical researchers not to pursue research that would produce human embryos destined for destruction through harvesting embryonic stem cells. Moreover, there is growing scientific agreement that research on adult stem cells is ethically a more prudent course and medically a more advantageous one. For example, the Editor-in-Chief of the journal *Science*, Floyd Bloom, strongly promotes this course.

Thirdly, through their regulative, educative and symbolic effect, our laws will reflect the parliament's regard for the inherent dignity of all human life, in both its generation and its existence. It is the view of the church and of many others of different religious traditions that the dignity of the human person is rooted in his or her creation in the image and likeness of God, the ultimate author of life. Respect for all human life must take precedence over respect for academic or scientific freedom to conduct research, especially when there are commercial incentives involved. Human life is never disposable at any stage of its development. It should never be seen as a commodity—as a type of property able to be exploited for profit—nor is its worth and claim to protection dependent on age or utility to others.

Fourthly, the distinction advanced in some quarters between so-called reproductive and therapeutic cloning is seriously misleading. Reproductive and therapeutic cloning both involve the

creation of human embryos. In the case of therapeutic cloning, it also involves the destruction of human embryos.

Fifthly, embryonic stem cells should be treated and accorded the respect and the proper protection due to a human embryo. There is a significant scientific reason to believe that, given certain conditions, totipotent human ES cells may develop into embryos. Happily, there is a certain confluence of thought in this regard between the position of the church and prominent bodies, such as the National Institute of Health in Washington. For example, Pope John Paul II has stated that:

... what is at stake is so important that, from the standpoint of moral obligation, the mere probability that a human person is involved would suffice to justify an absolutely clear prohibition of any intervention aimed a killing a human embryo.

In evidence at a congressional hearing on 26 January this year, the Director of NIH, Harold Varmus, said that he did not know whether it may sometimes occur that stem cells derived from embryos would recongregate and begin the early stages of embryonic development. He continued, saying that it would be unethical to try to establish this concern because such determination would require implanting the stem cells in a woman's uterus to ascertain whether they can reproduce a live birth.

Human cloning for the purpose of ES cell collection, as presently proposed, requires the creation, dismemberment and destruction of embryonic human beings or at least subjecting them to grave risks and unethical exploitation. It is unethical to create and/or to dismember human embryos in order to derive ES cells from them. Given the technological process of the creation and dismemberment of human embryos at this stage of our understanding, it is the view of the Catholic Church in Australia that it is unethical to collude with or participate in the harvesting and use of ES cells.

Cloning, however executed and for whatever goals, distorts the human meaning of procreation, which is no longer considered or practised for reproductive and relational reasons but programmed for medical, experimental and commercial purposes. The logic of market forces and the paradigm of the industrial manufacture of only the most perfect model, coupled with the attendant production and discarding of many less than perfect prototypes, must not be allowed in relation to cloning. Cloning, we maintain, must be prohibited throughout Australia.

Dr NEVILLE—Could I just make a couple of observations to the committee, most of which have been made by others overseas. A first question might be: why legislate rather than operate via guidelines? An instructive text in this regard is a fairly recent book called *Clinical Guidelines and the Law: Negligence, Discretion and Judgment*, published in the UK by a general practitioner in London and a senior lecturer in general practice at the Imperial College School of Medicine. He gives this example—and I hasten to add that this is not a script from a *Yes, Minister* text:

A dialogue which took place during the Scott Inquiry into the Arms for Iraq Affair illustrates the appeal guidelines hold to those attempting to enforce accountability upon professionals who have traditionally regarded their work as self-directed, and generally free from outside interference.

'Ms Baxendale QC: Some of the witnesses we have had have described these guidelines as a framework, within which to work ... Does that fit in with how you saw the guidelines?

Lady Thatcher: They are exactly what they say, guidelines, they are not the law. They are guidelines.

Ms Baxendale QC: Did they have to be followed?

Lady Thatcher: Of course they have to be followed, but they are not strict law. That is why they are guidelines and not law and, of course, they have to be applied according to the relevant circumstances.

Ms Baxendale QC: They are expected to be followed?

Lady Thatcher: Of course they have to be followed. They need to be followed for what they are, guidelines.'

I simply make the hopefully obvious point that legislation brings us certain regularity that guidelines do not, especially guidelines that are unenforceable. On the question of peer review, which has been raised a number of times before the committee, I question what might be able to be required in the course of the regulation of researchers who have pecuniary interests in companies associated with the new technology—as in other areas, in relation to matters of members of parliament in the disclosure of interests or in company directors.

As a third point, in relation to cloning as a means of remedying or rectifying difficulties of childless couples, in the same way that IVF does not solve problems in relation to infertility—it only solves problems of childlessness—so too cloning, if that is ever promoted in this regard, only solves problems of childlessness. It does not necessarily deal with the underlying problems of infertility.

May I conclude with yet another comment, but from the other side of the Atlantic. This is a comment in a paper presented by two brothers, one of whom is the Chief Judge of the US Court of Appeals in the 7th circuit and whose brother is a professor of law at the University of Chicago, Richard and Eric Posner, in a collection entitled *Clones and Clones*. I can give the formal details to the committee later. The particular thing that they direct their minds to is the demand for human cloning. Judge Posner and his brother Eric Posner conclude:

Our exploration of the likely demand for human cloning has been strictly that—exploratory. The demand is impossible to estimate; it depends on too many variables of uncertain strength. But the analysis does provide a rational basis for the widespread disquiet that the prospect of human cloning has aroused. Some of that disquiet has religious or emotional foundations that our analysis does not touch; some of it reflects an unreasoning fear of change. But consider: The most sympathetic demanders for human cloning, the infertile, may, over time, if allowed to clone, drive out sexual reproduction. These least sympathetic demanders, extreme narcissists and other psychotics and misfits, will be among the most enthusiastic for cloning, and their cloning too will feed on itself to the extent that the disorder that makes them unmarriageable is hereditary.

It is a rather extreme statement, but I simply bring it to the committee's attention in this collection of papers which seeks to canvass a range of issues which is obviously before it. Thank you.

Dr LOBLAY—I will begin by outlining the role of the committee that I chair—that is the Central Sydney Area Health Service Ethics Review Committee at Royal Prince Alfred Hospital. Our committee is responsible for the ethical oversight of two reproductive medicine units, one of which is in the public sector and one of which is in the private sector, so I believe we are able to take a fairly broad view of activities in this area. I would also like to say that the views I am going to express are not my personal views about the ethical issues. I simply want to discuss the way in which an ethics committee exercises its oversight in these areas.

As I am sure you all know, the ethics committee system in this country has evolved over more than 20 years. I believe it has evolved into a very good system. That does not mean there are not areas where we can do better and can improve. But I think it is a system which potentially could provide the kind of ethical oversight which many people would see as desirable in this area.

Ethics committees are constituted under NHMRC guidelines to reflect a wide variety of community views. I think it needs to be recognised, certainly those on committees do recognise, that we live in a pluralist society, which means that there are many issues on which there are differing perspectives and opinions, and some of the issues where there are such differences are the ones that we are discussing today. Also, the way ethics committees operate is that the people who sit on them recognise such differences on committees and within the community, and exercise or attempt to pay due respect to the perspectives and views of other people. It is in that light that I would like to now continue by bringing up points that are in my submission.

In the area of cloning there are clearly issues on which we can achieve a broad consensus across the community and within the scientific community and within the ethics review system. That is reflected by the submissions that were made to this committee. I do not think there is any serious disagreement with the notion that reproductive cloning should not be permitted. I would feel comfortable and I am sure our committee and most other committees would feel comfortable if there were legislation prohibiting that.

But there are other areas which people have referred to as therapeutic cloning—I do not think this is good terminology but it is terminology that we have been using—where there are legitimate differences of opinion held by people who are well informed and who are people of goodwill across the community. I think that it is in those areas that it would be appropriate to have a regulatory system which is governed by bodies such as NHMRC through guidelines which would allow ethics review committees to form judgments about specific research proposals and specific clinical practices. In other words, I think the legislation should define the limits of what is acceptable or what is unacceptable to the general community and then, within those limits, I think we should encourage the ethics committee system to exercise its powers of regulation.

The next point arises from some comments that were made earlier this morning. I think our committee would be very grateful to have the advice of an expert committee such as the one that Professor Serjeantson was referring to, a national expert committee that could give us technical advice in relation to experimentation or practices in the therapeutic cloning field. Such expert advice is normally sought in many other areas that ethics committees review such as in clinical trials of drugs and devices and so forth, and ethics committees use that technical advice to inform their ethical judgments.

It is not just technical advice about scientific issues, but it is advice about scientific merit and validity, about safety, and so forth. Then it is up to each ethics committee to form judgments based on the considered opinions of its members and, in forming such opinions, generally members and committees attempt to balance potential harm against potential benefit. I think a compelling case can be made that the use of cellular cloning methodologies do have great potential benefits for the treatment of human disease, and that has already been referred to this morning.

The last point that I would like to touch on is: how can the existing regulatory system be improved? In my submission I have put forward some advantages and disadvantages of legislation versus guidelines. I do not want to elaborate on those now but I do want to refer to my comments relating to the accreditation process of reproductive medicine units. At the moment accreditation is carried out by RTAC, the Reproductive Technology Accreditation Committee, which is a national committee of the Fertility Society of Australia. As I have said in my submission, I think that it is inappropriate for a professional body to regulate itself and I think it would be sensible to look towards developing a new system of national accreditation for reproductive medicine units which was truly independent of the people who run reproductive medicine units.

Secondly, I think that the NHMRC guidelines produced by the Australian Health Ethics Committee could be strengthened. I think that there are particular areas where they need to be much more explicit, especially in terms of the relationship between the Institutional Ethics Committee and the reproductive medicine unit that it is regulating. I think there needs to be a more arms-length relationship than might exist in some cases and more independence of the ethics committee. And I think the guidelines should be altered to enable ethics committees to review all activities conducted within reproductive medicine units rather than just research and the grey area of innovative practice where there is a lot of scope for practitioners to define what they are doing in such a way that they would not need to submit that for ethical scrutiny. Finally, I think there should be a mechanism of being able to apply sanctions when there is noncompliance with guidelines.

CHAIR—May I remind everyone to keep their comments as concise as they can in the interests of getting through them all.

Ms MORRIS—The perspective I will be presenting from today is as a citizen but from an indigenous heritage and an involvement in indigenous issues and indigenous law. I am afraid that, from that experience, I am going to be quite sceptical in the way I look at all this. The two areas I will look at are: therapeutical cloning and human cloning—that is very different to my original submission; I am going to add these, if you do not mind, because I have had time to think more clearly about this—and, finally, Australian law and community responsibility in relation to all this. As I say, forgive my speaking in relation to this.

On therapeutical cloning—in other words, the sale of human spare parts—I would suggest that the development in genetics is the greatest feat of salesmanship ever seen on the planet. The consumer will willingly enslave themselves to the corporate giants. I do not blame corporate giants but, rather, the apathy of society in general, for even the servants of corporations will fall foul of the vanities of their own egos. That is, in fact, the greatest selling pitch: once you have set into a consumer's mind that they can improve on their basically weak self-image, the soul of the consumer is bought. Turning to human cloning, this is again, to me, the greatest economic tool that will ever be invented because in the future these clones will be the future workers. They will have no souls, no rights, no unions, no benefits, they will sleep where they are told and do want is wanted. This may seem futuristic, but that is what I thought this committee was about.

First and foremost, these issues involve everyone from the corporate head to the Arrernte desert law man. I do not think anyone can be picked out, like scientists, to be homed in on as

though responsible for this. This is a total community responsibility. Nobody is excluded from the effects or the outcomes of such inventions. Everybody is responsible for the outcomes because the corporate Pandora's box and the economic goldmine has already been opened. To bog oneself down with the technicalities relating to cloning and regulations of controls is, I would suggest, an illusion to have control over a phenomenon which is out of our hands. It is a global economic issue not a local one, the reason being that Western man—unfortunately, this is an indigenous perspective of this—has not learnt to curb his predisposition for enslaving and dominating other societies, as can be seen in the soft slavery of offshore industries in lesser developed countries. I will not mention the recent human rights issues in Australia.

The most devastating outcome of this issue, and the area on which I think policy and public should focus, is the recognition that the bottom line of this amounts to the undermining of the Western legal tradition once the populous begins to perceive that humans, and not God, create a human being. You must remember it is the public view, not the informed view, which will cause this sort of thing. Western law is based on a Judaeo-Christian belief in a God as the supreme authority which, in turn, is endorsed by the law. So once the general public perceives—and that is based usually on myth—that they are creators, I think you are going to have a lot of social unrest and your legal tradition will be undermined in various sorts of ways that you do not expect. Therefore—and this is only a very quick presentation—I would suggest you spend some time with indigenous law keepers, and I do not mean political people or people who are articulate in English but people who are actual law keepers, and that you consult with them because they have a world view of how to be a co-creator and non-enslavement but still appreciate the global trade that this particular issue involves.

My field as a research fellow in indigenous intellectual property rights has taken me into the area of protocols, ethics and guidelines and has shown from international research that, unless the leaders demonstrate themselves as role models, you might as well forget it. I think it is up to the highest political authority to set role models and be examples on this thing as with other leading judiciary and religious leaders of this country.

Mrs VANCE—I am here as a layman, together with Mrs Macaulay, to express the concerns of members of the Country Women's Association of New South Wales. Before I go on, may I state that the Country Women's Association of New South Wales is not against research. In fact, over the last few years they have been responsible for raising over a million dollars towards medical research. I just wanted to advise you of that.

We say there must be uniform legislation. All research establishments, whether privately or publicly funded, must be subject to the same strict legislation throughout Australia with no exceptions. We abhor and totally reject the cloning of human beings as morally and ethically unacceptable. A most eminent scientist, Professor Einstein, warned that we should be on our guard not to overestimate science and scientific methods when it is a question of human problems and we should not assume that experts are the only ones who have the right to express themselves on questions affecting the organisation of society.

Another eminent scientist, Professor Ian Wilmut, who directed the experimental cloning of Dolly the sheep, believes cloning human beings would be physically dangerous and socially

unacceptable. He appreciates the complexity and danger of genetic engineering and believes such activity should be regulated by law.

We recognise that regulation to allow research on therapeutic cloning should be carefully considered. This branch of research highlights many of the critical issues: how best to regulate a rapidly expanding field of science and how to balance ethical concerns with the promise of benefits to medicine. That we may be able to not only diagnose and predict the course of debilitating and life threatening conditions but also ameliorate and even cure many of them would be a great gift to humanity. We believe this research should be for true health considerations only and certainly not for extraneous reasons.

Science is moving faster than legislation and part of the problem is the nature of scientific research. It is very complex and beyond the understanding of many of those enforcing the legislation. We agree with Professor Chalmers's suggestion that the AHEC should report again in three years. The thoughts of our members are with you and your committee. We pray that God will grant you wisdom and courage in your deliberations on the need for legislation regarding cloning of human beings. We ask you to remember the true wealth of a nation lies in its learning, wisdom and the uprightness of its sons and daughters. We say we must have uniformity of legislation throughout Australia. We support medical research for therapeutic cloning and we totally reject cloning of human beings. Thank you for your attention and for the opportunity to contribute to this important debate.

Mr HOFFMAN—I make a preliminary observation. As happens whenever the term 'embryos' is mentioned, Orwellian doublespeak follows. Emotive adjectives and euphemistic phrases are used instead of straight hard words.

I draw your and the committee's attention to the quite short paper submitted by Rabbi Raymond Apple, the Rabbi of the Great Synagogue in Sydney. In brief, Rabbi Apple supports all four AHEC recommendations, and he makes one additional proposal, namely:

... the establishment of a national ethical research institute involving religious and other ethicists.

Speaking for the Executive Council of Australian Jewry, which is the representative organisation of Australian Jewry as a whole, ECAJ agrees with Rabbi Apple's paper. We have one minor qualification. In his opening sentence Rabbi Apple voices concern at 'the relentless advance of scientific development'. ECAJ does not share that concern. Instead, the council sees the benefits that would be gained through the replication of organs and tissues sourced from patients themselves when used in lifesaving replacement operations. Accordingly, the executive council supports the provision of public funds for basic research including biological research.

The executive council also notes that United States President Bill Clinton and British Prime Minister Tony Blair have taken a joint stand, declaring that the human genome belongs to mankind as a whole. In other words, no company, corporation or individual should be able to claim a patent over any particular gene, gene sequence, gamete or chromosome. The executive council puts to the committee that Australia should of its own volition join that stance, preferably on an all-party basis. Mr Chairman, with your permission I would like to add a couple of sentences speaking in a personal capacity.

As far as 'reproductive cloning' is concerned, on that score the genie is already out of the bottle. Any person of sufficient means could, or soon will be able to, find laboratories somewhere in the world willing discreetly to offer such a service. Laws are likely to make little difference. You might as well pass a law prohibiting the falling of apples as a protection against the force of gravity. Better not to have law that is based on fear or on what might happen. Instead, restrain the rush to law and rely upon the much more flexible NHMRC guidelines which, as one of my colleagues has just said, can and probably will be strengthened.

Mr CAMPBELL—I would like to thank the committee for this opportunity. I am going to limit my remarks to a couple of key issues which were mentioned in the committee's discussion paper under the ethical aspects. The first is this question of reproductive cloning and therapeutic cloning. We have already had comments, both in submissions and in the forum in Melbourne, to the point that this is an unhelpful distinction. I am thankful for Dr Tobin's statement—a member of AHEC—at the Melbourne forum which reiterated that AHEC rejected the idea that the distinction between reproductive cloning and therapeutic cloning should act as a kind of framework for a discussion of the ethics of cloning. I think the Australian Academy of Science failed to indicate that this is a point of disagreement between the two bodies. I am thankful for the academy's comments here this morning which, in a sense, seek to broaden or make clearer that some people use 'therapeutic cloning' in an even broader meaning to incorporate a whole lot of different forms of cloning. However, I suggest that that broadening of meaning makes it even more problematic as one of the key terms in this discussion, because it becomes so broad we are not sure what procedures we are actually talking about, and it is certain procedures that are at the heart of our discussion.

So I support AHEC's initial rejection of this terminology as a framework and would indicate once again, for the record, that the Universal Declaration on Human Genome and Human Rights which used the terminology 'reproductive cloning' did not use the terminology 'therapeutic cloning'. They did not use that distinction. Unfortunately, as I mentioned in my submission, it appears that in the second recommendation of AHEC and in its resolutions 1 and 2 they leave the door open for the cloning of human embryos. They refer to the application of current cloning techniques to human embryos on page 6 of their advice.

Then there is the ambiguity of section 11.3 of the NHMRC guidelines—which has already had some reference made to it today—which prohibits experimentation with the intent to produce two or more genetically identical individuals. Some would seek to argue that if you do not intend for the individual to develop to a mature adult, then you are not producing 'genetically identical individuals'. There seems to be a blindness here to the existence of individuals during all stages of development. One way of resolving the ambiguity is to resolve the question of the status of the embryo. It would be a very brave committee that takes that on, but I suggest that if we are to talk plainly, as has been mentioned here today, this is something we need to do.

The discussion paper I referred to mentions as an issue for discussion the stage at which the human embryo 'assumes full human status'. With all due respect, this is a rather unfortunate way of wording the issue and, in effect, begs the question. It implies that at some time you can have a living human being which is not fully human or is not to be accorded the status of a human being. The fact is that all of us are continually developing, for better or for worse, from the day we are conceived to the day we die. I would like to think that in many areas of my life I

have not yet reached my full potential, and yet, sadly, in some areas of my life, my potential is diminishing. Am I fully human? A human embryo is a human being with potential. If we start to attribute human status according to some degree in which a person exercises their potential, then we have removed the equal protection that each of us expects to receive under the laws of our land.

My final comment is in regard to the role of IECs as they have been raised here in discussion again today and my disquiet regarding IEC as being a method of supervision or regulation monitoring in this area. My understanding is that IECs apply or have some force where public funding is involved. If we take the IEC model it seems to me we are just turning a blind eye to the whole area of private research and private funding. Then there are the internal difficulties of IECs, which have also been mentioned, as to how they are constituted. In this area we need to be seen in a way, as a public accountability, which rules out possible conflicts of interest, et cetera, so how IECs are constituted becomes a very real question. Thank you.

Dr SWANTON—Thank you for the opportunity to be here today. I should state that, although I work in a federal government department, my comments in my submission and at this inquiry are mine in my private capacity. I will provide a brief overview of why the Australian Health Ethics Committee's—AHEC's—ethical analysis is biased and seriously flawed. First, AHEC announced in a press release before their study commenced that they had already determined that human cloning is unethical. Given that their study was premised on human cloning being unethical, it is not a surprise that they concluded just that.

Second, an ethical view requires that we take the view of an impartial, objective observer. Unfortunately, AHEC, and many submissions to this inquiry, have argued selectively and subjectively against human cloning, often, I suspect, masking religious views or visceral yuck reactions to the technology. For example, some arguments suggest that a cloned child is a means to an end or that human cloning is unnatural. These arguments can be applied with equal force against other assisted reproductive technologies such as IVF, but they are not. Such selective argumentation is genetic discrimination and is just as unethical and abhorrent as sexism and racism. If other tortuous arguments against human reproductive cloning, such as those referring to some lack of interconnectedness of the clone with its parents, are accepted, then adoption would also be prohibited.

Third, out of all the submissions and evidence at this inquiry, I have not seen an analysis of AHEC's recommendation 1. This is based on a UNESCO declaration prohibiting human reproductive cloning. This declaration suggests cloning calls into question the uniqueness of every human being. Clearly, since identical twins are more identical and thus less unique than human clones, this selectively applied argument could also be applied with equal force to prohibit identical twins. If the intention is not to prohibit identical twins, then arguments such as UNESCO's and, hence, AHEC's are clearly wrong.

Fourth, one can concoct ridiculous situations if the AHEC recommendations against human reproductive cloning are accepted. It is possible, though extremely improbable, that a clone could be produced by IVF or sexual intercourse. It is also possible that a clone could emigrate to Australia. But the AHEC report contends that these people would be unethical. Human clones are people who should be treated as equal to everybody else.

Fifth, with regard to therapeutic cloning, there are no valid reasons why this should not occur. There are substantial benefits to be had for humans. Arguments against it are genetic discrimination, or also arguments against abortion, which is routinely carried out on foetuses up to some months old and is considered ethically acceptable by those who do not have a religious disposition against it. Arguments against human cloning seem to me to be an attempt to justify the unjustifiable, unless, of course, one considers genetic discrimination acceptable. I do not, and neither should this inquiry. It is important that people should be treated according to who they are, not according to how they were produced.

Mr CAIN—I am representing the National Caucus of Disability Consumer Organisations. I have a few brief comments to add to our written submission that is already published in the document circulating today. The first comment I would like to make is that this issue is extremely difficult and an emotional one for people with disabilities because often people with disabilities are the ones being 'done to'. They are one of the major reasons why we talk about even beginning to spend money, resources, time, effort and medical expertise in developing applications. So for people with disabilities—and the National Caucus is such a broad representation—there would be quite a diverse range of views on how to move forward or how to even react to the notion of the application of such developments. The mixture would be a combination of reactions ranging from, 'Yes. Can we have it tomorrow,' to 'No. The history of medical intervention is that there is more harm done than good.' In addition to that, it raises all sorts of questions about the actual nature of the human for people with disabilities who have spent the last century arguing for their inherent dignity as members of the human family. This again raises all sorts of emotional issues for their actual identity.

Further, as also mentioned in our submission, people with disabilities really do not have enough information at this stage to come to any concrete or firm opinion about these issues. Someone mentioned earlier that to have an informed debate we have to be informed. As a step forward—and I think the caucus is suggesting that we do have to make steps forward, but very carefully, and provide time for people with disabilities to actually get across these issues and become informed—we need very simple explanations for the community to understand these issues. I, myself, find it extremely difficult following the scientific arguments and the scientific explanations. That is not unexpected because of the expertise and the discrete discipline that such expertise brings, but I think we need very simple explanations of some of these issues so that the public debate can actually happen.

Another point I would like to make is the distinction between 'therapeutic cloning' and 'human cloning'. The whole word 'therapy' frightens people with disabilities because they have, again, been the people being 'done to' by therapies. In our sector, we have wonderful phrases like 'therapy craziness' and 'therapy crazes'. People with disabilities are very familiar with hundreds and thousands of so-called therapies that offer all sorts of hopes, but just end up to be a passing fad. In a lot of respects, this whole issue of therapeutic cloning requires an in-depth analysis and discussion of how that would work and what we mean by it. At this stage, it seems like it has been a distinction that has been developed to try to justify ongoing research, as distinct from simple human cloning.

A broader response to this is that people with disabilities are a little bit confused as to why we are often seduced into high cost technologies, as opposed to low cost technologies. People with

disabilities are still a large percentage of the homeless. There are large numbers of people with disabilities that still cannot get home based support or cannot get appropriate housing, cannot get into schools and cannot get the proper employment assistance that they require. As an example of that, the Australian Institute of Health and Welfare released a report three years ago of 13½ thousand people in urgent need of accommodation which would cost a mere $300 million, yet the responses of Australian governments have not been adequate or they have not responded to such recommendations.

We are talking about the application of medical research or therapeutic cloning improving the quality of life of people with disabilities, but there is much we can do right now. We do not need to do the research. It is a matter of commitment. For us it is a balance: do we support such developments that are high cost and very technical when we cannot proceed with very low cost technologies that we know work? Lastly, I want to emphasise the fact that people with disabilities need some structure to begin to learn about these issues and to begin to discuss them.

CHAIR—Before we continue, would any members of the public like to put a scientific question to any one of the scientists or to the panel generally?

Ms POLKORN—My name is Lydia Polkorn. I live in Sydney. I was always interested in these subjects. Who should I ask actually?

CHAIR—If this is a question on science, you can ask any one of the scientists, or you can ask a general question and they can choose if they wish to answer.

Ms POLKORN—To all of them, then: you started splitting embryos—human embryos—as far as I can see from the books. What about the soul? Have you started splitting our souls as well? Do you know if clones have souls or not? Maybe they do not have souls at all. Maybe the UN army is full of clones with no souls and doing all those atrocities because they do not have them. The splitting of the souls is also science. Maybe it is beyond you, but it is already done by aliens, and I have seen it.

CHAIR—Thank you very much. I am not sure that was a scientific question, but I am not precluding anybody from answering it if they wish to do so.

Dr McCULLAGH—I cannot answer your question exactly but it bears on something which has been mentioned earlier. I think it has been suggested that, for people who are opposed to reproductive cloning, the opprobrium attached to that procedure has been transferred, I think vicariously, to the people created that way. I do not believe at all in reproductive cloning. However, if someone is produced by reproductive cloning I am sure they have whatever we have, whether it is a soul or whatever else. I think it is very important to draw the distinction between the procedures that are applied and the outcome of the individual. This came up in a few of the statements earlier on—that the opprobrium from doing human cloning meant that the individual produced in this way would not be a card-carrying human the same as the rest of us. I would like to dissociate myself entirely from that view.

Prof. NORMAN—I would like to point out that embryo splitting would not occur and has not occurred in a scientific fashion anywhere in Australia in terms of putting back those em-

bryos. Nor do I believe it has occurred elsewhere in the world. We should not allow the general public to get the view that cutting up embryos is something that happens for producing twins.

Dr MAYO—There is some evidence that some of the drugs used in reproductive medicine can increase the frequency of twinning, but of course those twins are just like twins who occur naturally. They have a soul or whatever it is that we all have.

Mr WHITTEN—My name is Wesley Kingston Whitten. I am a visitor at ANU but I want to speak on a personal basis. Years ago, Tarkowski split embryos up so that they would not develop as full embryos but as blastogenic vesicles—in other words, a structure without an inner cell mass. That seems to me to be the ideal place to test whether an embryonic stem cell could form an embryo, if it were placed into that blastodermic vesicle. Has anybody looked at that possibility? I think we would need to do the preliminary work in primates. I am not suggesting that it should be done but I think it is something that we should consider.

The other aspect I wanted to know about was whether anybody has considered the possibility of doing therapeutic cloning from an artificially activated egg. We know that eggs are considered disposable. We take the nucleus out and replace it with a mammary cell nucleus, as in the case of Dolly. But many people have activated eggs to such an extent that they can produce tissues or tumours with many sorts of tissue. This has been done by Roy Stevens—he activated an egg by alcohol. It can be done with electric currents. A lot of work has been done on the activating process. So one can develop a set of disorganised tissues from an activated egg without a sperm. That is one possibility for developing tissues from which you can do therapeutic cloning without destroying an embryo but destroying the female contribution of an embryo. Would anybody like to comment on those two observations?

Prof. RATHJEN—The experiment of ablating the inner cell mass in a blastocyst and replacing it with embryonic stem cells has been tried and has not been successful; they have not been able to show that ES cells alone in that environment give rise to an animal. That was in the mouse. I think that is the only species in which it could have been possible to date.

Secondly, your idea of using an activated egg, I suspect, long term, is not the future for these kinds of things because, if I understand it correctly, that would not produce autologous or syngeneic cells for transplantation. It would produce cells that would be subject to immune rejection following transplantation.

Mrs MONGAN—I am a private citizen. I want to address the panel, particularly Professor Peter Rathjen, and ask whether it can be conclusively said that, under any circumstances, a stem cell cannot generate into an embryo. At some stage in our knowledge we would have said that cloning would have been impossible. Can we conclusively state that it is impossible for a stem cell to regenerate into a complete embryo?

Prof. RATHJEN—This comes back to a point which I raised earlier, and which is important in the context of legislation, and it is the nature of how science works. Science does not deal in absolutes of the manner that you are suggesting. Science works on precedent, it works on experimental results and it works on the best assessment you can make with what is known. With all those provisos, to my best knowledge that is not something which would happen. But I could

not say, nor should any scientist say: there is no possibility that it can ever happen. That is not a statement that a responsible scientist would make, unless there had been an experiment done that showed that conclusively.

CHAIR—Are there further questions from members of the public about scientific issues?

Prof. THOMSON—I have a general question about the state of scientific knowledge of the promised benefits of what has been here called therapeutic cloning. There is some discussion of that in the AHEC report and I would be interested to know whether the possibilities that are sketched there are any more scientifically certain than is indicated. There seems quite some doubt that all of those promises could be fulfilled.

Dr McCULLAGH—There has been a succession of attempts, I guess, since the early 1980s particularly in relation to transplantation to overcome the shortages. Once transplantation became a successful procedure there was a great imbalance between supply and demand. There has been a succession of approaches tried ranging from taking tissues from foetuses, particularly thymus tissue for immune incompetence, brain tissue for Parkinson's and islet tissue for diabetes, none of which has taken off, and more recently xenotransplantation has been pushed. The difference between xenotransplantation and transplantation from the foetal tissues is that commercial interests have in a very big way taken over xenotransplantation—I guess they are taking over everything now.

Cloning from embryonic stem cell lines, I think, has really been discussed seriously only since the publication in 1998 of Thomson et al, and taking tissue specific stem cells has really come into the literature only since 1999. I guess the benefits of all of these are conjectural. Certainly, there is some experience in the foetal tissue transplantation, particularly in relation to diabetes, and probably also in relation to Parkinsonism, that the actual disease which occasioned the need for transplantation effectively zapped the transplant.

It has also been very clear that immune rejection remains a problem despite people talking as they have for decades about it just being around the corner that it will be solved. My belief, as someone who is reasonably close to the action, is that it is still a long way off. There have been considerable improvements in remedial ways of cutting down on rejection but the problem has not been solved at all. Sorry, it is a very vague sort of answer. There has been a succession of proposals made, and none of them have established themselves. I always tend to regard this as a pretty good test if something has been suggested and published, and 10 years later it has not taken off. It is probably not going to take off, so I guess it is far too early to tell.

Xenotransplantation is a little bit ahead of the others but, again, most people are aware of the big risks there—retroviruses, prions and other things which might be transmitted with the graft. These are a very big hindrance. It is notable now, however, that with commercial support it is going ahead like a rocket in the United States irrespective. So we may finish up all running around saying oink. Sorry, it is not a very complete answer.

Prof. RATHJEN—The issue that really there have been only two years of detailed research in this area is correct and so you cannot expect too much of the technologies. We know that there are defects in what we know how to do and what we might use things for. There are no

diseases cured in humans yet, nor would that have been possible in the time frame. Nor am I aware of anyone who is doing experiments of that nature. But there was a report in *Nature Medicine* last year which showed that you could take embryonic stem cells and, using neural derivatives of those cells, alleviate spinal cord injuries in rodents. That was, to my knowledge, the first indication of therapeutic correction of a disease in an animal model.

It has also now been shown quite clearly that you can get neural cells to regenerate parts of the brain. And the corollary to that—the experiment that is being done at the moment but which I have not heard the result of—is that if you can do that in the brain of a mouse, for example, or a rat that has induced Parkinson's, can you start to alleviate those sorts of symptoms? I suspect over the next one to two to three years we are going to see an awful lot of experiments which will show whether we are going to get useful outcomes at least in rodent disease models.

Prof. SERJEANTSON—It is true that stem cells are constantly renewing certain parts of the human body even in adults. Stem cells are already replenishing blood, mending the lining of the gut, renewing skin cells, and so on. For that reason, it is the hope of new cures for debilitating diseases that is stimulating the excitement in this area of research. So although scientists are not conceiving growing organs in test tubes—though with the exception of skin, which is an organ—there is an excitement about the growing of tissue in the test tube that might eventually be used in some debilitating diseases such as Parkinson's disease, or stroke, or spinal injury.

Professor Rathjen referred to animal models where there has been some success in transferring cells derived from embryonic stem cells into the rat or mouse model, and curing models, as far as we can see, that equate with either Parkinson's disease or else in spinal cord injury. Some of the submissions suggest that this is science fiction. We, in the scientific community, believe that this is an urgent area for future research.

Mr CASSIDY—I believe that fundamentally we are dealing with manipulation, intended or not, of the human gene pool. We have seen, for commercial gain, Third World countries provided with high yield crop seed that has been genetically modified to be sterile. Professor Norman told us that 40 per cent of couples in IVF programs have to use injected fertilisation because their sperm count is too low to fertilise even in the test tube. If we source our embryonic stem cells from IVF programs, as was suggested by a number of the witnesses, are we at risk of manipulating the human gene pool, inadvertently or deliberately, to result in sterilisation of the human species?

Secondly, Professor Rathjen spoke of three methods of sourcing embryonic stem cells. He said that two involved destruction of the embryo and one was non-destructive. Is it possible that we could restrict the sourcing of embryonic stem cells to a non-destructive method or methods without prejudicing research?

Prof. RATHJEN—I would like to clarify the comment about the three methodologies. All three of those methodologies—none of which has yet been proven—work in the absence of embryo destruction. Two of them would work in the absence of embryos at all; the other one would use embryos but would not destroy them. So all of them were required for that.

There is an important point that you are raising here. When you talk about the gene pool, there is something that people need to be aware of. The sorts of therapies that are being talked about here should not, to my knowledge, impact on the human gene pool because the cells that are transplanted into a patient would not go on to give rise to or contribute to the offspring of that patient. If I transplant into you brain cells which help alleviate your Parkinson's disease, it will not make any difference to your offspring. So it will not make any difference to the human gene pool directly in that kind of way. The other thing worth mentioning is that a lot of the diseases that might be treatable by these sorts of technologies are degenerative type diseases which are often more prevalent in older people. Again, treatment of disease in older people will not affect the human gene pool directly.

Dr MAYO—Many advances in medicine allow people with defective genes—viewed from a certain perspective as being defective, that is—to reproduce. It is entirely possible—I do not say it is a fact—that some of the 700,000 people produced by reproductive technology, as well as their parents, may have genetic defects that led to their sterility. But we are talking about a very small number of very privileged people. They may not think they are privileged in having to seek this advice because they are infertile, but they are privileged in the sense of living in countries where there are resources for this purpose. There are 6,000 million people in the world. I do not think medicine has had much effect on the human gene pool yet.

Prof. NORMAN—I would like to address the issue of whether embryos derived from IVF are genetically abnormal, because that is an important question that has been asked. It really relates back to the nature of infertility, and couples who come for treatment usually deem themselves to be infertile. Our understanding of the causes of infertility, between genetic and environmental, are very imprecise at the moment and it would generally be conceded that the minority of causes of infertility are due to genetic conditions. As each day goes on we understand more and more about it, but there is no doubt that the majority of embryos created by in vitro fertilisation would be genetically normal—whatever genetically normal means, and all of us have variations—and it would certainly be possible for people to choose embryos that come from environmental conditions of infertility such as blocked tubes, or whatever. So it is important to emphasise that the majority of IVF derived embryos are as genetically normal as people conceived naturally.

CHAIR—Thank you. There will be an opportunity later in the afternoon, following the general panel discussion, for questions from members of the public on ethical and regulatory aspects of the issue.

Proceedings suspended from 12.36 p.m. to 1.41 p.m.

CHAIR—Ladies and gentlemen we will continue with the hearings. I apologise for the delay in recommencing.

Mrs UHLMANN—On behalf of the bioethics working party of the Catholic Women's League Australia, I present the following points from the submission written by Joyce Balnaves, my esteemed colleague who died of cancer on 14 February and had a great passion for life. After reading the document from the Australian Health Ethics Committee of the National Health and Medical Research Council on scientific, ethical and regulatory considerations relevant to cloning human beings, Joyce noted:

... that the aspects of human cloning presented in the document are contrary to human dignity and should be universally banned.

We believe that each state in Australia and the federal government must have common legislation to this end. In recognising that HEC has considered two issues, the direct cloning of human beings or reproductive cloning, and the cloning of human parts or therapeutic cloning, this submission presents arguments against both except in limited use in the latter when human embryos are not used and disposed of in any form whatsoever but when a use such as is already done in skin grafting can be achieved.

The AHEC notes the Universal Declaration on the Human Genome and Human Rights, which was written in order to protect the inherent dignity of all human beings no matter what their status, disability or genetic characteristics. It states that practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organisations are invited to cooperate in identifying such practices and in taking, at national and international level, the measures necessary to ensure that the principles set out in this declaration are respected.

Whilst affirming this article, the AHEC document separates the cloning of human body parts from that of whole human cloning. This is regrettable as it leaves open the use of cloning techniques which, on the one hand, have a compassionate application in providing the possibility of the provision of organs for transplant but which, in turn, could lead to human cloning. The possibility of human cloning came closer with the arrival of Dolly. Although hailed as a success, the cloning of Dolly was fraught with many dead and disabled embryos. There are still many unknowns, and Dolly was not a complete replica. She is ageing more rapidly than her mother and had one black foot which her mother did not. The document *Reflection on cloning* from the Pontifical Academy for Life 1997 notes:

... should the extension of cloning to the human species be desired, this duplication of body structure does not necessarily imply a perfectly identical person, understood in his ontological and psychological reality. The spiritual soul, which is the essential constituent of every subject belonging to the human species and is created directly by God, cannot be generated by the parents, produced by artificial fertilization or cloned. Furthermore, psychological development, culture and environment always lead to different personalities: this is a well-known fact even among twins, whose resemblance does not mean identity. The popular image or aura of omnipotence that accompanies cloning should at least be put into perspective.

Whether one believes in God or not, the statement on the inability to produce exact replicas needs to be emphasised as there is a popular notion that this is the case. It also appears to give a possibility of 'compassionate' reproduction in cases where there is a sadness or tragedy—a compassion which Pope John Paul II called 'vague and shallow', giving false hope. The difference should be pointed out between the conception of life as a gift of love and the view of the human being as an industrial product. The latter we find unacceptable.

Human cloning belongs to the eugenics project and is thus subject to all the ethical and judicial observations that have amply condemned it. The Human Genome Project, as in genetic engineering and gene manipulation as well as cloning, has this shadow of eugenics as its basis. The consequences of all that the Human Genome Project research offers can be to the real benefit of society or its detriment. Benefit largely depends on the attitude of society and, of course, of government. Presently, society is being bombarded with the idea of creating a fit society as the be-all and end-all of what it is to be truly human, thus the concept of cloning.

It is noted that at a conference in March 1999 in Brisbane of the Ethics Committee of the Human Genome Project, which was attended by more than 400 scientists from around the world, a statement on cloning issued by the participants agreed there should be no attempt to produce a genetic copy of a human being by somatic cell nuclear transfer, citing profound unease, the effects on a clone living in the shadow of its genetic template, and other issues relating to identity and more particularly totally unknown consequences. It did support research into cloning techniques to investigate a wide variety of scientific questions, including technology to produce specific cells and tissues, for example, skin, nerve and muscle. This latter can be done, as indicated previously, without resource to the use and subsequent disposal of living embryos. However, the statement added that in cases in which research offering indisputable and widespread benefit to humanity required the creation of embryos without any opportunity for development in utero, such research might be considered. We cannot support this proposal. This is the slippery slope where, on the one hand, there is concern and, on the other, support for therapeutic cloning.

Since embryos are aborted in their millions around the world and since in vitro fertilisation permits experimentation on embryos at different stages of development, depending on the law in states and countries, it is not difficult to imagine the slide to the next stage of cloning which could give people spare parts, all in the interests of benefits to humanity. The use of embryonic stem cells for reproductive or therapeutic use leads us to the question of the scientific and moral reality of embryos being used and discarded. Would one be cloning oneself for the use of the clone's organs or tissues? What exactly would 'therapeutic use' be? In many instances we have crossed the threshold of what is permissible to do in relation to human life. We allow partial birth abortion. We keep embryos on ice until a woman is prepared to consider it is time to have a child. There is already a demand for the screening of embryos for genetic disease.

It is in the imaginable future that all moral considerations will be put aside and cloning of human beings will be allowed in the so-called best interests of humanity. Apart from what has already been mentioned, we must discard the self-interested attitude which has been engendered that if something is possible to be done it should be done. We are leading to a society in which those who do not conform to genetic imperative or fitness will be disadvantaged in medical terms. We also face the loss of justice, autonomy, identity, privacy and confidentiality in ethical terms or medical terms. In addition, the legal ramifications do not bear thinking of.

In conclusion, there are many ways in which medical research and technology can benefit humanity. Cloning is not one of them. We must concentrate our human and financial resources on medical procedures which are beneficial to society and not morally and ethically suspect. The answers which are sought by those who want cloning can be achieved in medical research without the cost of a single human life and without sacrificing the dignity of the human person from birth to natural death. Tom Wilkie, in his book *Perilous Knowledge* says:

> This then may be the final challenge posed by the human genenome project, to redefine our sense of our own moral worth and to find a way of asserting in the face of all the technical details of the genetics that human life is greater than the DNA from which it sprang, that human beings retain a moral value which is irreducible and which transcends the sequence of the three million base pairs within the human genome. The same thinking applies to cloning. A human being has a moral value which is irreducible. A clone cannot have this sum of all that makes a human being.

Prof. PETTIT—I am here in a private capacity, but I should mention that I was a non-scientist member of the Academy of Science committee that issued the report which you have and I have been a past member of the Australian Health Ethics Committee.

By way of opening, what I would like very much to urge on people generally—and the committee I know will be receptive to the thought—is that as we debate about, as you debate about, and as parliament eventually debates about what to do on this issue it is really important to understand that we are plural society and to keep that in mind. There are many different religious and metaphysical views and we all understand perfectly well why people with such views should take particular attitudes on this issue. But there must be honesty about differences.

I do not share and nor does everybody here share, for example, the religious views—and I respect them fully—held by the last speaker. When we come to the matter of what does ethical consideration require of us in regard to allowing something of this kind, then we have got to realise that ethics does not belong to those of any particular group with any particular set of metaphysical views. The ethics that should guide our deliberations is an ecumenical ethics—an ethics that is pluralist, that recognises that it involves the sorts of principles to which any good-willed, clear-headed people can come to understand and be moved by. That is the ethic that must determine how this committee recommends and how I think people in general should decide about what we are going to do with the new cloning technologies. I would appeal to those with particular metaphysical views to recognise that the rest of us with different views are also ethically serious. We are also deeply concerned about human life, about safety, about respect and also about respect for the religious views of those people in our community. But we have to openly, in acknowledging those differences, come to a view as to how we should proceed here.

The spirit in which I would like to see the issue approached is well struck in the AHEC guidelines on artificial reproductive technology, in particular section 6 on research and embryos, which begins by acknowledging that there are differences of opinion amongst Australians regarding the moral status of the human embryo, particularly in its early stages of development. We have to put that up front. We have to be absolutely honest, not try to sneak in views and presume, as it were, that there is a consensus that is not there.

There are three principles I would particularly recommend that we keep in mind in this debate. I am boiling them down to three because of the shortness of time at our disposal. Our first principle is that we should not divide among ourselves prematurely and unnecessarily. We should look for a common framework of concepts that will enable us to think in common from our different perspectives, religious and otherwise, about these issues.

Let me give an example of that. One background issue on which we need not divide, but on which we are already dividing, is the issue about the distinction between different types of cloning. I understand that, the Academy of Science document and indeed a lot of documents in this area are now distinguishing between reproductive and therapeutic cloning. I fully understand the point of view that says this is a bad way of describing the distinction because, as some of the documents and submissions we have seen say, it is intended in some way to cover up the commonalities between the two.

I would be happy to drop the word 'therapeutic', but what we all have to recognise is that there are different things here. Firstly, there is cloning at the individual level where you are cloning with a view to the purpose of reproducing an individual: a foetus, a child, an adult. Then there is other cell level cloning or reproduction, where that is not part of the enterprise. Some people will say, 'Oh yes, but you have to do the second in order to do the first,' but that does not make them the same thing. Lighting a match is something quite different from setting fire to a house. The first is perfectly innocent; the second is a crime. Similarly, cell level cloning is quite different from individual level cloning, and to say that, just because it is involved in individual level, it should be tarred with the same brush is simply misrepresenting how things are. We can agree on this distinction, however we describe it. Let us describe it as cell level cloning and individual level cloning. My first suggestion would be that we try to set up a framework of concepts on which we can agree, rather than having one side saying, 'There's a big difference' and the other saying, 'No, there is no difference at all.'

The second principle I would suggest is that we do not lump things together. There are many different issues, and in my submission I have tried to indicate some of the distinctions involved. To look at lumping them together under the name of cloning and then going for a ban, or for any common line can only be cynical. It certainly is very shallow as a response to a moral complexity. For example, take allowing the de-differentiation of an adult's somatic cell. For the purpose of treating a given illness, we remove a cell from the lining of a person's mouth—it is a simple swab procedure. We then take the nucleus of that cell and, with whatever technology has come to be available, we de-differentiate it to pluripotency—to the stage where that cell can do not just the lining of the mouth job but any of a number of jobs and perhaps can be cultured to create cells that can then be used in the treatment of that individual. Whatever we do, we surely do not want to ban that sort of activity, and yet it is part of the many complex and different issues involved under this 'cloning' heading.

Take another example: suppose there are embryos which are excess to requirements in ART—artificial reproductive technology—processes. These embryos will be allowed to degrade in time. Suppose we have a technology, as certainly looks possible, for isolating embryonic stem cells from those embryos without destroying the embryo. I cannot really see who could have an objection to that. The embryonic stem cell is certainly capable of generating an embryo if it is treated in exactly the way a somatic cell is treated—that is to say, with nuclear transfer; that is, if it is implanted in an enucleated egg and placed in a womb. But that is true of the cell on the inside of my mouth. The ES cell itself, the embryonic stem cell, is just a cell. If you can isolate a cell from an embryo without doing harm to that embryo, and that embryo is going to be allowed to degrade anyhow, what on earth would stop you doing it? There are many different issues like this. Whatever happens we have to separate them out and to think about each one separately as an ethical issue and as an issue of regulation. It is a great mistake, and in a plural society it is a disaster, to try to lump them together and to treat them as of a kind.

My first principle was: do not divide prematurely; let us look for a set of concepts on which we can all agree. The second was: do not lump things together; let us try to be sophisticated and tease them apart a little bit because there are very different moral issues involved. The third principle is: do not rush to premature resolution. Do not rush to a particular piece of legislation that will once and for all settle it, because if we have learnt anything in the history of human legislation, it is that if you legislate prematurely—without qualification and without openness to

regulatory authorities—then you will not cater for the complexity of the cases. You will end up banning what you do not want to ban and almost certainly allowing what you may not want to allow. You need a structure of regulation that is capable of responding to the complexity of cases and to the ever changing complexity of cases in a period of rapid technological development.

For example, it is quite possible under some of the proposals that I have heard that legislation would go through which would ban the following possibility, which surely no-one in this room would have any problems with. Imagine a woman taking a drug that facilitates twinning. We know that some drugs are probably having this side effect anyhow. Imagine that a woman in the early stages of pregnancy deliberately wanted to take a drug in order to have twins. I take it that no-one would have an objection to that, yet a lot of the proposals would ban that, for example. If you go to a blunderbuss that tries to knock everything out, you will knock out things you do not want to knock out and you will not knock out things that you do want to knock out. So my three principles at this stage of debate would be: do not divide prematurely among ourselves—we represent many perspectives and we can still find a common framework of concepts; let us not lump things together as if they all have to be treated as one; and let us not rush to a premature resolution whereby we get legislation of the sort of prohibitionist mentality. Let us not be panicked into that as if, so to speak, around the corner lies *The Boys from Brazil* or some terrible scenario. The story of the slippery slope is a story of panic and fear. We surely are mature enough as a society and as a legislature to be able to draw the distinctions required. You can set down those distinctions quite clearly and you can have regulatory authorities that would be able to police them.

I end with one rather general remark. We are not only a plural society, as I said at the beginning; we are also, I hope, a self-respecting society—a society that has got over the colonial cringe. I have heard it suggested, that we should ban cloning here, but it will be done elsewhere so we will get the benefits anyhow. That is the colonial cringe. That is not being a self-respecting society. That is not saying: let us support and trust, regulate our scientists. That is saying: block it here; if it is a goodie, it will come to us anyhow. If we are not prepared to allow certain forms of research then we should not be prepared to allow ourselves to benefit from those forms of research. We are at the forefront of the countries of the world. We are not a colony which can depend on things like this happening elsewhere.

Mr TUDEHOPE—Perhaps I ought to commence by commenting in relation to some of the matters which have just been raised. It is a coherent argument that Professor Pettit has put forward, really demanding that this is an ethical debate. However, the notion of ethics, as I have always grown up with is that it is a pursuit of right and wrong. And that is what we are here about. We are here to engage in a pursuit of those issues which relate to human cloning and to come up with a view about whether this is right or wrong for the Australian community. You as legislators and you as a parliament, at the end of the day, if that is the direction in which these hearings point you, would then form legislation and regulation which you had decided needed to be done for the benefit of the society in which we work.

The second thing that Professor Pettit addresses is that you ought to be able to disseminate all the issues so that we can come up with a common set of principles upon which we can agree and those upon which we cannot agree. He gave us the example that lighting a match is not nec-

essarily a problem because it is not a crime, and yet setting fire to a house is a crime. The reality is that you need to light a match to start the fire to the house and the reality of the argument that we are all facing here today is that you need an embryo to create a human being. That is why we are concerned about the whole of the issue relating to cloning. It starts with an embryo. It is the match by which we all exist.

Having dealt with those two issues, I ought to say something about where we come from as the Australian Family Association. I will pin my colours to the mast, as Mr Campbell has asked us to do. We say, quite unequivocally, that we stand for a set of principles which says that life begins at conception and ends with death. All our members would accept that as the primary guiding force by which we come to this body and by which we operate. It is patronising in the extreme to say that, because someone has a religious affiliation, their views are somewhat lesser to be taken into account because they have some metaphysical prejudice which they bring to bear on the argument. Quite frankly, that gets away from the real argument about whether what they are saying is given credibility because it is right. Those particular metaphysical considerations which a particular religion may bring to bear on the argument may be worth listening to, not because they are a religious point of view but because they are correct.

We urge these considerations on the committee in relation to family. I do not profess to be an ethicist or a moral theologian, but these are three issues which I think are worth taking into account. We say that the cloning of human beings is an attack on the integrity of family in favour of personal rights and individual autonomy. We say that a lot of the arguments which are put forward as supporting cloning are used by virtue of suggesting that there is some of disease to be cured or some other problem which can be solved for human beings. We say that the emphasis that ought to be adopted is where we look at family first.

We say that humans are created through a commitment to marriage and a commitment to one's spouse. Children are a fruit of that commitment. Family is about begetting children in an atmosphere of commitment, whereas cloning is about making children in a vacuum. The family, we say, is the prime social institution for the bearing and the nurturing of children. The responsibility we have to future generations is the manner in which we nurture and care for our children we have begotten. The cloning of humans risks transforming children into products of technological achievement, rather than gifts created in love. As products, children become objects, and objectification violates what it means to treat a child as a gift.

One aspect that was raised—and this is the third point I make—was that David Swanton seemed to suggest that interconnectedness is an issue which we ought not give any credibility to because if people are allowed to adopt children then clearly, if consistency is to be the rule by which we live, an adopted child does not have the same connectedness with its biological parents as a cloned child. Although I disagreed with everything that David Swanton said, I admired the fact that he required us to be consistent; that is something that we ought to do. But he ignores the fact that even adopted children have a yearning and a hankering to find their biological parents. The nature of cloning would be the first step in creating a race of human beings which does not necessarily connect to a mother and father. There is a Roman Catholic theologian who suggests that this sort of cloning violated the essential reality of human family and the nature of the socially related individual within it. She says that we all take part of our identity, both material or biological and social, from combined ancestral kinship networks.

Whether socially recognised or not, this kind of ancestry, we would say, is an important part of the human sense of self, as well as a foundation of important human relationships. Cloning humans to create children would constitute an unprecedented rupture in those biological dimensions of humanity which have been most important for social cooperation. We would say that family and social cooperation are things that are often ignored in the scientific debate.Further, we say that the cloning of humans would symbolically represent an enormous shift in our understanding of the relation of the generations. This would create an environment whereby our children would owe no responsibility to their ancestors or generations which begot them and upon which society is currently based. This symbolic shift would have incalculable risky effects that should not be unleashed. Mr Chairman and members of your committee, the Australian Family Association urges this committee not to go down the path of giving unfettered control and power to the whims of science which, in this case, are taking us in a direction which we would prefer not to go.

Mrs WOOLF—Mr Chairman, I am here to speak on behalf of the Australian Federation of Right to Life Associations, which is a loose grouping of pro-life organisations throughout Australia. As you probably know, we are identified in the community as being opposed to abortion and euthanasia, but our interests are rather wider than that in the defence of human dignity. We embrace members of all religions, and are not prone to give religious justification to our arguments, but all our member bodies in the federation share one basic philosophical premise: that each human life has a value, and it should be accorded a dignity according to that value. Furthermore, it has rights. Each human life has rights, the most fundamental of which being the right to stay alive.

The techniques used in cloning of either whole humans or of stem cells taken from a developing embryo present issues of great significance to our federation. We consider that cloning with the intention to reproduce a whole human surviving person is, in most circumstances, contrary to human dignity. Our views on this are in complete accord with those of article 11 of the Universal Declaration on the Human Genome and Human Rights. There appears to be a general community consensus about this, although it is not absolute. In practical terms, the technique, on present calculation, would involve great risks and many abortive attempts to produce such a cloned person, with the loss of many lives.

We are, however, also opposed to so-called therapeutic cloning. We think it is a misnomer in the first instance. It is the reproduction of material, probably gathered from embryos who are variously destroyed, disabled, reassembled and generated in some way—all the methods that we have heard here today—for the purposes of research. This research is not intended for the benefit of those organisms. Therefore it is not therapeutic, in the most radical meaning, but for the alleged greater good of society or members of the society.

We do not agree with the propositions put by the Australian Academy of Science that such creations—which is the only term I can find for them—or products should be precluded from legislative regulation, and that it is not overrestrictive to have legislation that would limit or preclude the way that they could be used in research activities. The whole idea that you can create an entity or hive one off or manipulate it—with the possibility that this entity might be able to develop as a human but that it should be devoted entirely to research for the good of others and not given any ethical significance in its own right—seems utterly contrary to the principles

of human dignity. Our submission sets out in some detail that we also consider it a breach of a number of international documents to which we are either signatories or in fact have ratified—UN declarations and conventions—and I would refer the committee to those, of course.

If there is any doubt that these creations have a potential for full development, then the benefit of the doubt should be accorded to them, and legal protection should be provided for them. It is extremely reckless to proceed as though they cannot have that capacity, and I do not think that the scientists should lead us down that road. The federation urges the Commonwealth to assist in the framing of uniform legislation in the states and territories to prohibit destructive experimentation, currently called therapeutic cloning, in addition to full cloning of an individual. Under its own powers, the Commonwealth should act to ban the import and export of embryonic material intended for such research.

I disagree absolutely with Professor Pettit in saying that we have to be consistent in that we should not benefit from things that other people do if we are not prepared to do them ourselves. I think one has to take the view that, whatever the rest of the world is doing, we should not do what we think is wrong. This argument has been used so often in respect of so many things that if you do not do it someone else will. I think it odd to have it turned back on us and have it said that if someone else is doing it you have to do it or it is somehow immoral. I think we are a self-regulating society and we can say we will not do certain things. I do not think that we should allow other considerations of what might happen down the track to influence us in that. After listening to people here, it is difficult to accept that there are not better ways to attain benefits to humans medically and pharmacologically and so forth than to virtually cannibalise ourselves.

The other ironic thing that seems to emerge from discussions of the law here today is that almost everybody is quite anxious or willing to have the parliament legislate to ban cloning of full individuals. Well, that is nice, but that is the least contentious thing. So we will invite the law into those matters which are not contentious, and those matters which are contentious and have far more capacity for perversion for commercial and other uses, that is, the production and development of ES stem cells and various other matters, we will leave to regulation by ethics committees.

Two previous committee members went into some detail about the use of institutional ethics committees. In fact, Dr Loblay, as he progressed in his discussion, more and more tried to bring sanctions even into the operation of committees. He is clearly not quite happy with how they are operating, with the variety of conclusions they reach about the efficacy or the ethicalness of what they decide. When you mention sanctions, they are sounding terribly like law, so we might as well go the whole hog and make laws. I think this is the role of the parliament. You can actually frame good law that would say that something should not be done. There are ethical imperatives in addition to scientific and technological ones and some things should not be done.

To judge what it is that a particular experimental protocol is proposing, I think it would need to have some sort of regulatory authority which would have lay and scientific members but their contribution is to match the application of the law to the facts or the facts as they best understand them that are involved in their particular experiment. If in fact they confess that they are not certain that it has not the capacity to develop in a full way, then they should say so and their protocol would not be acceptable. We will always be in their hands to tell us just what variety of

development is happening in the scientific world. But I do not think that stops the law asserting principles of matters that we will not accept. I think the 20th century, for those who think it has concluded, bore horrific witness to the ignoring of this principle that there are moral imperatives and there are things that you just should not do. I do not think that human dignity can possibly be protected if we treat any one of ourselves as some sort of means to other people's benefits.

Mr EDDINGTON—May I thank your committee for inviting me along this afternoon to this forum. Through your committee, we have a wonderful opportunity here to take this discussion out into our community, and I think we should take this opportunity with both hands. But there is a problem, and that problem is about communications. I still do not have a clear idea in my mind about the alternatives, the short-term risks, the long-term risks and the benefits. The technology needs to be demystified. Someone needs to tease these things out of the jargon-filled pages that I have seen. With simplicity comes clarity, and our society needs the clarity to make the choices.

I see this research in terms of a balancing beam. It has a weight that can be moved along the beam to show where the balance might lie. That balance is a choice between the benefits that the technology offers and the price I might pay to get those benefits. We can start by saying, 'Let's look at cell research. Is it unacceptable to me if the embryo is to be sacrificed? The answer is yes, it is. At what point would I accept that research? At the five- to six-day point, at the 14- to 18-day point or some other point?'

At the moment I will say no to both of those propositions and wait for the scientists to get to a stage where they can extract that information out without sacrificing the embryo. I will also say no to buying the information offshore. To buy is to support, and it makes no difference whether that is genetic material from Singapore or ivory from the elephants of Africa. But let us up the ante a little. What if we drag a couple of teenagers out of a wrecked car on the Hume Highway. Their bodies are broken and their limbs are useless. This technology may offer the opportunity to repair those limbs at some time in the future. Does that make me move the weight up the beam? What if we watch an elderly relative drift away with Alzheimer's disease or a friend being dragged to their grave by cancer? What does that do to the weight on the beam? Does it make change my view? The answer is that it probably does. It probably pushes me towards animal research. I do not like the choice. I am very fond of animals. But I may make the choice anyway.

The question is: where on that balancing beam does our society want to place the weight? I know some people will come back and say that is just the 'slippery slope' deal. But I have no patience with the slippery slope argument. It presumes that we have a choice about these things. It presumes that we have not started on the journey. Well, we have started on the journey. We are on the balancing beam right now. To demystify the technology, Mr Chairman, I am asking your committee to consider a public awareness campaign that sets the issues out clearly so that our society can decide where on that beam the weight should be placed. I am asking your committee to make this the start of the process, not the end. I am asking your committee to look at the requirements for legislation which have been canvassed, possibly based on the gene technology regulator model as a starting point. The public awareness campaign should be about cloning and related technology. It should deal with the lack of awareness there seems to be about the impact of ownership of the technology. It should deal with the lack of awareness

about the long-term impact of the technology. It is not the period of three to five to 10 years that the scientists are talking about. I am talking about the 25 to 50 years, something that only the social scientists, the philosophers, can tell us about. Mr Chairman, I look forward very much to reading your report.

Prof. SAVULESCU—Thank you for giving me the opportunity to provide one argument in favour of allowing the creation of embryonic stem cells and therapeutic cloning in Australia. I have a number of excellent overheads here but, in the interests of time, I will pass over them. Let me take you forward to one possible future in 30 years time. My three-year-old daughter is now 33 and she has leukaemia. She is bleeding from her mouth and vomiting litres of blood each day. She needs a bone marrow transplant if she is to be cured. She has no compatible donor. Scientists are working on and are very close to developing a drug which would cause one of her healthy skin cells to turn into a bone marrow cell and in fact be able to repopulate her bone marrow and cure her leukaemia. I would think it is not only morally permissible for scientists to engage in such research but actually morally required that they engage in research to develop such a drug. If such a drug was available, it would be negligent of doctors not to use it in treating my daughter. That is what is potentially on offer. The question is not whether therapeutic cloning should be allowed in Australia but why we are not doing it now and actually encouraging it.

I should say there are a number of reasons why we need therapeutic cloning. Firstly, as has already been alluded to, there is a serious shortage of organs and tissue for transplantation. In the United States as few as five per cent of the organs that are needed ever become available, and the discrepancy between potential recipients and donor organs is increasing by 10 to 15 per cent each year. There are still serious problems with incompatibility of tissues and organs, which means that very dangerous immunosuppressive therapy with serious side effects is necessary.

More importantly, the applications of this new technology will go way beyond treating hematological malignancy. The human body has a very limited ability to regenerate. When we have a stroke, our brain dies. It is replaced by scar tissue. When we have a heart attack, it is replaced by scar tissue. But this technology has the potential to allow us to replace that tissue with functioning tissue. I think it is very easy to say that we should wait until we can use a technology that does not involve embryo research, to perhaps differentiate adult cells. But remember, every day that you delay the discovery of a treatment for these conditions thousands, if not millions, of people around the world die. This offers an extremely cost- effective way of treating human disease and a humane way of treating human disease. So why are we not engaging in the research? Of course, the issue is that it involves destructive embryo research. What I want to put to you now is a case for why we should revise our views on whether destructive embryo research is permissible.

The view that destroying embryos is impermissible is based on the view that we have heard already articulated here today: that the embryo from the time of fertilisation or nuclear transfer has a special value. It is like one of us; it is a little person. It has the same rights and interests as all of us. This view has a number of logical problems which I have outlined in my submission, but I just want to draw attention to the way in which this view conflicts with, I believe, many of the implicit values in Australian society today. This view implies that post-coital contraception, the morning-after pill, is not just morally wrong but that it is like murder. It involves the de-

struction of an embryo. This view implies that abortion is not just impermissible but like murder. It is important to remember that over 100,000 abortions occur in Australia every year, and all of us pay for those. This is mass murder on a massive scale if the view is that the embryo is a little person like you and me. This view has also resulted in the absurd situation in Victoria where the law requires that hundreds, if not thousands, of embryos are destroyed each year even if couples want to donate them to research and even if that research is into life saving medical treatments.

There are, of course, a number of alternative views about the moral status of the embryo. But what can we learn about society's values? Many Australians are now coming to the view that at the end of life their lives, in a morally significant sense, end when they are no longer conscious. There have been a number of important legal cases that have endorsed the withdrawal of life-prolonging medical treatment when a person is permanently unconscious. If life ends when we become permanently unconscious, perhaps it begins when we become conscious, and that does not occur until at least 24 weeks into gestation. On that view, destructive embryo research, in general, would be permissible and, indeed, the creation of embryonic stem cell lines and therapeutic cloning would be permissible.

I now want to make a couple of brief comments about a separate issue, and that is experimenting on existing embryonic stem cell lines and the importation of embryonic stem cell lines into Australia. Is this permissible? One important issue is whether these embryonic stem cells are embryos, and this I believe turns on the question of whether they are totipotent or pluripotent. I define totipotent is a cell capable of producing a whole individual. Pluripotent is a cell capable of producing any tissue but not a complete individual like you or me. It seems to me that the weight of scientific evidence suggests that embryonic stem cells, as are being experimented on in Australia, are pluripotent and not totipotent; they are embryonic tissue, but not embryos.

The second issue relates to the final point that Professor Pettit alluded to and relates to a point that Alan Cochrane raised. I completely agree that, if creating embryonic stem cells is immoral, then importing them is immoral. I happen to believe that creating them is moral and so is importing them. But if this committee takes the view that it is immoral to create them, it should also take the view that it is immoral to import them or to use any of the products that are derived from them. I would urge the committee that if it comes to the view that it is unethical to engage in this research, it should endorse the banning of the importation of any of the products that are derived from this research overseas. We would not think to use the products of unethical research on Holocaust victims for our benefit.

What way forward is there? One principle which I would urge in addition to Philip's is that, in the face of reasonable moral disagreement, our society should accord greatest weight to liberty. What the abortion debate has told us is that when people are fully informed and continue to morally disagree, we should give greatest weight to the individual liberty of those concerned. At the very least, we should allow those people who want to donate spare embryos from IVF to research to do so. In general, I believe we should allow destructive embryo research.

CHAIR—I will lead off some discussion. I want to look at the principles which you raised, Professor Pettit, the first one of which was that we should look to a common framework—and

you put that more eloquently than I have summarised it. That is an attractive proposition. My question is: how do we find that common framework? There are different ethical views in circulation within the community, indeed in this room. There are those who would ascribe to a deontological ethic, there are those who would subscribe to a teleological ethic, there are those who would be attracted to a utilitarian approach to the subject, there are those who would be attracted to a values based or natural law approach to the subject. To some extent, as I was listening to Professor Savulescu I thought—and I may be misreading him; he will tell me, no doubt, if I am—he was talking about the way in which we look at values in the community and therefore the use of the morning after pill, abortion, destruction of embryos as almost a 'popular will' way of coming to an ethical system. The difficulty I have, Professor Pettit and others who may have a comment about this, is that whilst it seems to me easy to say we should have an ecumenical ethical framework, as you described it, how do you actually arrive at it?

Prof. PETTIT—On that first principle, my thought was that so far as possible we should find a common framework. I was illustrating that with the therapeutic/reproductive cloning distinction. I think the terminology is obviously contentious because those on one side, for example, of a divide I sense around this table think that the word 'therapeutic' is not the appropriate word to use. What I was suggesting is that people on both sides can agree there really is a distinction between cell level reproduction and individual level reproduction. I was thinking of that as an example of where we may have to change the terminology to get agreement, but we can surely agree that there are two quite different sorts of procedure involved in those two cases. We may argue about how exactly they should be best described, and that is a tricky issue—as we have all discovered who have been involved in any way in this debate—but surely at least that distinction is there.

Incidentally, somebody mentioned that the AHEC document rejected the therapeutic/reproductive cloning distinction. Yes, but it introduces a similar distinction under other terms. It talks about the reproduction of the whole individual versus reproduction of the parts; it talks about individual and cellular cloning or reproduction. So that distinction is an example of where we do not need to disagree. Let us put that distinction in place.

CHAIR—That takes us some way down the road. Yes, let us look at the individual procedures which we are dealing with and—to perhaps paraphrase what you said—let us not treat the replication of an entire human being exactly the same as you would the replication of a skin cell, for example. There is a lot of common sense in that and in having some clarity of language and description of procedures. But I am still interested in the broader question which I thought your comment raised. That is: how do we ultimately try and come to some decision about the hard issue? The hard issue here today, which we are all facing I suppose, is: what do we actually do in terms of what do we allow? Is it appropriate to use ES cells and to replicate them? I am interested to know whether anybody thinks there is an ethical framework that can logically be applied to this without ultimately having to make some arbitrary decisions about which framework of ethics you choose or some compromise amongst a number of them.

Prof. PETTIT—I did not think we would find a common ethical framework in its full colour, so to speak, in detail. What I was thinking is that first of all we should try to get as much common ground as we can, before we begin to divide. The thought was: don't unnecessarily divide. The second principle was: let us separate out the issues. I think if we lump them together, even

having got the common framework, and say, 'Is it yes or no to cloning?'—undifferentiated—then, of course, immediately you will get a quick divide on that. But it could be different if you break down the issues into separate issues. For example, it would be interesting to know how people around this table feel about the de-differentiation of an adult somatic cell for purposes of therapeutic—in this case it is certainly properly called 'therapeutic'—use with that individual, in dealing with the given disease like the one that Professor Savulescu was mentioning with his 33-year-old daughter, as he was imagining her down the road, with this leukemia. Would we agree on that, for example?

I suspect most of us would agree on that. And, if we agree on that, whatever happens we must not introduce legislation that would make that impossible. It is not technologically feasible at the moment but it is the sort of thing that could be technologically feasible in five years time. If we separate out that issue and then separate out other issues of this kind, the smaller the issues become the easier it is to gain agreement on them, even from a base that maybe allows a lot of difference. That was my thought.

Mr CAIN—Something that just crossed my mind is that there will be a terrible lot of value positions with the people who are nonscientists. But do scientists have values? I am just curious as to: is it everything? Are there no limits? If we were to come to the balance beam or some ecumenical ethics, is there no limitation to what the science community would want to do? Do they have their own sense of balance and value of what is in and what is out? To begin the discussion of achieving some sort of consensus—for want of a better word—I would need to know what their view is of the question of values in their research, or is it to them not a question?

CHAIR—We might come back to that, because we are going to have an opportunity for some cross-discussion. But we might deal with our questions first, although I suspect part of the answer would be the comment that I think most of the scientists here are opposed to reproductive cloning. That must reflect some value in itself, without going into your question in further detail.

I am interested in anybody else who might have a comment about how we as a committee might look at the framework, which I think Professor Pettit was raising indirectly, in addressing this issue. If there are any other views about that, I am interested in them. Maybe at the end of the day you say, 'That is your problem, and go away and determine it yourself.' But there is an opportunity to look at whether there is a way in which, to take a point in a plural liberal democracy, there is a framework in which these issues can be addressed.

Mr TUDEHOPE—The only one that appears to have emerged from the discussions around the table is that you start with what promotes human dignity. I know that is not a very helpful way of expressing it and probably does not give you a lot of guidelines. But those that have spoken about and given definition to the framework have started from the premise of: does it promote or does it detract from human dignity? That is as I read the value submissions that have been made, by and large.

Prof. SAVULESCU—I have two points to make on that. One is that I tried to articulate one principle which I think is very important in a liberal democracy, and that is when there is reasonable moral disagreement to give way to liberty, but many people will reject that. So I would

like to put to you that your problem is actually much more difficult than perhaps many of us realise. On the one hand, if you allow embryo research, you allow the destruction of embryos and what many people believe is the murder of an innocent person. But if you do not allow that, you allow many innocent people to die because you do not develop the technologies that will save their lives. So both groups have a very serious moral claim. I really do not know how you are going to get off the fence on that: you have to fall down one side or the other. I do not think that there is a way of bringing them together. I think the only solution is what Mr Eddington suggested, and that is to put it to the people in really a very broad way and to see what the majority of Australians want. I do not believe that inquiries in general involve enough ordinary Australians in this debate. I would urge that the real way to resolve this intractable ethical issue is really to see what the majority of the public want when they are properly informed. We are here because we have interests. We are interest groups, most of us.

CHAIR—The conventional way within our system of doing that is actually the parliament. That is, the parliament is meant to represent, through two houses, in an imperfect way if you are talking about in pure terms, the wishes of the people. Is the way to deal with it to say that we ought to have something before the parliament?

Prof. SAVULESCU—Yes, clearly that is one mechanism. The problem is that I think when the public act and vote out one government on the basis of an issue, they are not generally acting in an informed way. When the general public hear cloning, they will have *The Boys from Brazil* in their mind at the present point. There are alternative ways of stimulating public debate: citizens' bureaus and debates and so on. I would urge the exploration of alternative ways of ensuring that there is properly informed public decision making.

Mrs UHLMANN—I was interested in Professor Pettit saying that we divide, but he is the one who seems to get most angry and cause the division. Perhaps we do, when we divide, identify areas of disagreement and from there we can find areas of agreement. I would think that, if we did destroy the embryo, we perhaps would look then at that as being an area of agreement. They say they are very close to being able to take the stem cells without destroying the embryo, and we immediately have an area that we would say we could certainly agree with. I would like to say that there is a tendency to divide. If we talk about a pluralistic society, the religious views are equally ethical and valuable, and there is a tendency today for those who speak representing religious groups to be downgraded or attempted to be silenced. Is this not prejudice?

Ms MORRIS—I agree with the idea of opening it up to the whole society, and I will just give you an example from an indigenous perspective. This discussion to me is very anglofied and you are emphasising the right to life, or keeping people alive. One of my latest submissions I had to put in about biodiversity was the right to stay dead—our biggest problem being indigenous dead, especially mummies. It might be a joke to you, but mummification is the way we had burials and you are quite prone to be digging them up and, unfortunately, bringing them back to life. Again, all of this is bizarre to you, but when you are a minority, by God, you lot look bizarre. When the person is 30, what about the right to die? Okay, they have leukemia, but maybe it is this person's time to die. There are no discussions about the thing to do with death. Death is part of life—there is coming alive and there is dying. You certainly do not seem to value this idea that one has the right to die.

CHAIR—Professor Pettit, did you want to comment again?

Prof. PETTIT—Just on your comment, Mr Chairman, I absolutely agree: parliament is where these debates have to occur, and in this sort of committee. In the committee and in parliament you are obliged to argue this out and to form your own views but to represent them as the views of a liberal democracy, where you recognise there is this variety. In seeking agreement, I absolutely agree that you will not find the framework that everybody will accept. You should go as far as you can that way, but eventually you are going to have to make decisions on grounds like the following: one group thinks that this is the destruction of a human individual, and another group does not think that and thinks that there is a loss of fantastic benefits to human beings. Where dignity lies is itself divided—there is a matter of division between them—and you just have to make a judgment call on exactly what represents a fair compromise between these different views. That is the only way you can make a decision.

I will just add one thing: if one is interested in what the community thinks, there is only one known way of doing it now—it has been trialled in this country once, as it so happens—and that is to hold a deliberative opinion poll. If what you really want to know what public opinion is, you get a sample of 200 or 300 of the Australian population—it takes a bit of work, but it is quite doable—and you bring them to a single location. You have them together for three days, you take an opinion poll at the beginning and, over the course of the three days, you allow every opinion group to represent its point of view. You then take their opinion at the end of the three days. That will give you a very interesting take on what the reflective feeling in the community is—that is to say, where people would tend to go if they gave their mind to the issue.

CHAIR—Although, interestingly, in that instance the outcome as I recall of the deliberative opinion poll was significantly different from the outcome of the referendum.

Prof. PETTIT—Indeed, but the outcome of the referendum was more or less what the opinion poll was before the reflection. I am not defending the view on that.

CHAIR—I am not putting a value one way or the other; I am just saying that there are differences of outcome.

Archbishop HICKEY—I think we would be mistaken if we were simply to have referenda on these matters. In Western Australia they talk about having a referendum on capital punishment. I am opposed to it, but I think the numbers would vote in favour of it. Our standards must take into account not just the will of the people at any particular moment but a history of principles that we have developed—respect for the people with disabilities, respect for the rights of children, and so forth—and not just to keep on testing the waters to see whether something is acceptable or not by the majority. We cannot make moral laws by majority opinion.

Destruction of the embryo is one of those matters. In our submission we did not see the choice as being no research or destroy embryos. We asked that research look in other directions, for instance using adult stem cells. It seems to me that we can come to a humane and almost unanimous view on the direction of research if we can point to something that we can all agree to. It would seem that the use of adult stem cells gives some hope of providing the repair mate-

rial that we see as therapeutic, so it is a matter of the direction of research, not a matter of cutting it off.

Dr SWANTON—We are going to have to use judgment to make a decision as to which way to go. Mr Tudehope mentioned the issue of human dignity, but you could also look at that from the other point of view. You could say that for human dignity—however that is defined—there should not be unnecessary disease and people should be kept healthy; therefore, that is an argument in favour of therapeutic cloning. You could also argue that to have human dignity, childless couples should be given the opportunity to have a child if they cannot otherwise have one, and that is an argument for human reproductive cloning. For every issue, there are two sides to the story.

Mr Chairman, you gave us a hint of how we should approach this, because you used the word 'logically'. I think we need to start from the basic principles and to develop logically and reasonably the conclusions that we need to come to. That is going to be a difficult task. Of course, we all have different views here and, as much as possible all those views need to be taken into consideration, but I am not sure whether community consensus is the way to go. If we went out for some sort of referendum at the moment, I suspect I know what the views would be of the people out there because I was speaking to my mother-in-law last night. She admitted that she was not very informed on the issues, and I think a lot of Australia is like that. The parliament might be one place to have the debate but, certainly, a community view is not an ethical view because a lot of gut reactions predominate.

Finally, the religious views—yes, they are valid views, just like a scientific view. We all operate within certain frameworks in which we argue and develop our ethics. But, to some extent, the religious views are not necessarily ethical, because if religion A says something is unethical and religion B says it is, there is no way to resolve that impasse because they work in that fixed framework. In conclusion, I think a logical and a reasoned approach to developing a conclusion on this matter needs to be tried.

Dr NEVILLE—Could I draw the committee's attention to the role of law. As legislators, one approach would be to use law as a vehicle to protect and to educate and, on another level, through that educative role, to direct. For example, if it were possible to legislate to ban destructive embryo research, legislators would direct researchers to go down other paths that very often, when presenting arguments in absolute terms, we are seeking to close off. As legislators, rather than saying, 'Let's take liberty as our paradigm or as our mark against which we will measure, there are other traditions that look at the role of law as being educative, protective and directive. That might be, again, something of a framework that would be of assistance.

Mrs WOOLF—I will comment on something that Professor Savulescu said: that the parliament was faced with an unfortunate choice, and that if it thought a particular thing was wrong, it should not do it. But if it did not do it, other sorts of 'disbenefits' or disadvantages might flow to people who would miss out on medical discovery. That is an offer with menaces. They are not moral equivalents at all. If I think something is wrong, I am in no sense obliged to do it because other things might flow from my not doing it. If it is wrong to rob the bank, you might as well say, 'If you do not do it, the family won't be as well off.' That is ridiculous.

The other thing that I am concerned about is that the fruits of science—I would hate to comment, of course, on scientists' views—are with us already. Professor Pettit talked on his third principle about who could object to the use of material from embryos—from the IVF procedures—who are excess to requirements. What a beautiful phrase: embryos excess to requirements! Professor Savulescu sees no problem with people donating their embryos, 'If they want to do it, this is a liberal society.' In both those expressions, to see embryos as excess to requirements, and to see them as being donated, clearly stamps them as property. They have no status whatever in their own right. People said this during the debates on slavery in the 19th century, 'I would not keep slaves myself but, if you want to, that is entirely your affair'.

I am afraid there are some issues where the status of the subject that we are discussing does not really allow for a lot of compromise. We have skated all around it today but it does not seem possible to avoid questions about the status of the embryo. If there is no particular significance or status to it I agree with both my professors here that it is nothing worth worrying about. And to talk of embryos as excess to requirement and donating them clearly labels them as property. That the IVF clinicians and practitioners have indeed run ahead of us and have presented us with a whole lot of excess individual human organisms is a real problem to us. But I do not know that because they have done it legislators should ignore the whole body of law—and Dr Neville talks about that, too.

In the submission from the New South Wales Right to Life Association, in particular, Greg Smith, a barrister, has put there for your consideration a great deal of the body of law to do with the laws of succession, of inheritance, of torts, all of which acknowledge a status to the unborn child—succession having to be kept frozen, as it were, until we see whether a child comes to fruition. So certainly you do not gain full legal rights as a person until you are born, but there is a considerable body of common law and case law which gives status to the embryo. All of these are outcomes of the law, not just legislation but courts' decisions, and so I do not think that we should frame the alternatives available to the parliament simply in terms of embryos as properties and how they may be manipulated for the good of other humans.

There are lots of limited goods. I can buy more leisure from myself by having a slave. I can buy more wealth for myself by oppressing my employees. I can do lots of things in relation to other humans that will benefit me. We do not have a right to be free of disease and, as the lady on this said, there comes a time do die. My life, my comfort, my wealth, none of these secondary goods, can necessarily be bought by the subjugation of other human entities, and I suspect that a lot of the discussion today is perverted by that belief.

Mr HOFFMAN—I would like to put a slightly different way of looking at the problem we are talking about that might be of help to the committee. I have been concerned for quite some time about the questions of human rights. There are the rights of the aged, the rights of men and women, of teenagers and of the child—none of these are deniable. But when you go beyond that and postulate the rights of the dead or the rights of the unborn, it does seem to me that you are moving into an illogical position. The invention of rights is unlimited—you can keep on inventing rights of this and rights of that. It is much more significant to think in terms of obligations. Does a foetus, an embryo, have any obligation to its mother? So long as it is an embryo or a foetus, the decision should rest with the mother, with the woman. It is a question for the women and we men enter into that at our own danger. .

Prof. SAVULESCU—I would just like to express an area of agreement with Archbishop Hickey. I was not suggesting that the way that we resolve ethical issues is through some sort of public vote—far from it. I think we have to go with the weight of reason. However, in this situation we have a rather unusual case. Mrs Woolf believes that a fertilised egg is a person like you and I. I believe it is just a cell. It is a precursor to me, just as a particular sperm and a particular egg were a precursor to me. That is a fundamental disagreement between us. How are we to resolve that issue? Generally when we have discussions about what you believe and I believe, the outcome is not that important. But when the outcome is potentially denying future generations or condemning them to early death and disease, it is a very significant issue—and that is what this issue is about. I am very concerned that the moral beliefs of what I believe is a minority in Australia will actually dictate what happens to future generations. What I would hope is that, if we are to act on the basis of that particular moral position, we would at least ensure that it is held by an informed public.

CHAIR—I think we have had an opportunity for anybody who wants to to address that issue. I was going to move on, but did you want to say something on it, Dr Mayo?

Dr MAYO—I just want to say that scientists in general do have moral views and they vary quite a lot among scientists. I have moral and ethical views. However, I have come here today as a scientist with some limited expertise in a particular area and, while I feel that my moral views have as much worth as anyone else's moral views, I do not regard myself as expert and therefore would not want to enter a debate with all the experts here.

CHAIR—I think the rest of the scientific panel want to state a view too.

Prof. SERJEANTSON—I am here representing the Academy of Science, where, as you would expect, there is a wide range of views on very many matters. However, in this particular instance, and in formulating this particular position statement, the Council of the Australian Academy of Science is unanimous.

Prof. NORMAN—Mr Cain asked what I think for him was a genuine, innocent question that was not necessarily received by me in that sense. I got the impression that the scientists who are geographically located in one area of the room are somehow distinct as human beings from the other members here. I am sure Mr Cain does not mean that. But if Mr Cain asked the question, 'Do scientists have experience of disabled members in their family?' I do. 'Do scientists have religious beliefs and a personal God?' I do. 'Do scientists have a feeling about the rights of the unborn child?' I do. So I hope that explains to you that scientists are part of the human race and our views are very much representative of those of you who have expressed views today.

Ms ROXON—I have some questions which are in a completely different field and I think most of them will be able to be answered fairly quickly. My first one is to Mr Cain. I must say I am very grateful that you are here today. I did express some concern in Melbourne that we had a lot of evidence from scientists about the opportunities that this new research might provide to the disabled community at large and that we did not have any representatives there at all. So I am grateful that you are here and I hope that your submissions in relation to being involved in the process will be taken up, not just by the scientists that are here but by the community working on these issues.

There is something I want to be clear about, however, in your submission. You make reference to a moratorium on this research, but in terms that I am not 100 per cent clear about. You say that there is much to be said for a moratorium on the cloning of human body parts, to be reviewed in a few years time. But I did not understand that to be something that you were specifically recommending to the committee, on behalf of the groups that you represent, as what you believe to be the best option. I am just not sure how highly you are putting that comment, so it would be useful if you could address that.

The other question is also to you, Mr Cain, with respect to the low-tech non-controversial technology with no adverse side effects that you were talking about. I can appreciate your views on the money that does not go into the disability sector and some of the needs in non-scientific areas, but I am wondering if you could give us some examples of the low-tech non-controversial technology that you are talking about that would assist some of the groups that you are representing today?

Mr CAIN—I think the position of having the moratorium is a general theme of our submission. We have a saying in the disability sector, 'Nothing about us without us,' because the history of human service to people with disabilities is its being done to us as objects—being considered less than human, being defective and so forth. The history is well documented. People with disabilities have suffered extensively in terms of solutions to their problems such as sterilisation or even murder. It is also an acknowledgment of the broad views within the disability sector. When we say disability, it is quite broad. People have the image of people with disabilities with either a white cane or a fluffy dog, or they picture wheelchairs. But people with disabilities include people with psychiatric disability, people with disabilities from non-English speaking backgrounds and so forth. It is quite a broad range of people. You would suggest, as has already been suggested here, that the values within that group would be just as broad as the diversity of the disability groupings. The moratorium is based on the idea that, if in fact this is a group that would be a target of or would benefit from the application of such research, we need to take some time to get its views, to make sure the people are well informed and to document that breadth of view. Having been involved in disability policy for some time, I know that when we tried to actually put together a view on euthanasia it was quite difficult. That moratorium comes from that perspective. We need to, as someone has mentioned, demystify—I like that word—the technical language, put it in a simple way and take it to people with disabilities so that we can get a roundness and a balance of their views.

The second part of your question regarding dollars in the disability sector is a difficult one. The history of human service to people with disabilities has been so pervaded by the medical model. It is always a solution that people and governments leap to. As Dr Christopher Newell tells me, it is sexy, whereas we do not seem to get the same attention, response or extensive amount of taxpayer resources for very simple things—as simple as an incontinence pad. There are no government resources for an incontinence pad for a child who is under 16. These are very simple things that would assist people with disabilities in terms of their quality of life. When you compare something like that to something that is not absolute, where we are at the very early stages, we do not know how long, we do not even know whether the current population who are alive will benefit from it, people with disabilities find it very difficult to get very enthusiastic.

The point there is that, if we are looking at developing technologies in the medical sector for improving the lives of people with disabilities, we know that there are a number of things that we can already do that are non-medical or medically related that could be easily funded. For us it is a contextual thing and a whole of government issue. If we are seriously accepting one of the values or underpinnings of why we are all here being for the benefit of human life and the quality of that, then we have to start with people first rather than medical technologies first. That is why we say 'people with disabilities' instead of 'disabled people'. Even though the press loves saying disabled people because I am sure it is shorter and easier to say, they are people first; they are human first. We must remember they have needs other than to be a patient or a client. They have needs for a house, accommodation support, education and a job, and we cannot take any of these things for granted. In fact, people with disabilities are so overrepresented in the disadvantaged areas of our society it is quite horrific. I attended a meeting on the human rights of people with disabilities last week, and we are overrepresented in the pension and unemployment area, in those in low literacy and those who are homeless. To me, there are many things that we can do that are cheaper and more immediate, rather than putting all our eggs in a technological medical basket. But that is not to necessarily just pour cold water on it. The possible benefits are seductive and are worth not throwing totally out of the picture. It is just that it is very hard for us. People have used 'reason'. People with disabilities cannot see the reason why we cannot do the immediate things, yet we are asked to see the reason in giving permission to do these very long-term things.

Ms ROXON—My second question is to Dr Swanton. I am concerned that you made some comments in your submissions and, as the only person here who has put a submission to us today essentially supportive of human reproductive cloning—not therapeutic cloning—I am anxious to understand how much weight we should give that view. You have told us that you appear in your private capacity, but I know that your submission refers to you as a consultant, and you indicated in your opening statement that you work in a department of the public service. I am anxious to know who it is that you are consulting for when you present these views to us and whether you are a doctor of something that is relevant to the submissions you have been making today.

Dr SWANTON—Swanton Consulting is a name I use when I work between 10 o'clock at night and midnight writing submissions on various things on various issues. I am a doctor of theoretical chemistry in quantum mechanics.

Ms ROXON—So that means that, when you say you appear in a private capacity and you are working between 10 and 12, you are not being paid to be here by an interest group?

Dr SWANTON—Indeed. I am just here in my private capacity.

Ms ROXON—Okay, thank you. Dr Loblay, you made some submissions about how ethics committees work. One of the things that I am not 100 per cent sure of is whether the model is normally to operate on a consensus decision making process. I understand that you have community representation on these committees. Clearly, it would make some great difference, I guess, whether it were consensus decision making or things went to a vote. Could you explain that.

The second thing is: when ethic's committees are actually based at an institution, how do you resolve the potential conflict of interest—or confluence of interest—arising from the fact that everybody on that institution's ethics committee has some interest in the institution going forward, doing well, being perceived to achieve great things? Thirdly, do you think that the sort of structure that is being developed in Australia for ethics committees, obviously with some success, could actually operate in a way that is not institutionally based? Could you have perhaps a Victorian ethics committee—in fact you probably already do have, for some matters—that could actually play that role, rather than it being based in an individual institution?

Dr LOBLAY—On the first point, there are many ways in which committees can reach decisions, but generally in Australia it is by consensus. I think the way our committee operates is pretty representative of other ones. I spend a lot of time at seminars and meetings of other groups of people who belong to committees, and discussing it on electronic forums. Almost all of the time, committee decisions are unanimous. Occasionally, when there are thorny issues, differences of opinion need to be resolved. There are often many ways of resolving them, by maybe offering researchers alternative methods to approach their research or their subjects, and so on and so forth. That is commonly done. When there is no alternative that is acceptable to everybody then, very occasionally, there is a vote. I can only remember one occasion in 10 years on our committee where there has been a vote. Occasionally, a committee member will abstain because they have deeply held personal views, but that is really quite uncommon. There are many mechanisms and most committees work mechanisms out among themselves which are agreeable to the members, operating under the guidelines of NHMRC which does give some guidance about these issues.

On the question of promoting the institution and the conflicts that some members may have in their allegiances to the institution, in a big institution like ours there really is no single institutional direction of research or activity; it is very diffuse. When a particular research protocol involves a member of a committee, when that person is maybe participating in the research, that person must absent himself from the discussion and decision making process. If it is an area of interest to that person but he is not directly involved, then different committees will have different attitudes as to the extent of the participation of that person in deliberations.

The difficulty which I was alluding to in my submission is where the institution's focus is narrow and therefore the focus of the ethics committee attached to that institution is narrow. If, for example, a private reproductive medicine unit decided to establish its own in-house ethics committee, then that ethics committee's focus would solely be on the activity of the reproductive medicine unit's work. That is where I think problems can arise, and that is where I think we need to have more explicit regulatory guidelines as to that relationship between the institution and the activities of a specialised unit. I am not sure if I have answered all your questions.

CHAIR—There was a final one, and that was, rather than having institutional ethics committees, could you have ethics committees which were over a larger geographical area, if I could put it that way? For example, could you have an ethics committee for public hospitals in Sydney or could you have an ethics committee for a group of institutions, and, if there is some inherent bias in the natural way in which they are formed, would that meet that bias?

Dr LOBLAY—Briefly, there has been extensive debate about that question throughout the Australian ethics committee system and at the Australian Health Ethics Committee. There are some advantages to sharing resources, particularly when it comes to people with expertise in special areas, but there are other advantages to having a more distributed system of ethics committees throughout the country. It is a debate that has been going on to my knowledge for at least eight or nine years. I think it will continue, and I think we are always struggling with where to find the best balance between a committee that can, on the one hand, adequately review research within the context where that research is occurring and, on the other hand, the committee being able to adequately reflect the broader views in the population. In fact, there is, for example, in New South Wales a state-wide ethics committee based at the Health Department which can review broader issues and which other committees can refer to. It is quite a useful thing to have, but it is probably not wise to rely on that as the only mechanism of ethics review.

Mr CADMAN—On the same topic, you say in your submission that under the guidelines RMUs have the discretion to redefine innovative practices. I want you to tell us a bit about that, because that is a bit of a worry, and also your thoughts about non-compliance and possible sanctions.

Dr LOBLAY—This is a crucial question for this committee to know about. In 1996, when the new guidelines were produced by NHMRC on the ethics of ART technology, for the first time a section was inserted that covered innovative practices as distinct from research. Up until then, the only activities that were reviewed by ethics committees were research proposals that had research funding and that had all the formal attributes of a research study. But ICSI—the intra-cytoplasmic injection of sperm—for example, that was referred to before, was not considered to be a research project. It was introduced as an innovative clinical practice.

Mr CADMAN—But we heard evidence earlier that that was the first area that we had moved away from the previous practice of trialing. It was moving straight to the human application, and then you have the double whammy of it being classified as innovative. I have a few problems with that. I would like some explanation on it, please.

Prof. NORMAN—In South Australia we had to go through the ethics committee and through the reproductive council before instituting that. In your state, Dr Loblay, I think that would not have been necessary. This just highlights the differences in practices between the states with legislation and those without.

Mr CADMAN—So in South Australia you are able to avoid the primate process and move straight to an ethically endorsed research process, whereas in New South Wales that would not have been possible; is that what we are looking at here?

Dr LOBLAY—I guess I am using that as an example. Maybe it is not a good idea.

Mr CADMAN—That is not a bad one. It is very helpful to us.

Dr LOBLAY—Many clinical practices have been introduced within IVF where there are minor variations or slightly larger variations which were never submitted to an ethics committee for scrutiny before 1996. It was recognised by NHMRC that this is a problem and that is why in

the new guidelines there is now a section which addresses innovative clinical practices and requires them to undergo ethical scrutiny.

The difficulty here is that first of all this is quite a change in the ethical culture within reproductive medicine and so practitioners are having difficulty adjusting to the need for ethical scrutiny of their clinical practice. Secondly, it is still open to interpretation of the practitioner as to whether or not they will submit a new procedure or a new activity for ethical scrutiny. A committee such as ours can only scrutinise things that are submitted to it. That is what I was alluding to when I said I thought the guidelines need tightening. It should become a requirement for all procedures to be submitted for ethical scrutiny.

Mr CADMAN—Investigate all aspects of the activity?

Dr LOBLAY—Yes.

Mr CADMAN—So that is not just the one that is referred to you. You mean to go behind that; is that right—as an ethics committee?

Dr LOBLAY—Yes. In relation to sanctions, many people have expressed reservations about the effectiveness of a guideline system because it cannot be enforced. As I have outlined in my submission, there are ways of making guidelines enforceable, not necessarily by law but by introducing a system of sanctions which will dissuade practitioners or researchers from engaging in activity without appropriate ethical approval.

Mr CADMAN—Can you give an example?

Dr LOBLAY—Let us say a practitioner decided to do a new procedure but thought it was not really necessary or desirable to apply to our ethics committee, perhaps because he felt we might not approve of it or because he might feel we were treading on his clinical independence. Therefore he did not submit this new process for ethical scrutiny. At present, we do not have any means of applying sanctions to that individual in order to say, 'We think you should have done this. We want you to do it and if you don't do it the following things will happen.'

In order for us to do this kind of regulation effectively there need to be those kinds of sanctions in place. Hopefully they will never be used. There are sanctions, for example, in the broader approval process under the NHMRC guidelines. For example, if a researcher in any other field does something without ethical approval or contrary to ethical guidelines, it is open for us to report that to NHMRC. NHMRC can report that to the parliament. It can withdraw funding from not just that project but from all projects for that individual and for all projects to the institution. On occasions when we have once or twice mentioned that possibility to researchers that is a very strong incentive for them to actually do what is considered to be ethical.

I will make one comment in addition to that, Mr Chairman, in relation to a statement that was made by Mr Campbell who asserted that the ethics review system only applies to publicly funded research. I want to make it quite clear that that is not true. In fact the ethical guidelines of NHMRC and the approvals that are generated through the ethics committee system apply to privately funded and unfunded research as much as they do to publicly funded research. It is

quite different from the way the system operates in the United States and I think it is one of the tremendous strengths and advantages of the ethics review system in this country.

CHAIR—It is fair to say though, Dr Loblay, is not it, that that has only got persuasive value so far as private research is concerned? There is no effective sanction, is there not, for a scientist who wants to go and do something in a laboratory by himself with privately funded research funds?

Dr LOBLAY—I guess that is what I was referring to in terms of having appropriate sanctions and where I said that I felt withdrawal of accreditation would be at least one appropriate mechanism because it is fairly hard to conceive of this kind of research happening outside a reproductive medicine unit. In fact, even the Fertility Society of Australia would consider that to be grossly inappropriate. Health departments would move in and close units down where these kinds of things were happening if they found out about them. So I do not think there is a realistic possibility of this kind of thing happening in somebody's garage in a backyard. Provided the system is appropriately strengthened, adequate control can be achieved over things happening in the private sector.

Mr ST CLAIR—We have had a lot of discussion this afternoon on the human side of the embryos, but I just go back to Dolly and I just wonder whether anyone can tell me when Dolly became Dolly, considering the fact that you had an unfertilised egg, and it was denuclearised, and you had the nucleus of a cell from a mammary gland inserted. Then you fused it electronically and then you implanted what you had into the uterus. When did Dolly become Dolly, because that is what happened? I just wonder if anyone has a view on that? After 275 tries you ended up with something at the end of the gestation period.

Prof. PETTIT—I would recommend a book to you by a priest and philosopher from Melbourne, Norman Ford, called *When Did I Begin?* It looks at these issues that are terribly complex and terribly hard to make a judgment on. But at least he sets out the background scientific facts very well and there is an argument for a particular conclusion there. For example, what he draws attention to that is very relevant is the fact that in the first 14 days with a human being—I am not sure what the case is with a sheep—there is always the possibility of twinning, so that it is not determinate at any point in that 14 days whether you have got one or two. One argument you might have is that so long as it is not determinate that it is one or two, or three or four, in that period you do not yet have Dolly. It is only when this determinately becomes one individual that you can talk about it. That is at least one line of argument, and I do recommend Norman Ford's book *When Did I Begin?*

Mrs WOOLF—Could one then argue against that view put by Father Ford: that if, in effect, Dolly or this new organism does not divide within that time, then, retrospectively, you know when we had Dolly? It is something of a nonsense argument, in my view, because the fact is that as soon as a cell starts to divide and show that sort of organisation which an embryo shows, I presume that we have begun Dolly. To hold our judgment? That is all right. If Father Ford wants to hold his judgment frozen until he sees whether Dolly becomes twins or triplets or whatever, then that is fine. But he would have to concede then that, retrospectively, if that does not happen, it was Dolly all the time.

Mr HOFFMAN—My recollection—and it may be faulty—is that it was not until the lamb was actually born that they found it necessary to attach a name to it. 'Dolly' was after parturition.

CHAIR—Mr Hoffman, I was tempted not to ask you this question because in your submission there were questions about fatherhood and the relationship there. I wrote in my notes—and you do not need to answer this—'But who is Dolly's father?'

Dr McCULLAGH—Without addressing when she was named Dolly, I guess one could take the point at which it was no longer reversible. Dolly could be stopped, like any embryo, at any stage; or you could walk in front of a truck and that would stop you in adult life. At what stage was reversibility possible? You could have a cup of tea, but can you get the hydrogen and oxygen out of it, and the tea leaves? No—or not very readily. Once the nucleus has been put into the cell and the cell is zapped or given a shock to start off, at that stage Dolly may not proceed. It may stop, from intervention or from just natural causes, at any stage, but it is not going to go backwards from there; whereas up until the stage you put in the cell, things are reversible—you could take the two test tubes apart containing the two cells.

Mr CADMAN—Could I just make sure that I understand this: from the point of insertion and the shock—

Dr McCULLAGH—I am just saying from the point at which it is no longer possible to reverse. You can stop it at any stage, but the stage where it is no longer possible to reverse and go back to—

Mr CADMAN—At what point of division within the nucleus?

Mr ST CLAIR—In the cell structure?

Dr McCULLAGH—Once the nucleus is placed in the cell, you can no longer reconstitute the oocyte—the egg cell—and the cell from which the nucleus came. I would suggest no-one has probably tried to look at it, but it would be very difficult, if not impossible, to do that, so at that stage it is no longer reversible. It is easily stoppable at any stage, but no longer reversible. At the stage at which it is no longer possible to reverse it, that certainly seems to me to be a landmark point.

Mr CADMAN—Is that a fairly uniform view?

Dr McCULLAGH—Probably not.

Prof. SAVULESCU—I think there is an important distinction to be made. The question of when I began or when Dolly began or when a clone begins is similar to the question of when I end. Many people have drawn a distinction between biological life and when you can say an entity is biologically dead and when an entity is biographically dead. There are divisions about when you and I die. Some people adhere to a whole brain definition of death, some people adhere to a brain stem definition of death, some people adhere to a cardiovascular definition of death. That is about biological death.

Many people also talk about: when does my life end in a morally significant sense, to the extent that I no longer want my body kept alive? I think that is the important ethical issue. In terms of cloning and in terms of embryo experimentation, we have to ask: when does my biographical life begin in a very significant sense? And that has to have something to do with our conscious life, with our minds, not just our physical state, our biological state. It is important to distinguish that. With a fertilised egg, there is no doubt that, in some sense, a new human life comes into existence at the time of fertilisation. But when a morally significant life begins to exist may well be at a different time, just as the two deaths may occur at a different time.

Mrs VALE—I want to bring up the point about exactly when life begins. Mrs Woolf, I would like to direct my question to you initially because I did hear what you said, especially about excess to requirements in donations and how therefore we are treating embryos as property. I really would like comments from others too. This is my understanding. Pardon me if I am struggling with it, but I do not have a scientific background. My understanding is that embryonic stem cells are initially derived from the blastocyst of about six to eight days duration. This is before the blastocyst actually attaches to the uterus, when the potential human life begins to develop. I also understand that 50 per cent of these blastocysts actually do die, are wasted or never ever attach to the uterus anyway, so they are lost. Is it before the blastocyst actually attaches to the uterus that that cell or blastocyst can then be construed to be an embryonic potential human being? I probably have not put that correctly. Is the blastocyst the potential human being if it has not yet attached to the uterus?

Mrs WOOLF—I would not use that terminology at that stage. I would think that at that stage the embryo is seeking a suitable environment in which to develop further. If it does not attach to the uterus, it will not do so.

Mrs VALE—Exactly.

Mrs WOOLF—Its independence of that environment as it occurs normally, in utero, is well established by the fact that you could remove it from one host female and put it in another and it will not affect its genetic package. The message is there and the development is there. In fact, who is the carrier mother can even be across species. So in a sense it carries its own formation and evidence. I do not think anything begins at this blastocyst stage. I cannot see how that could be demonstrated. How it behaves in the cells that form a placenta and do things to sustain itself is another matter. Many are lost at this stage, or so we are told, and I do not know how we exactly know that but I think it is based on some small series. But, so what, with all respect to everybody. Nature produces tidal waves, earthquakes, volcanoes and disease and is very wasteful of human life in general. But nature does not have a moral aspect in that sense. Humans do, and it has developed, or we would not have parliaments and committees. What we choose to do in destroying a developing human organism is quite distinguishable, I think, from the wastage that does occur in nature—you are probably right. But that is for the scientists.

Mrs VALE—That is my particular dilemma. If at that stage, if it has not yet docked onto the uterus and therefore is not yet developing its full potential as a potential human being, stem cells of the blastocyst could be accessed for the benefit of other human beings—that is the moral dilemma.

Mrs WOOLF—Do you mean destroying this embryo?

Mrs VALE—Yes. If 50 per cent of these are lost anyway—that is my moral dilemma: exactly when does life begin?

Mrs WOOLF—You have to make a decision, don't you, whether you are going to take and destroy a particular embryo. It has really nothing to do with what nature does to it. That is one part of the question. You do not form your own moral imperatives by what happens through disease, accident or disaster, from natural causes. Yes, of course it has a growing and developing identity because in fact you can move it around. I think that is one thing we do owe to IVF, because it did demonstrate once and for all the independent package, that you can exchange carrier mothers. If you decide to interfere with it at a particular stage—just as Dr McCullagh said that if you fall under a bus you will come to an end, if someone does not nourish a newborn baby it will die or if someone does not nourish me I will die. If you decide to interfere and not allow it to create an environment in utero then, of course, that is your decision, but you have destroyed a developing human life. I do not think there is any scientific disagreement about that. It is the value you placed upon the life that you interrupted. It is a value thing.

Mrs VALE—Okay. But until it actually does attach itself to the uterus it is not developing its potentiality as a human being. I may be really splitting—

Mrs WOOLF—You stop it doing so. There is nothing significant about that. You can destroy a growing embryo or foetus at any stage at all; you can indulge in infanticide. At any point in our human story you can be stopped. An embryo at this sort of stage is not an imperfect baby; it is a perfectly respectable embryo at this stage. I mean, a baby is not an imperfect adult; it is perfectly normal to this stage of development. So to interfere with its ordinary behaviour at any particular point is to interfere with it. There is no morally free zone. Once you have a fertilised egg which has potential you still have to make decisions about what you will do for it, with it, or to it.

Mrs VALE—I suppose I could follow that particular line of reasoning if 100 per cent of these blastocysts did actually dock and attach to the uterus. But when, I am told, about 50 per cent are actually lost through a natural process that is a particular dilemma on which I am focused.

Mrs WOOLF—I am sorry to repeat it, but the point is that maybe, unfortunately, say, 10 per cent or 20 per cent—I am not certain—of children die of measles or malnutrition and other diseases in Third World countries, that by no means would justify us spreading such a disease or providing without warning what we did. In some countries corporations sold skim milk products which were not suitable to infant feeding. What we choose to do as moral beings is quite different from what nature does.

Mrs VALE—Thank you, Mrs Woolf

Dr SWANTON—Just a brief comment on that matter. I think the difficulty with answering your question is: how do you define life? I think one of the issues that has come up as a result of new biotechnology is that potential life is a continuous process—there is no start and stop. I suppose, what you could do is define at any time in the embryo's and foetus's life the probabil-

ity that the baby will come to term and then that should be a monotonically increasing function so that at birth the baby is alive and, anytime beforehand there is a finite probability that it could be alive—but that is a probability thing, I would think. Until you define 'life' it is very hard to say when life starts, quite obviously.

Mrs WOOLF—Could Dr Swanton suggest at what point life does start in pregnancy? I would know if a child I was carrying were dead or alive. Would he like to define it?

Mr CAMPBELL—I am not sure how morally significant is the issue of what used to be called 'pregnancy wastage' but you seem to be somewhat caught up with it. I did some literature search on this some years back. My conclusion—and I have not got the papers with me but I can certainly send them down—was that a figure of 50 per cent was very ill-founded. I simply suggest that you seek out solid scientific opinion and see what it is based upon to arrive at this figure. Some of the literature these days does refer to it as a 'myth'. So the point simply being made, and I am not sure that I would rely on that figure—and I am certainly willing to provide a literature search which I admit is now some years old that does not support that figure at all.

Ms ROXON—I am anxious to put this question—it is actually on behalf of my colleague, Mr Murphy, who was here this morning. It is directed to Archbishop Hickey and came as a result of the somewhat conflicting views from various representatives of the Catholic Church in Melbourne. Mr Murphy was keen that I ask you for the conference view in respect to the treatment of existing stem cells. I am sure you are aware of the debate we had put to us in Melbourne, at least by one representative, that whilst the Catholic Church opposed research in this area because they regarded it as contrary to the sanctity of life, they thought that it was still logically consistent with—I think the words were 'allow to succumb'—the existing stem cell being allowed to succumb. Would you be able to confirm for us the view of the conference in this aspect?

Archbishop HICKEY—Yes, I can. The conference has taken the position that while there is some likelihood that embryonic stem cells could develop into embryos we are dealing with human life and we may not take it. Therefore, the only answer, if we are not to use the ES cells, is to allow them to succumb—to let nature take its course. So, on that matter, we would disagree with the position put by Dr Ford. He is speaking as a moral theologian, and they rightfully reflect on various matters and come up with opinions, but the ES cells, from the state of our present knowledge, would appear to be able to develop into embryos. Therefore we must consider them as human life and allow them to succumb. Should further research show us that that is not the case scientifically, they would succumb but it would not be human life. We still could not use them because at the moment they come from destroying another embryo. So there are two reasons why we cannot use them, and that is why we ask that research look at other directions, such as the use of adult stem cells.

You did not ask this, but it has come up: on the question of twinning and Dolly and the rest of it, we say that human life exists from the moment of fertilisation of an egg. Individuation is a more complex matter but, without evidence to the contrary, we would presume that the fertilised ovum is individualised, so that Dolly would exist right from the very beginning. Should there be at a certain point twinning—or even triplets should the embryo so divide—there is an alternative hypothesis to that put forward by Dr Ford: it is not that before that moment there is no indi-

vidual, it could well be that before that moment there is Dolly. Division into two would produce Dolly, and Dolly would remain. Molly would be produced and, if there were three, then Polly. So it is conceivably another way of looking at the phenomenon of twinning and not simply presuming that Dolly comes to exist some time after the possibility of twinning is over.

CHAIR—Thank you.

Proceedings suspended from 3.47 p.m. to 4.04 p.m.

CHAIR—Ladies and gentlemen, can I say, before moving to the third area, which is the regulatory aspects, and asking the representatives of the Attorney-General's Department to make some introductory comments, that we appreciate that some of the panel here today have to leave to catch flights, and indeed some have left to catch flights. So I will say just a couple of things which I would have said at the end.

We appreciate the contributions that everybody has made today. It has been very useful for us as members of the committee to hear the various contributions. We have found that this format of a panel discussion, whilst no doubt it has its frustrations for all of us from time to time during the day, nonetheless is one which is very useful because it does help us to tease out some of the issues and not just rely on our inexpertise as members of the committee but also to rely on the expertise of various people from various disciplines and fields around the table. We have appreciated the contributions of the various members.

Can I also say on this particular subject, where one of the recommendations from the Australian Health Ethics Committee was that there should be a process of education within the community, that we hope that this process of having these two forums in this manner has helped to educate all of us about the issues involved. Perhaps all of us will leave a little more informed about the views of various people, whether they are scientific, ethical or regulatory, about the aspect. Rather than say that at the end when there may be fewer people here, I express the appreciation of the committee now for your contributions today.

We move to the regulatory aspects. I invite Ms Hearn and Mr Atwood from the Attorney-General's Department to comment on regulatory aspects.

Ms HEARN—Thank you for the opportunity to make some additional comments to those that were made in the submission that we have already put to the committee. Principally our role here today is to provide information and answer questions that people may have, particularly in relation to any relevant international law issues. I should just say that our area of expertise is not in the constitutional law area. We do have a specialist area, the Office of General Counsel, which would be able to deal with detailed questions about constitutional law, so, if there were any questions of that nature, it may be the case that I will have to take them back and then provide them to the committee at a later stage.

The submission that we presented to the committee attempted to provide a descriptive overview of a couple of relevant international law instruments. I will talk about those very briefly, but I wanted to respond to some of the issues that have been raised here today. One is the distinction between reproductive cloning and what is being called therapeutic cloning. Just for those who have not actually had an opportunity to read the submission, we made a distinction

between reproductive human cloning and what we would call human tissue cloning and we did not want to use the term 'therapeutic cloning' because we felt that this did not adequately describe the different practices and purposes of the use of cloning techniques.

So, instead of using the term 'therapeutic cloning', we asked that the distinction be made between research, diagnostic and therapeutic purposes to ensure that those distinctions were adequately elaborated in the committee's deliberations. The reason that I refer to that now is that, as Professor Pettit pointed out earlier today, the kinds of issues that the committee is dealing with are very complex and it is important to delineate the actual purpose and practice that we are talking about rather than, if you like, conflating these concepts, which may cause more confusion than provide clarity.

The second issue that I wanted to touch on briefly, and I am happy to respond to questions, is the issue of the right to life, which has been raised periodically throughout the debate, and in particular the question of what international law has to say about when life begins. There was a reference earlier to the international instruments that Australia is already a party to, and I think the statement or comment was made that there was a belief by some groups that human tissue cloning itself would violate the right to life as it is expressed in those traditional international human rights instruments. Article 6 of the International Covenant on Civil and Political Rights states:

Every human being has the inherent right to life. This right shall be protected by law. No-one shall be arbitrarily deprived of his life'

I want to clarify that this a statement of principle, but it does not provide—and nowhere else in the ICCPR does it provide—a definition of 'human being'. Similarly, in article 2 of the European Convention on Human Rights, which is drafted in similar terms, there is no definition of 'human being'.

I should say, of course, that we are not a party to the European Convention on Human Rights, but it is a comparable international instrument. These instruments do not expressly determine the point at which the protection of life begins. Part of the reason for that is that this issue, which is a controversy in Australia, is similarly a controversial issue in most countries around the world. When states are deliberating on the development of international instruments, they are trying in a sense to do what you are trying to do, and that is to reach some consensus about common concepts and to agree on principles that will have a broad application. But it is a principle of international law that states that parties to international instruments have what we describe as a margin of appreciation—in other words, a field of discretion as to how they implement those obligations, or how they, at the domestic level, achieve what they regard the scope of their obligations to be.

The question of whether or not cloning techniques may lead to the destruction of an embryo does not therefore engage the ICCPR. Of course, there are other views that in fact it does so, but the travaux preparatoires to the instrument—that is, the working documents—indicate that the proposal to include expressly a reference to life beginning at the moment of conception was rejected by the drafters. That is not to say that one could not make the argument that the provision does provide protection for an unborn child, but it does suggest that at an international level it is very difficult to assert authoritatively that the convention would prevent this type of experi-

mentation or research. If people want to debate that, perhaps we can talk about that at a later stage.

The concept of human dignity is one of the core organising principles of the UNESCO Declaration on the Human Genome and Human Rights. This concept has also been referred to as a basic principle to be relied upon when analysing the issues of cloning, particularly in relation to the use of embryonic stem cells. Again, the Universal Declaration does not define when life begins and does not define a human being, so one is left with the somewhat difficult task of attempting to interpret the declaration without the benefit of clear definition.

The article that was referred to earlier this afternoon, article 11, says that practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. There is, as you can hear, an express reference to reproductive cloning of human beings—that being the replication of a whole human being with an identical gene set with a viable postnatal existence. There is no express prohibition on cloning techniques per se and the declaration does not expressly refer to the use of embryonic stem cells or embryos. It does not refer to the issue of whether embryos can be created for research purposes or how the convention would be applied in circumstances where an embryo is destroyed in the process of research and experimentation.

That is not to say that the Universal Declaration does not have an application to those subject matters, but it does mean that one has to interpret the meaning of 'practices which are contrary to human dignity' to arrive at some informed opinion as to what the obligation is, if you like, under the declaration and whether or not such practices would in fact offend the principles set out in the declaration. I might just say, for the purposes of clarity, that as a declaration it does not create binding obligations on the states that have endorsed it. Australia was one of the many states that was involved in the development of the instrument and supported it. It was, as many of you would know, adopted unanimously at a UNESCO conference, I think in November 1997.

The declaration sets out a set of individual rights that apply to the human subject who may be either the donor of tissue or the recipient or beneficiary of subsequent therapeutic product or intervention. It also provides a set of principles that are designed to guide research, particularly on the human genome, because it was developed in response to concerns about the human genome project, but also more generally on the exercise of scientific activity.

The other instrument that I will just mention briefly is another instrument that Australia is not a signatory to, but is relevant to this debate. Some of you will already be aware of it. It is the Council of Europe Convention on Human Rights and Biomedicine. As the title suggests, this is an instrument produced and developed by the European Union. Again, it sets out a mixture of individual rights which relate to the human subject. Article 18, which deals with research on embryos in vitro, states:

Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.

In paragraph 2 of that article, it states:

The creation of human embryos for research purposes is prohibited.

The issue of embryo protection was so controversial in the development of this instrument that the member states agreed to postpone the development of provisions on that subject matter and to develop a separate protocol which will deal exclusively with embryo protection. As a first step in relation to the issue of reproductive human cloning, the European Union has already developed a protocol to this instrument which prohibits reproductive human cloning.

I do not think that there is much more that I want to say by way of introductory remarks. I just wanted to sketch a broad landscape, if you like, of some of the main aspects of the international law on this topic. I would conclude by saying that at this stage there is no international legal obligation upon Australia to prohibit reproductive human cloning. The question of whether or not our existing international human rights legal obligations have any significant impact on the scientific research on embryonic stem cells I think is still an open question and certainly not one that we have formed a concluded view on. I would say that if anybody would like to explore those issues in greater detail, I am happy to answer questions.

CHAIR—Thank you. One of the suggestions that has been made by various people today and also in previous public hearings is that there should be some national approach in Australia to this issue. Leaving aside the nature of that national approach and leaving aside for a moment the substance of that approach, if I can put it that way, are there constitutional bases within the powers of the Commonwealth within the Constitution or by virtue of any international instruments which, by virtue of the external affairs power, would provide power to the Commonwealth that could be relied upon by the Commonwealth to act?

Ms HEARN—As we said in the submission to the committee, it may be possible to legislate in a very piecemeal fashion using a number of Commonwealth heads of power such as the trade and commerce power and the corporations power, but the view has been taken that ultimately it is probably the case that the Commonwealth parliament does not have the power to enact legislation that would provide a comprehensive basis for prohibiting the scientific research aimed at achieving reproductive human cloning or cloning research that involves the use of embryonic tissue.

In relation to the external affairs power, the scope of legislative power under the head of the external affairs power depends on whether or not Australia is a party to an international treaty. There are some other bases for legislating under the external affairs power but, for the purposes of this discussion, it would be necessary for us to be a party to an international treaty that deals with that subject matter. It would then depend on the nature and scope of the international treaty as to the scope of the legislative power to regulate. The mere existence of a treaty itself would not then allow the Commonwealth to legislate as it pleased. It would have to develop legislation that was directed to the implementation of its obligations under that treaty, and that legislation would have to be capable of being regarded as reasonable and adapted to that purpose. In other words, any domestic legislation would have to fall within the scope, if you like, of the treaty and have a reasonable degree of conformity with that treaty to be valid constitutionally.

CHAIR—There is no such treaty that we can easily rely upon?

Mr ATWOOD—I think Ms Hearn is saying that certainly at the moment the state of international law does not provide clear answers and, indeed, clear obligations on these issues. Ac-

cordingly, it would be very difficult to look to international obligations as they currently stand to provide the basis for a legislative regime in Australia—certainly a comprehensive legislative regime. It would, at the very best, be extremely piecemeal.

Ms HEARN—There are other avenues for achieving perhaps what we might call a uniform approach or a national approach. It is my understanding that the Minister for Health and Aged Care is actually engaged in dialogue with his counterparts in the states and territories with a view to achieving some common approach. In relation to the details of that, it falls outside the responsibilities of the Attorney-General and is not something that we have been involved in. Those details would have to be provided to you by the department of health or the National Health and Medical Research Council.

CHAIR—Thank you.

Mr ATWOOD—I would just add one contextual follow-up to that, which is that the question about the Commonwealth powers to legislate is one part of the issue, but, even assuming the Commonwealth parliament does have power to legislate, it would be doing so because there was a perceived gap in state and territory legislation, or in order to override state and territory legislation. The Commonwealth parliament does have the power to do so to the extent of inconsistency. I would make a quite obvious point which is not peculiar to the legal issues, and that is that, even if the Commonwealth parliament were to legislate on these issues, because of the level of interest in these issues at the state and territory level I think it would at least be necessary to consult quite heavily with the states and territories and ideally to have agreement with the states and territories. So the question of the legal capacity to enact legislation is one part of the picture, but there are some other political dimensions as well.

CHAIR—But on the face of it one would have to say there has been some reluctance on the part of some states and territories to do anything, because one of the recommendations of the Australian Health Ethics Committee is that those states—namely, Queensland, New South Wales and Tasmania—that do not have any legislation in this area be encouraged to do something. But that recommendation in itself is a repeat of urgings by the Australian Health Ethics Committee in the past. So at least the question needs to be asked of those states: why haven't they done anything and are they planning to do something, and what is it?

Mr ATWOOD—I think that is correct. We would not necessarily want to make any comment on the reasons why those states may not have enacted legislation; it is beyond our area of interest.

CHAIR—I am not asking you to answer that. I am just putting it on the record, so to speak, for those states.

Mr ATWOOD—It is correct that for those states there is an absence of legislative regulation at least, and very often that is a reason why the Commonwealth parliament may wish to intervene if it is seen as a gap in regulation.

Mr CADMAN—On the commercial exploitation of research, patenting of discoveries, importation and exportation of embryo material, all that sort of thing, there seems to be a Com-

monwealth role in that aspect of it. We have already heard about the importation of stem cells from Singapore. Where does the Commonwealth stand in a legislative sense in those areas?

Ms HEARN—I would just make the statement that, as far as I am aware, there is no international trade law that regulates the international trade in human biological material, but the Commonwealth does have power in relation to customs.

Mr ATWOOD—It is my understanding that in the existing customs legislation the minister is able to prescribe products of any description, whether they be products of human cloning or cardboard boxes, and to either prohibit their importation or export or to place conditions on the importation or export. So I think there is existing legislative power at Commonwealth level to regulate the importation and exportation. I will add the caveat that the customs legislation is an area beyond my expertise, so you might want to fortify those conclusions with someone else.

Mr CADMAN—From what you have said, there has been a move, particularly in Europe, to have some sort of umbrella legislative framework, if not by law then by agreement, treaty or understanding. From your knowledge of international aspects of this type of activity, is the trend towards broad understanding and agreements between nations or within nations?

Ms HEARN—I think that the development of the biomedicine convention is very clear evidence of the concern amongst the European Union states in relation to the issue of human cloning and then more broadly the relationship between biomedicine and human rights, and of course the UNESCO declaration is evidence of that as well. However, I would say in regard to the European convention that the last time I looked at the list of ratifications, 28 of the 40 members had signed but only six had actually ratified.

I think it is always worth while to remember that what states do on an international plane and what they commit themselves to on an international plane may take some time to translate into domestic action. Until they have acted domestically, it is a little difficult to form a really clear view about what consensus actually exists amongst states. One would have to look at what the practice of states is to form a view conclusively as to what the level of concern is about the issue.

Mr CADMAN—So Australia may be breaking new ground with others, with a limited number of nations, in a legislative sense if we were to legislate. Is that right?

Ms HEARN—I think that many of the European states would consider that their existing legislation is already sufficient to deal particularly with the issue of reproductive cloning. I could not speak with any real authority about their views of whether that legislation deals with the more general issue of scientific research using embryonic stem cells. But certainly this is a new issue that states around the world are dealing with, and in that sense Australia is breaking new ground, if you like.

CHAIR—Are there any questions from members of the panel?

Prof. RATHJEN—This is not a question. I suspect that, legislatively particularly, Europe is ahead of Australia, because I am aware of at least four countries where programs to isolate new

human embryonic stem cells have been initiated in the recent past. It is my understanding from the scientists involved that the legislation in those countries has been changed relatively recently to allow those people to do those experiments.

Dr NEVILLE—Mine is partly a comment to the department and also perhaps to the committee. I will deal with the second part first. You would be aware that your Senate counterpart committee is currently inquiring into the Democrat sponsored Anti-Genocide Bill. Under the revised definition of genocide, in relation to the genocide convention, some of the questions that have arisen here at an international level about the status of different categories of human life may well require consideration by that Senate committee in relation to that particular bill because there is a very wide definition of what constitutes genocide in that new bill. I simply leave that for your edification.

The other one actually follows on from Professor Rathjen's comment in that I would agree, from my reading of the legal literature of the abundant work that is being done in this area of patenting of genes and genetic sequences and the proliferation of literature, whether it is the European *Intellectual Property Review* or similar such journals, that there really is a vast amount of literature that can be looked at, and equally so in Australia. Some of those are noted in our submission.

CHAIR—I must comment that the whole area of patenting is something which we have not addressed really in any detail at all, and the intellectual property aspects of this, which no doubt would almost be another inquiry in itself. But it has been raised with us and we are aware of that, and we will have to have a look at some of those matters.

Dr NEVILLE—I would have thought that under the separate heads of power under the Constitution that is obviously one area in which the Commonwealth does have power to—

CHAIR—My recollection is that the Australian patent legislation actually contains a provision which was introduced by way of amendment a number of years ago, within the last five or six years, prohibiting the patenting of human materials or human orgasms or some wording to that effect.

Dr NEVILLE—Do you mean organisms?

CHAIR—Reproduction gets to you, doesn't it? Are you aware of that, Dr Neville?

Dr NEVILLE—No, I am not. What of the latter question or the constitutional one?

CHAIR—No, the provisions in the Patent Act?

Dr NEVILLE—No, I am not.

CHAIR—It is getting late in the day, as we can all see.

Dr LOBLAY—Mr Chairman, I would like to elaborate on an issue you raised earlier about what is happening in other states. I have a little knowledge of New South Wales. About three

years ago the government issued quite a long and detailed discussion paper through the health department about all the issues that arose out of the ART guidelines of the NHMRC. That was specifically with the intention of eliciting responses about whether legislation or other steps should be put in place in all these areas. They solicited submissions very widely. Every ethics committee was requested to make submissions. All the people in the different reproductive medicine units made submissions and many other people did so as well. I am not aware of any conclusion having been drawn from that process, but the legal office in the health department is actively involved in reviewing the existing legislation. Some time in the next few months there will be a meeting of all the ethics committees involved in regulation of reproductive medicine units. The health department and legal affairs people will be participating in that conference.

CHAIR—Thank you.

Ms MORRIS—My submission relates more to this in the international arena. Australia is a member of the World Trade Organisation. Look at the recent incidents in relation to salmon in Tasmania and how that can override legislation or any sorts of decisions you would make here and also Australia's recent behaviour in relation to mandatory sentencing and the overseas interference in that. You can make all sorts of decisions yourself on policies and legislation but these international forums, and especially the World Trade Organisation, are going to be the most dangerous places once commercial exploitation of this sort of research moves away from human rights and the technicalities of stem cells and therapeutic and human cloning and really gets to artificial life as against anything to do with humans. When you get into artificial life, you can get into that commercialised way of looking at things in relation to all this.

Dr SWANTON—I have a few comments. Firstly, I would like to confirm that the UNESCO declaration has not been ratified by Australia and that in those international agreements you are talking about human dignity has not been defined and cloning has not been defined.

Ms HEARN—Australia was one of the 186 members of UNESCO that adopted the declaration at the UNESCO conference two and a half years ago. It is not a binding international instrument. Normally when we talk about ratification, we talk about ratification of the binding international legal instruments, so there is a slight distinction to be made there.

Dr SWANTON—Okay.

Ms HEARN—In relation to the concept of human dignity, the various UN human rights committees that exist to monitor a range of other international human rights treaties, which I refer to in the submission as the traditional international human rights law, surprising as it may seem have had very few opportunities to elaborate their views on what the concept of human dignity means. It has arisen more commonly in the context of where individuals are deprived of their liberty by incarceration, whether that is administrative detention or in prisons. Human dignity in that context has been interpreted to relate to the conditions of detention and humane treatment. It might be to do with the sufficiency of light, the size of cells, adequacy of food and so forth. There has not been a detailed exploration that I am aware of which explores human dignity as a legal concept.

Dr SWANTON—With that background I would be very wary about enacting legislation too early because I am quite sure that I can think up ways around any cloning legislation unless the words 'cloning' and 'human dignity' are well defined. For example, it might be possible—perhaps the scientists could correct me—just to change a few base pairs on a DNA molecule to make my skin turn lighter or change some junk DNA. That would not actually be cloning if you changed the nucleus of my somatic cell only by a few base pairs. It is not then cloning, because it is not actually me. It is me with a few minor changes.

Those slight changes would enable me to get around any legislation. This is aside from the safety aspect of human reproductive cloning, which is a legitimate ethical argument against human reproductive cloning at this stage and which no-one here seems to have really addressed. I am in favour of human reproductive cloning but if legislation is put in place too early there will be ways around it and I think that will aggravate the Australian community more than if a more reasonable regulatory system is put in place.

Ms HEARN—All I can say in response to that is that I am not a legal drafter but it is always a problem for drafters to frame laws in a way that achieves the purpose of parliament in the wide variety of circumstances and conditions that might arise. That kind of argument can be put in relation to almost any law.

Mrs WOOLF—While I have no argument whatever with what Ms Hearn has said, there is certainly no definition of a human being in the traditional and weighty covenants like the ICCPR. Nor does it say exactly when human life begins. But in response to the rather extravagant views of Dr Swanton, it certainly does say when it does not begin. Article 6(5) of the International Covenant on Civil and Political Rights says:

Sentence of death shall not be imposed for crimes committed by persons below 18 years of age and shall not be carried out on pregnant women.

In the travaux preparatoires, the works that go on behind the writing, it makes abundantly clear its reason. It says:

The principal reason for providing in paragraph 4 [now Art 6(5)] of the original text that the death sentence should not be carried out on pregnant women was to protect the life of the innocent unborn child.

Certainly there is a very definite view that it does not begin at birth. Scientifically, you will have to choose some other point and that is beyond what the covenants wish to address. To be more particular, in the Convention on the Rights of the Child, we do not simply have the statement that we have in article 6 of the covenant on civil and political rights where, it is true, it just talks of every human being having an inherent right to life. As Ms Hearn said, they do not define a human being but certainly its life does not begin at birth, as the sub 6(5) says on execution. But if you want a little more information you go to article 6 of the Convention on the Rights of the Child which provides:

States parties recognise that every child has the inherent right to life.

Not every human being, every child, has the inherent right to life. It goes on then to note that:

The Preamble to the Convention recalls that 'as indicated in the Declaration of the Rights of the Child—

an earlier document—

the child by reason of his physical and mental immaturity, needs special safeguards before as well as after birth'.

I suggest if you put the ICCPR and the Convention on the Rights of the Child together, you most definitely have a statement because in the larger document it says that you should not execute a pregnant woman—and it does not say at what stage of pregnancy—because you will take the life of an innocent unborn child. It certainly tells you when it does not begin; it does not begin at birth. It is up to you with your scientific knowledge and sophistication to decide if you want to pick some arbitrary point—the convention does not. Then if you go to the Convention on the Rights of the Child, it talks of the child as having 'an inherent right to life' and it needs protection before as well as after birth. It does not settle when life begins but I suggest that the weight of a lot of that has to be taken into account if you are trying to be arbitrary and say that life begins at birth. The covenants do not support any such view.

Ms HEARN—I just want to clarify my earlier comments. I do not want to suggest that the ICCPR categorically provides no protection for the unborn child at all. It is unclear, as you point out, at what point that protection would apply. Certainly I take your point about the prohibition on the execution of pregnant women. All I can say in relation to that is that the only authority—and it is certainly not binding on Australia—is that the American Convention on Human Rights and the American Declaration on Human Rights which also contains provisions relating to the right to life. The Inter-American Commission on Human Rights, in its interpretation of that document, came to the view that the protections in that convention applied at the point at which the foetus was able to sustain life on its own accord.

The decision in that matter was in response to a challenge to the American abortion laws. So, if you are looking for a judicial, authoritative legal view, you can certainly say that there is an argument that some protection is required after the first trimester. But, again, that is only one view of one body. The Human Rights Committee, which is responsible for the interpretation of the ICCPR, has not had an opportunity to look at this issue at all, either in the context of abortion or in relation to the very sophisticated scientific experimentation which we are talking about today.

I might add one final comment. In relation to the Convention on the Rights of the Child, it is correct that it refers to the inherent right to life of the child. I do not think 'inherent' equates with moment of conception, so in a sense it does not really get us that much further, and 'child' also does not get us much further because, again, the Convention on the Rights of the Child does not define 'human being' or 'child' or when the protection of the convention should actually commence.

Mrs WOOLF—But birth is no defining event at all.

Ms HEARN—It is because of, as I said before, the very controversial nature of the issue. I think one can see how difficult it is to come to a final consensus on that, even within our own

jurisdiction. If one can imagine 189 countries now debating that issue, you magnify the problem 189 times.

CHAIR—Just on that, Ms Hearn, my recollection of reading Coke or Blackstone or someone like that some years ago was that there was a common law principle which was expressed in the French as en ventre sa mere, which was the same principle about executing or not executing a pregnant women—not that it has been tested, thankfully, in this country, that I can recall. But presumably that principle is still in existence.

Mrs WOOLF—I think it has, in a case of damages in Victoria some years ago. I cannot remember the name of the case, I am sorry; I did not come prepared.

CHAIR—There are cases of damages—there is Kosky and St Vincent's Hospital, and other cases relating to damages. This probably does not take us anywhere, anyway; it just certainly adds complexities to the issue.

Ms HEARN—I will have to defer to your greater knowledge on that point.

CHAIR—If there are no other questions, I want to ask whether there were any from members of the public and there is one other question I have for Professor Rathjen or Dr McCullagh. Dr Loblay?

Dr LOBLAY—I just want to briefly comment on what Dr Swanton said. It is often said that just because something is legal or, in this case, not illegal, it does not mean that it is ethical. Dr Swanton may well seek to circumvent the law by changing a few base pairs and defining his new biological entity thereby as not being a clone, but he would not get it through my committee; and if he tried to do it anyway, we would do everything in our power to close him down. I am not saying this just to be flippant. I am saying it to illustrate the fact that a strong regulatory system can very effectively supplement legislation and provide a robust safety net.

CHAIR—Dr Swanton.

Dr SWANTON—Thank you very much for the chance to respond. Of course my situation was a purely hypothetical one; I would not envisage doing that myself. However, it raises a question about how many base pairs you need to be different from somebody else to be ethical. What if I change my whole genome to be that of Sue Serjeantson? Am I all of a sudden not ethical?

I suppose what I am trying to do by raising these sorts of situations is to have people think about the issues because I really do not think the level of discussion here today, in the submissions, has been sufficiently detailed and robust to withstand strong scrutiny. And while yes, we could change a few base pairs, if changing lots of base pairs, changing the whole DNA, is still unethical, that would mean lots of people currently are possibly unethical. There are ramifications to all sorts of things we have been talking about today that need further consideration.

CHAIR—I am not sure whether Professor Rathjen, Dr McCullagh, Professor Norman or Professor Serjeantson can answer this question. There has been mention during the afternoon of

private funding and private interests involved in some of the research in Australia. I do not think anybody has actually asked if that is the case because it is not an area about which we have heard evidence from any private funders of research. Is there private funding of this sort of research in Australia?

Prof. RATHJEN—The answer to your question is yes, there is private funding of this kind of research. I know of at least two significant sums of money that have been diverted to this kind of purpose. The research is being done in Australian universities under the appropriate ethical guidelines and legislative guidelines. One of the things that has occurred to me this afternoon is that this committee would benefit from hearing from those companies that are involved in funding that research—I should say it is company-funded research—to find out what it is that they are seeing for their advantage, and for Australia's advantage, in these sorts of technologies, and making sure that their issues and concerns can be encapsulated in any legislative changes.

CHAIR—We could make some inquiries about who they are.

Prof. NORMAN—While this research may be going on, these companies will not have access to human embryos, certainly in three states where licensing of the units occur, and in the other states and territories where all the units are audited and accredited under the Reproductive Technology Accreditation Council. So as much as these companies might want to obtain human embryos from within Australia, I cannot see at the moment any way that they would be able to access those embryos.

Ms ROXON—I have one other question for the scientists. It is not directly related, but it is something that has been troubling me for some time, and I am sure there is an easy answer. We have had a lot of discussion about Australia's fertility rate. I am concerned about the fact that we call it Australia's fertility rate when I suspect what we are talking about is the fact that people are choosing to have fewer children, or at a later date, and that affects our birthrate and our population. Is there actually a scientific reason why we call it our 'fertility rate'? Are we really talking about the capacity of women to be able to bear children changing in our society, or are we using that as shorthand for describing what we can measure just by how many children people are having and the times that they are having them? As I say, it is not directly on this subject but I thought, while you are here, you will be able to answer something that has been annoying me for some time,

Prof. NORMAN—There is no doubt that the live birthrate in Australia, per woman, has gone down dramatically over the past couple of years, and that has been a source of concern obviously to many communities. However I think the term fertility is used in a very loose way. I am sure that the ability of people to have babies, if they so choose, has not been compromised over the past couple of years but this has been heavily impacted by social and other events that have led to people choosing not to have more children. So I do not believe there is any evidence in Australian society that people's ability to conceive has in any way changed but certainly their choices and the end product have changed.

Ms ROXON—My question was really directed towards the terminology. I think from your answer fertility rate is a very imprecise term. Is there something else that it should really be called?

Prof. NORMAN—There must be and I cannot think of it right now.

Dr LOBLAY—Could I attempt to answer that question at least partly? We have explored this very question with the people who work in our own reproductive medicine unit, wondering the same thing you are. Their belief is that there is, in fact, a decline in fertility, that is the ability to become pregnant, because statistically women or couples are choosing to become pregnant when they are older. Fertility does decline with the age of the mother. So it is a sociological phenomenon related to choices about when to have families. That conclusion, I think, is supported by statistics that they presented to us.

CHAIR—I think the actual measures that the ABS use are the crude birthrate and the female net reproduction—I think I have got it around the right way. It is those words if they are in the right order. I think they are the two major measures of births rather than fertility, but the shorthand expression is fertility, I suppose. Are there any other questions before I ask for questions from the public? If not, are there any questions from any member of the public for any of the panel?

Dr WHITTEN—I am speaking on my own behalf. I think we should also ask about the possibility of Australian firms funding research overseas in this field. I have a hunch that there is some going on. The other thing is—I do not know whether it is the right place to bring up this subject—we have heard a lot about preservation of embryos and preservation of the aged by developing some clones of therapeutic value or tissues for replacement. I think we should also consider the possibility of overpopulating this planet. There is good evidence that it is suffering from our presence here. I understand there is a meeting in Philadelphia next month on how long we should attempt to prolong human life with these new techniques. Thank you.

CHAIR—Thank you.

Mr CASSIDY—Unfortunately my question would really be directed at Professor Pettit but he has had to leave.

CHAIR—We are happy to take it on notice and ask for a response. If you want to put it on notice, do so.

Mr CASSIDY—Yes. I think that other people may be able to comment on it as a proposal. Just by way of background, it seemed to me from what Professor Rathjen said about the scientific process that we are largely not dealing with a scientific process. He seemed to be saying that there is not much publication for peer review of results of this sort of research. It seems to be more a commercial enterprise and I think that if we are dealing with regulating commerce there may be a different perspective to be considered.

The comments—I am not sure whether they were from Professor Serjeantson or Dr Mayo—about the need for a nationally consistent regulatory framework and the comments from Professor Norman that what would be possible in Victoria, as is happening with the imported embryonic stem cells, would not be possible in South Australia generally seem to be saying that, with reproductive technology legislation, we have had a bit of a mess mainly because it was let go for so long.

Professor Pettit very persuasively argued three principles which seemed to me not to be principles at all. In the first instance, he was asking us to only look at things that everybody can agree on. There hardly seems to be a need to legislate if everybody agrees. It is the things that there is contention on that, it seems to me, need to be the real subject of legislation and regulation. So I have a problem with that principle, as such. He finally, in his third principle, spoke about the need not to be premature in coming to some resolution. That seemed to me to be at odds with the situation that was mentioned about the lack of regulation for, I think they mentioned, 20 years in reproductive technology. If we refrain from addressing this issue legislatively or in some regulatory framework now, it seems to me that we are in fact doing the nation a grave disservice, because the potential here in talking about human cloning and the use of human biotechnology is far greater than it has been with reproductive processes as we have seen them to date.

Professor Pettit's second principle was to recognise the diversity of issues and not to lump everything together. If we try to be very specific in legislation or in regulations then it seems to me that the point that Dr Swanton raised becomes the real danger: that the more specific we are in the circumstances and in the detail, the easier it is, particularly bearing in mind that this is a commercial environment we are talking about, to circumvent the legislation. All you have to do is to change a few terminologies or whatever and you will at least confound the law and drag the matter out for many years. The effect may be that the regulation becomes totally ineffective. I would just like to put the proposition forward that those three principles are not really principles we should be following at all.

CHAIR—Thank you. Are there any other questions or comments?

Ms POLKORN—I am very surprised that there are no abductees here, because I expected them to be here. I am personally an abductee. I do not know where Mr Cadman has gone, but he knows me. I have been abducted for many years. Actually they are the people you should ask about cloning, about genetic engineering, because it is done on them, not on you. It looks that way because you have never experienced that. That is not a very pleasant place to be—genetic laboratories. My mother, my sister, my husband, my son and I have all been abducted many times. Genetic laboratories are everywhere underground. We live in Castle Hill, and there is a huge one underground—under the council, by the way.

What I would like to say is that there are hybrids working these days. You could look at their eyes many times and not suspect that they are hybrids—aliens and humans. I would not say that all hybrids are bad. It is not the case at all. There are both. Clones exist in government. Please do not switch off my microphone. I notice that you are selecting people, that the microphone is switched off and on depending upon who is talking. Every VIP has a clone—even our Queen, who has been here. It was not her; it was her clone. This has been done for more than 70 years. It is only now that we have started talking about it.

The biggest illusion on this earth is that a man or a woman has limitations providing they have a soul which connects us to the universal source, and your whole attention is on our physical vehicle. Clones do not have souls. That is the big difference between hybrids and clones. It seems to me that none of you experience genetic engineering personally. Abductees are the right people to ask, and they are not here. Other positive races in the universe consider us royalty for

what we can do. Maybe you do not know who you really are, but I will tell you. What amazes them the most is our ability to create all physical things with our mind and our extremes of emotions. They use technology to do that, but we do not need technology to do that. This is an extremely important feature we have got and we do not even know that. We also hold all the physical things you see around yourself with our mind. As soon as we decide not to hold it they would fall apart right in front of your eyes and you do not know about it.

Our ability to laugh amazes them too. We can immediately take any stress from anybody, even ourselves, with our sense of humour. They do not have it, even positive phrases, not to mention negative phrases. And these genetic atrocities have been done for many years here, underground, underwater, and on the moon. There are so many moons in just our solar system where things have been done without our consent, and it is time now to speak about it and to say no to it because everything should be controlled by us, not done behind us. They are now trying to do their dirty job with your hands. This is why I am not surprised that the Commonwealth does not have any laws to control it, and it is high time to have them.

CHAIR—Thank you. The committee has noted your views. Are there any other comments or questions? If not, ladies and gentlemen, can I once again thank you all for your contributions and your participation today. I will not repeat what I said earlier. We have appreciated it greatly and it has helped us in our deliberations. It has probably raised more questions for us to address than we had at the start of the day, but that is the nature of the inquiry.

When the general public think about the way in which the parliament operates, they have images of adversaries squaring off across the table at question time, which they see on their television screens at night. There is another side to the way in which parliament operates, and this is an example of where we can be an educational forum and one which can tease out some important issues for Australians and the nation generally. I thank you for being a part of that.

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.

Committee adjourned at 5.09 p.m.