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**HOUSE OF
REPRESENTATIVES**

STANDING COMMITTEE ON LEGAL AND CONSTITUTIONAL
AFFAIRS

Reference: Human cloning

THURSDAY, 7 JUNE 2001

CANBERRA

BY AUTHORITY OF THE HOUSE OF REPRESENTATIVES

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Thursday, 7 June 2001

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

Members in attendance: Mr Andrews, Ms Julie Bishop, Mr Cadman, Mr Griffin, Mr Kerr, Mr Murphy, Ms Roxon, and Mr St Clair

Terms of reference for the inquiry:

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

Committee met at 9.37 a.m.

MORRIS, Dr Clive Michael Grave, Acting Assistant Secretary, Centre for Health Advice, Policy and Ethics, National Health and Medical Research Council

PETTIGREW, Professor Alan, CEO, National Health and Medical Research Council

SAUNDERS, Professor Nicholas Andrew, Chairman, National Health and Medical Research Council

THOMSON, Associate Professor Colin, Deputy Chair, Australian Health Ethics Committee

TOBIN, Dr Bernadette, Member, Australian Health Ethics Committee

CHAIR—I declare open this public hearing of the Legal and Constitutional Affairs Committee inquiring into aspects of human cloning. I welcome all those present today. I particularly welcome representatives of the National Health and Medical Research Council and the Australian Health Ethics Committee. We are pleased that you are able to be here today, given that our task is to review a report of the Australian Health Ethics Committee. It has also been the convention of this committee, when reviewing a report or a piece of legislation that emanates from a particular body, to invite that body back, prior to the conclusion of the inquiry, to give an opportunity to canvas any matters that the committee, or in this case the National Health and Medical Research Council or the AHEC, might care to discuss. 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 houses themselves. The giving of false or misleading evidence is a serious matter and may be regarded as a contempt of parliament. Before we open the discussion, I invite you to make a statement or some opening comments.

Prof. Saunders—We are grateful for the invitation to come and meet you. It would be fair to say that we really do not have anything in the way of formal documentation to put before you that you do not already hold. Part of the reason for that is that work by the Australian Health Ethics Committee in this area has been waiting for the findings of your committee so that we can build into our own work plan a review of the 1996 guidelines which, under our policies, are up for review because they have now been in existence for five years and need to be looked at again.

So we have nothing really new to present to you. We acknowledge that since the Australian Health Ethics Committee report was referred to you, there have been a number of developments such as the Gene Technology Bill, the states' meeting in terms of the ban on human cloning and the more recent letter from the Prime Minister with regard to COAG, but we would welcome the opportunity to answer any questions that you might have of the evidence that has come before you that we might be able to assist you with.

CHAIR—Thank you, Professor. I suppose this question is a sort of opening overview question, and I am not sure whether it should be directed to the NHMRC or the Australian Health Ethics Committee. Given the report we are reviewing was tabled in December 1998 and

we are now in 2001, there have obviously been many developments in the field, including scientific developments, so we would be particularly interested in how you see that report now.

Dr Tobin—Yes, I would be happy to say a few things about that. I think that one very great strength of that report, which is still a strength, is that we recognised immediately that there were two issues involved in any report to the minister on a ban on human cloning: one was the issue of producing asexually fully actualised human beings; the other we recognised was the issue of the experimentation on embryos. We saw that they were related but they were distinct. And it was because we saw that there were those two issues, and in particular the second, that we refused to use the language of reproductive cloning and therapeutic cloning.

We repudiated that language because we felt it concealed rather than disclosed the second of those two issues. I think it is a pity that we did not actually make that point in the report, but you will see that those terms are not used except in the last section where we quote other people's documents. But we refused to do that because we felt it kind of disguised the second issue. I think the other thing to notice is that we said in that report that when you are making an ethical evaluation of anything it is not enough to look at its potential consequences, in particular its potential benefits; you have to look at what the proposal would involve in itself. So for those reasons we deliberately avoided those terms. I think that is still a great strength.

However, I think there are three ways in which things have moved on since that report. One is that the science has moved on and I think nowadays the scientists think the therapies that you can develop from stem cells are developable without getting the stem cells from the embryos. I mean even Professor John Shine is quoted in today's Canberra paper as saying we can deprogram adult stem cells, say skin cells, and reprogram them into nerve cells or something else. I do not think that was as clear when we wrote the report as it is now. I think we were more taken by the possibilities then than I think the scientists are now.

The second thing that has happened is that we made the mistake in that report of talking about cloning in terms of genetic identity. We made the mistake of thinking that when you produced a new organism by cloning it would be genetically identical to some other organism. All the legislation in the three states that have legislated in this area and have talked about cloning has made that mistake too. People are still doing it. I am just talking about that report. We made the mistake that we thought Dolly would be genetically identical to some other organism.

Since 1998, it has become clear that an organism produced by cloning is not genetically identical to any other. You might think that is not important but I think it is important because if, say, you want to ban the asexual production of actualised human beings, you clearly now cannot word that ban in terms of a ban on producing an entity which is genetically identical to some other. I think the debate has moved on there.

Thirdly, just looking at again, I think that the way we define an embryo in the glossary is outdated. If you look at that definition I think it is too narrow. I think that nowadays you need to define it in a way which recognises that there are some asexual means of producing human embryos that we know of. By asexual I mean not by the union of sperm and eggs but by any other means. We now know of some of those but I presume we do not know of all the ways you can produce an embryo. For instance, it may be with an embryonic stem cell line it is possible to produce an embryo out of that. I think if you are going to be talking of embryos you will need

to do better in your explanation of an embryo than we have done there. I have a couple of suggestions to make to you if you are interested. My own view is that in some absolutely critical respects that report has stood the test of time but, in some respects, things have moved on.

CHAIR—Does someone else want to comment?

Prof. Saunders—I think it should be acknowledged that, first of all, none of us are scientists who work on stem cells or cloning. Secondly, I think it should be put on the table quite up front that we actually value the diversity of opinion about the moral position that people take about assisted reproductive technology and the cloning discussion. But from what Bernadette has said there is a range of views among scientists about the use of adult stem cells versus embryonic stem cells and the ability to reprogram or deprogram adult cells. From my point of view it would not be a closed issue that now we do not need to consider embryonic stem cells anymore because we have moved on from that. I think there is still long way to go in that regard. There is a range of views about whether or not, by using embryonic stem cells, one can actually generate a formed embryo that can then differentiate into a human being. Certainly, I am aware of many scientists who would say that that in fact at this stage is not possible to achieve. We have to acknowledge that just as there are different moral positions that might be taken here there is also a range of opinion among scientists about what can and cannot be done at the present time.

CHAIR—I suppose the great difficulty that we all face, whether as AHEC, the National Health and Medical Research Council or this committee, is that the science keeps developing. Ten years ago Dolly was science fiction. Now there is not only Dolly but Polly, Molly and God knows who else or what else.

Prof. Pettigrew—Andy was there.

CHAIR—Andy was there. Sorry, I missed that one.

Ms ROXON—It seems to me that all of the scientists that are actually practising in the field do not seem to share your view, from what they have put to us in the course of the inquiry. That is one of the things that has been confusing for us. Perhaps if you were all here appearing on behalf of AHEC rather than in your independent capacities, it would be helpful for us to understand whether AHEC actually has a voice on these developments or whether you are really expressing some individual views.

It seems to me—you can tell me if I am completely wrong—that it was a difficult report. There were compromises that needed to be made. If individual members had written it themselves, they probably would have done it differently—we will face that same position. It is a bit worrying to me that we then have a rewrite of what was intended, what could have been, what should have been or how it would be if the science were different without really having all the participating members. I would like to be clear—it may be the point that you were making, Professor Saunders—that you are not in a position to rule in or rule out things, but I would be quite uncomfortable with the evidence that has been given to us until now to say that there was no need for us to deal with the use of embryonic stem cells because we can do everything that we want to do through adult stem cells. I would have thought that that was a bold—or perhaps it should be called ‘courageous’ for politicians—leap for us to make. I would like to be clear

exactly how or if you are speaking on behalf of AHEC when you do that, because it seems to me that the scientific evidence that we have so far is far less clear where we are up to, and in fact in a lot of situations quite the opposite was put to us.

Dr Tobin—I was thinking over the last 24 hours or so about how this 1998 report stands now. I thought that in some ways things have moved on and in some ways it still has that very great strength. Opening up the paper this morning, I saw a direct quote from Professor John Shine, who heads the Garvan Institute of Medical Research in Sydney. He is quoted as saying:

We are now able to take a skin cell, deprogram it back into stem cells and regrow them into a nerve cell or something else.

It is my view that the science has moved on. I think Professor Saunders is right: there is a range of views about that. There is another range of views here, too, about another way in which scientific knowledge has moved on. I put it this way: scientists now know much more about the safety issues associated with producing embryos in this way. All kinds of abnormalities in embryos are being revealed. It is not surprising that this is happening. They now know more about how many embryos you need to produce in order to get one that you are interested in getting going. They now know more about problems of histocompatibility. They are now generally—again, there would be a range of scientific views—less optimistic about embryos produced asexually being useful for the production of tissues and, ultimately, organs because of problems of histocompatibility. Again, if you had a range of scientists here, you would get differences, but those things that I have just said would be truthful accounts of general developments since the writing of that 1998 report.

Prof. Saunders—Bernadette is talking, I think, as an individual, because the Australian Health Ethics Committee does not have a formal position on embryonic stem cells. It has a position on for what purposes you might create an embryo and it certainly has a position about what you may or may not, or should or should not do in terms of embryo experimentation, but there is no formal position once you have embryonic stem cells, or indeed adult stem cells, sitting in front of you. The position of AHEC or the NHMRC on that has not yet been determined. As I have said, we have been waiting for this committee to give us some leads as to where you would be looking for help.

Ms ROXON—Do not take my question as being critical if you do not know; I just wanted to hear about it because we do not want to misrepresent people's views. It is difficult, if you are presenting to us as AHEC and the NHMRC, to be clear whether you are speaking on behalf of them when you make those comments.

Prof. Thomson—Partly in response to your question, to the extent that the gaining of embryonic stem cells involves the treatment or use of human embryos, the AHEC position in the report to the minister is not changed. It is based upon AHEC's broader consideration of any kind of work with artificial reproduction and its 1996 guidelines about that and about the limitations that should apply, in its opinion, to treatment of or research involving embryos. As Bernadette said, all of those positions still stand—

CHAIR—Which is essentially, as I recall, that the creation of embryos—and correct me if I am wrong—should be restricted to artificial reproductive technology treatment for the purposes of infertility, et cetera.

Prof. Thomson—Yes. It is probably true to say that those guidelines are primarily about treatment. They include descriptions of unacceptable practices, which include research practices.

CHAIR—If I could be clear, there is an AHEC position and an NHMRC position in the 1996 guidelines which remains unchanged on allowing the creation of embryos for a particular purpose, which is for IVF type treatments. What Professor Saunders is saying is that once you have got embryonic stem cells or, for that matter, adult stem cells, there is no AHEC position or NHMRC position at the moment on what you do with them and how you use them. Is that a fair distinction?

Prof. Thomson—That is the case.

Dr Tobin—In 11.3, depending on how you read it, there is some reference to the development of embryonal stem cell lines with the aim of producing a clone of an individual—so there is something in there in the position about it being prohibited, if you have an embryonic stem cell line, to develop it further to produce—

Mr St CLAIR—To grow it out to a human being?

Dr Tobin—No, to grow it out to an organ—

Mr KERR—But ‘with the aim of producing a clone of an individual’ is what you read to us. I am just a little puzzled at what seems to me to be a fairly disparate set of representations with respect to this issue. I suppose it is not surprising. I would like to go back to the point that Dr Tobin commenced with, when she sought to make a distinction in terms of an ethical framework between the consequences of an act and the act itself. Disaggregating those things out, then presumably, at some point, you have to form a view with respect to the use of any human tissues. In that sense, if you are using adult stem cells or human tissues, the act in itself involves manipulation of human materials. If you absent out the germ line issues, which are the reproduction of whole individuals, what is the moral or ethical difference between the manipulation of one particular piece of human genetic material—for the purpose of proving drugs or doing something else—and another piece? That seems to me to be a threshold issue which we are all circling around, and about which you are in profound disagreement and unable to help us.

Prof. Saunders—I am not sure that we are in profound disagreement.

Ms ROXON—But are you still unable to help us?

Prof. Saunders—I just do not think that the issue is as black and white as Bernadette has presented. There is a range of views that needs to be acknowledged about where we are in terms of science. In terms of the ethical issue that you have raised, I turn to my colleagues here and ask them to address that.

Prof. Thomson—The AHEC documents draw a difference between one kind of human tissue and other kinds of human tissue. The kind of human tissue that is addressed in the report and in the 1996 guidelines is at least embryonic.

Mr KERR—But we have just heard from Dr Tobin that every piece of human tissue is now potentially embryonic.

Dr Tobin—Can I answer Mr Kerr's question in terms of what is in the 1996 guidelines and the 1998 report. Both those documents contain the point that, whatever you think about the human embryo, there is a range of ethical views in the community about the status of the human embryo. Both documents acknowledge that on neither occasion did the committee try to settle that issue because it could not do that. There was a fundamental range of views on the committee. However, on both occasions, the committee was unanimous about the fact that if it is an embryo, it cannot be treated as though it is just another bit of tissue. It has a different status. We did not try to go on to settle what that status was because we could not have agreed. However, it was agreed that it is utterly different if it is a human embryo.

Mr KERR—Perhaps I can take us back a step. By your evidence earlier, you have just undermined the scientific validity of that proposition. If we are now to conceptualise that every piece of human tissue is essentially God-centred in the sense that it can be made to have the capacity for reproductive life, is not that fundamental assertion now being challenged by the passage of time?

Dr Tobin—I think the point is that whatever way you create an embryo—and it used to be just by old-fashioned fertilisation of sperm and eggs, but there are now a whole new range of ways to do that, and we are open to the fact that there are a whole lot of other ways of creating embryos of which we are unaware—if it is an embryo, it deserves a certain kind of respect that one is not required to give if it is just any other kind of tissue. That was a position that was unanimously held by AHEC on both those occasions.

Mr KERR—You say it deserves a certain kind of respect. Let us assume that we have a process in respect of a piece of muscle tissue that involves the potential development of some new improving and beneficial technology. Let us break all this down: where does this difference come from? I can understand, although not necessarily agree with, the fact that a person might take the view that a human egg and sperm united involves the potentiality for human life. The argument over which the moral philosophers are forever divided involves assuming a point along that continuum where certain assumptions are made. For example, different religions have different points along that continuum where certain steps can be taken. In Australia, we permit the termination of life through abortion at a certain set of points and not beyond them except under very limited and extreme circumstances.

We do not have a framework which lists a set of inalienable rights and we understand that there are certain continuums here. However, for the life of me, I am puzzled by the argument that a piece of muscle tissue can suddenly acquire inalienable rights through a manipulation process and that it turns into something which may, at some stage, conceptually, were it allowed to be implanted and various other things happen, do things which we know it is never going to do. It seems absurd to treat that as anything other than another piece of tissue. It might be a fingernail. It seems that a bizarre set of propositions are being put to us. I was asking earlier about the views of the Raelians. I am now puzzled about the ethical framework that you propose is appropriate. What is the ethical framework? Where does its moral or ethical foundation come from?

Prof. Saunders—The 1998 report to the minister drew heavily on the work of the 1996 guidelines. That focused on addressing the kinds of treatments of what were then known to be the ways of producing embryos: what was appropriate, what was not and what guidelines there should be for reproductive technology. It also included some research. Implicit in the recommendations, as you rightly point out, is a preferential treatment for reproductive tissue—if I can call it that—based on what was known about the way reproductive tissue could come into existence. But it was not so much because of the way that it could come into existence, but rather because of its nature and its potential. It went not only to embryos but also to unacceptable practices in relation to gametes and fertilised embryos.

Mr KERR—I am trying to break down this two-step process that was asserted to be the logical framework through which we had to consider these things: to separate the consequences from the act itself. It seems to me that you blurred your own framework. There is some coherence about a position that says that, if we are dealing with reproductive technology, with cells that the body designs for these purposes, then the consequences of that, manipulated, would be the reproduction of whole cloned individuals, et cetera, and that this is not a good thing and so we have a whole range of different things. Plus, there must be consent regimes and frameworks to make certain that materials and people are not improperly subjected to experimentation. But I am trying to get back to what this involves. I cannot understand how, if you start with something that is a piece of tissue which is not reproductive in nature, manipulate it for purposes entirely unconnected with reproduction—that are entirely disconnected from that purpose—to produce something else entirely unrelated to reproduction, we ever get ourselves into a moral dilemma. I want to know where your morals are. I want to know what the ethical issues are that you assert are involved.

CHAIR—Aren't we talking about two different things? You are talking about, say, an adult cell. To quote Professor Shine:

We are now able to take a skin cell, deprogram it back into stem cells and regrow them into a nerve cell or something else.

That does not give rise to questions about the use of embryos.

Prof. Saunders—No, it does not.

CHAIR—If you take, in somatic cell nuclear transfer, a piece of skin cell and put it into an egg and produce an embryo from it then you have an embryo. Then there are questions that arise as a result of that. When I asked a question earlier, I understood that the NHMRC and AHEC have a position in terms of what you do with embryos but not a position in relation to embryonic stem cells. In response, Dr Tobin said, 'There is a qualification to that,' and also that the 1996 guidelines, at 11.3, mention development of human embryonal stem cell lines with the aim of producing a clone of individuals. If you were then to take the stem cell and try to clone another Dr Saunders or Kevin Andrews then you have a position because it falls under the 1996 guidelines, but there is no position with just non-reproductive cells, as in forming an entire human individual, type research with embryonic stem cells. I am trying to get the distinctions that exist at the present time without—

Ms ROXON—I understood that Professor Saunders or Professor Thomson said that we have a position on the creation of embryos for anything other than assisted reproductive technology, so we do not think we should create embryos, and then Kevin set out the use of embryonic stem cells, but what about the use of embryos that were not produced or created for the purpose of research but are in existence—as we know there are. Is there any position on the record that you can all agree on about the use of embryos not specifically created for the purpose but in existence, which is—

Prof. Saunders—That sits under 6.4 in the 1996 *Ethical guidelines on assisted reproductive technology*. That says that non-therapeutic research—so there is a distinction between doing something to the embryo with the intention of having a therapeutic outcome for the embryo and non-therapeutic research or interventions, which are interventions on the embryo which are not directed at the embryo's wellbeing but the wellbeing for some other technology—is only approved in exceptional circumstances. The approval would require: a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed research, that the research involves a restricted number of embryos, and that there is informed consent given by those who are donating the embryos for that purpose.

Ms ROXON—If I recall correctly, Dr Tobin—and please tell me if I am wrong—in Melbourne you told us that the wording of 'some therapeutic benefit' meant that, when AHEC was looking at that, therapeutic benefit meant only to the particular organism that you were treating and not any broader medical benefit. However, as I understand you reading that and explaining it, what you really mean is that there is potential to approve it if there is some outweighing larger public benefit which may not be for the particular embryo or—

Prof. Saunders—I think it is really the use of the word 'therapeutic' in the context of these guidelines. The use of the word 'therapeutic' in the context of these guidelines means therapeutic as it relates to the embryo itself. It is not to say that non-therapeutic research cannot have other therapeutic applications in adults or babies or whatever. It is just that, in the context of these guidelines, there is a need to distinguish between doing something on the embryo for the sake of the embryo—which in these guidelines is considered therapeutic—versus the other.

Ms ROXON—Just to be clear, the guidelines basically say, 'Yes, you can do some research on an existing embryo for the benefit of that embryo, and in exceptional circumstances where there is great potential or some other reason, and if a small number of embryos are used, then it is also permissible.'

Prof. Saunders—That is correct.

Dr Tobin—And that is what in these guidelines is called non-therapeutic research.

Ms ROXON—And that is why it has had us all totally confused.

Prof. Saunders—It is the context.

Dr Tobin—That says that non-therapeutic research may be done in these exceptional circumstances.

Ms ROXON—That is why I just wanted to be sure about that. They are still the guidelines as far as you are concerned?

Prof. Saunders—Absolutely right.

CHAIR—Can I just tease that out a little? Is it contemplated or anticipated by those guidelines that if permission were to be given for the non-therapeutic research that that is applied for and considered and granted or not granted on a case-by-case basis—that this is not a gate that you can just walk through; you have to apply to open it, to use an analogy?

Prof. Saunders—That is correct.

Dr Tobin—To NHMRC.

CHAIR—For non-therapeutic research, so that we are absolutely clear, the current guidelines are that you cannot create an embryo for that purpose, but if there is a spare embryo and you can make a case out to say that scientific knowledge would be advanced in a way which satisfies a particular body—and I will come to that in a moment—

Ms ROXON—And there were small numbers?

CHAIR—I was capturing that. To pick up Nicholas's point, you cannot say that we want to do it on the next thousand embryos, but you can say hypothetically, 'We want to experiment on three embryos in order to develop a new stem cell line, because the stem cell lines we have don't meet what we think is a particular problem,' or, 'There is some particular genetic disease factor'—whatever it is; I am not pretending to be a scientist. That is generally what—

Prof. Saunders—That is correct, and an absolute requirement is that there is consent of the donors.

Dr Tobin—And indeed its consent to the particular research proposal. That is somewhere earlier in the document. The conditions are tight-ish.

CHAIR—You have to jump the hurdle together.

Dr Tobin—You have to jump a significant hurdle, yes.

CHAIR—I think we all understand that. Did your guidelines contemplate that the body to whom you must make the application would be an institutional ethics committee?

Prof. Saunders—That is correct.

CHAIR—Let me put on the record my scepticism about the operation sometimes of an institutional ethics committee, and I do it as an insider having been on about five of them. Is there a major public interest case to say that there should be some state or national body? For example, why should not something like it come to AHEC?

Prof. Thomson—The parallel situation in which something like that happens is gene therapy research. All HRECs in Australia are directed that, if they receive an application for research involving gene therapy, they should make it available to the gene therapy and related technologies advisory panel, which is a subpanel of the research committee of NHMRC, and that is in order to give that kind of specialist expertise. That would be a parallel pattern. That does not exist at the moment in relation to research proposals under the artificial reproductive technology guidelines.

CHAIR—I know that you do not have an institutional view on this, because we are discussing it now, but I would be interested in an indication of your views as representatives or members of the NHMRC and AHEC. I put on the record my concern: with a semi-private, public organisation it is easy, because there have been instances in the past where you set up the institutional ethics committee you like and there is no scrutiny and no transparency of the operations of institutional ethics committees, and there is a gap if we are talking about public confidence in what is going on. My question is: what would your view be if we were to hypothetically recommend that, where an application for non-therapeutic cloning involving an excess embryo was involved, it had to at least be referred to, say, AHEC?

Prof. Thomson—The usual grounds for doing that in the past have been the need for expert scientific advice, and that was the basis of establishing GTRAP and the reference for gene therapy research. Here, that would be a question that we have to decide. It seems to me that the guidelines indicate that. The first requirement of 6.4 is that there be a likelihood of significant advance in knowledge. That presumably is more a scientific judgment than an ethical judgment. We would need to get that kind of specialist advice. An established source of that would be a tidy way of addressing compliance with that.

Prof. Saunders—It has just been drawn to my attention that, in the paper that is before you, resolution 2 of AHEC actually says that, until legislation—and it is talking about ART legislation—is introduced in all the states and territories of Australia, the NHMRC should consider the establishment of an expert advisory committee to assist institutional ethics committees which seek advice on the scientific aspects of research projects relating to the application of current cloning techniques. So AHEC itself I think would support the position that you are putting—that somewhere in NHMRC there needs to be embedded some group that can provide scientific support and advice to institutional ethics committees.

Ms ROXON—And that has not been done yet, because the report has not basically been accepted or acted upon.

Prof. Saunders—That is correct, although I would make the general point that AHEC realises that institutional ethics committees need continuing support and that in fact one of the key actions of the current triennium for AHEC is to go out there and engage with institutional ethics committees and try to find ways of providing increased support for them. It is recognised in that way.

CHAIR—I should say that my criticism of institutional ethics committees is not that they do not fulfil a valuable role; I believe there are inadequacies in terms of transparency and accountability in the way in which they are established. I have said that for a long time.

Prof. Thomson—If I could just very briefly comment on that, yes, AHEC accepts that that is the case. There is presently some extensive work on the notion of compliance and better methodology in seeing that the processes of HRECs do conform and that there is some way of assuring that quality happens. We are attending to it. It will take a little while, but it is certainly on the agenda.

Dr Tobin—Just thinking on my feet, I think that, if you were to make a recommendation that research projects of this kind go to an expert body for scientific advice, one thing that might be considered would be whether there are alternative ways of doing the research to get the benefits that are hoped for than research which involves destruction of embryos. That is one thing. The second thing is that I would be very concerned, if you were going to recommend that this research should go to a body, that that body would have the wide representation of views that a body like AHEC is constructed so to have.

CHAIR—We have accepted, at a national level, that there should be a national ethics committee, and AHEC is the committee which has been created for that purpose. I may have missed something, but I have not heard any major criticism of that body, and it does have a wide range of views. That is why I was asking, given that we have a body in place, why we should not be using the body that currently exists.

Dr Morris—I would like to say that the research committee of NHMRC has given to the Gene and Related Therapies Research Advisory Panel three areas to look at: one was gene therapy, one was transplantation, and I think about 12 months ago they added human cloning to that list. GTRAP is very broadly constituted; it has cross-membership with AHEC, Colin Thomson is a member and there are other people there purely for that reason—to give the broader base as well as having scientific expertise. At the moment we are not doing anything on human cloning; it is just there on the understanding that this is really an issue for AHEC. But if it did come back to the NHMRC, there might be a process for making it broader still or making another subcommittee of GTRAP.

Ms JULIE BISHOP—Could I just ask something arising from that. AHEC is part of NHMRC. Is there any case to be put for there being an oversight committee independent of NHMRC?

Dr Tobin—AHEC does have an independence of NHMRC on one matter, and it may be the relevant matter that you want. On the development and issuing of ethical guidelines or guidelines governing the conduct of research on human beings, AHEC has an independence of NHMRC. NHMRC may do nothing other than accept those guidelines and put them before the parliament. It probably has the independence that you are thinking desirable there.

Ms JULIE BISHOP—So you do not see a case for a separate oversight committee?

Dr Tobin—Again thinking on the spot, I do not. I think the problem with GTRAP, as currently constructed, is that it does not have the breadth of representation that AHEC currently does have.

Ms ROXON—But if you were intending to use a body like AHEC with that breadth of representation, given the clear difficulties in having a consensus on anything, isn't that exactly

the sort of organisation that would find it incredibly difficult to be able to approve or not approve a particular process? It is one thing to use a body constructed in that way to give advice on general guidelines and to try to get a cross-section, but, if governments, scientists or whoever it is that make the particular application say, 'We want you to tell us whether this particular research should go ahead or not,' you need someone who can make that decision, don't you? Would AHEC be well placed to do that?

Dr Tobin—I think that is right. My own view would be that AHEC is better spending its time writing good guidelines for HRECs, given the criticism you have of them. It is better spending its time on that rather than making individual judgments in individual cases. That said, though, I think it is not quite right to say there is all this lack of agreement on AHEC. The fact of the matter is that there is an agreed position on these matters in those two documents—1996 and 1998. Whatever you think of it, on both occasions, they were unanimously agreed.

Ms ROXON—Unanimously agreed, but littered with 'these differences of opinion were unable to be resolved'. These guidelines have been agreed to despite all of that. Can I ask a completely different question?

CHAIR—I just want to check on timing. Professor Saunders has to leave at 10.40. I think we spent a fair bit of time on the first point you raised, Dr Tobin, but I also have a question about genetic identity. You were talking about the definitions, which I want to tease out as well. Perhaps if there are questions which are particularly for Professor Saunders, given that he will need to leave in a little over 10 minutes, we could start there and otherwise just try to work through the process.

Ms ROXON—Mine relates to genetic identity too, the views of NHMRC and AHEC on the amendments to the gene tech act and presumably some criticisms you would have for that wording, given the point that Dr Tobin raised. I do not know whether they are things that you want to call—

CHAIR—Can I ask a technical question first. When you referred to genetic identity, was that a reference to mitochondrial DNA as being non-identical or was it differential gene activation?

Dr Tobin—The lack of identity can take many forms. You have mentioned two.

CHAIR—So it could be both of those things?

Dr Tobin—It could be both of those, but this is not my area. All I know is that Dolly is not genetically identical to anybody else. That lack of identity may, as I understand it, have a range of different explanations.

CHAIR—So talking about genetic identity or genomic copying or using language like that, if the objective was to ban the human Dolly, would not legally achieve that?

Prof. Saunders—Perhaps I could start the discussion, and I am sure Colin will have something to contribute here, and so will Clive, I think. As you are aware, the NHMRC was asked to facilitate a discussion amongst the representatives of the states about the issue of

human cloning. This issue of genetic identity did come up. That report is with the minister's office at the moment, so it is not a public document and I cannot actually table it or talk to it in detail. But I think probably around the time—

Ms ROXON—It does not seem to be stopping the Prime Minister talking about it.

Prof. Saunders—I think around the table there was a view that, whilst technically the words 'genetically identical' might be challenged, it probably is an expression that could be defended and could be made operational. The people who were contributing to the discussion felt 'genomic copy' was a better description, but also recognised that it is also imperfect and could be challenged. There could be debate about what 'genomic copy' means as well. So we left that issue open. We suggested that it did need to be thought through carefully in subsequent discussions but felt that, whatever term was chosen, you could make it operationalised to work. We did not think people should be too hung up about that. Would that be fair comment, Clive?

Dr Morris—Yes, it would. I have been liaising with the Interim Office of the Gene Technology Regulator on various matters, trying to set up communications with the NHMRC. They appear to be confident that the provisions that they have can be implemented through the provision of some sort of guidelines fitting underneath the act. I think it is more a matter of turning it round from the starting point to the end point. To give an example, if you have identical twins, they are, by definition, identical. But a scientist being asked to do genetic testing on them would admit that during development there are somatic mutations and various differences, and they may not be fully identical through genetic testing. They are far more identical than people who are closely related. It is a matter of getting a legal and scientific definition or a number of significant places for 'genetically identical' in place.

Ms ROXON—Professor Saunders, what are you at liberty to tell us about the discussions that have been had with the states? We as a committee spent 18 months reviewing this, only to find that obviously there had already been earlier discussions. You have been given a brief to go and talk to the states about whether or how they intend to try to implement this ban that everybody said is a great idea. Presumably the definitions are just one issue that it is difficult for everyone to agree on. What are you at liberty to tell us about where the states are at or how much agreement there is? Or do we have to wait until tomorrow?

Prof. Saunders—I think you will have to wait until tomorrow. What I can say is that there is uniform abhorrence to the idea of being able to clone a human being, and everybody agreed that we need to have in place mechanisms that would prevent that. There was absolute unanimity about that. Amongst the states—

Ms ROXON—It did not take your consulting with all of them to find just that out presumably.

Prof. Saunders—Exactly. Secondly, I think there was a difference of opinion state by state or territory as to whether the way to approach this was to actually do it as part of assisted reproductive technology legislation or whether it should just stand alone in its own right. Some states will be pursuing the matter through one path and others I think saw another way forward. All the states and territories intended to be doing something about this promptly, although the end points varied from state to state again, and that in part depended upon how much

preliminary work had already been done in the states. I think that is really about all I can say at this stage.

Ms ROXON—But there is an intention that that report would be public.

Prof. Saunders—It was a report requested by the health ministers to the health ministers. We did this report to them.

CHAIR—So that has gone to all the state and Commonwealth health ministers?

Prof. Saunders—I do not know.

Dr Morris—It is with the minister's office.

Ms ROXON—Which minister's office?

Dr Morris—This minister: Minister Wooldridge. It is designed as a report to state health ministers and Dr Wooldridge.

Ms ROXON—But it is not provided to the state health ministers.

Dr Morris—Not as yet.

CHAIR—Who comprised the committee?

Prof. Saunders—It was a committee of the states and territories, so all states and territories were represented by people who had been referred by their governments.

CHAIR—So these were departmental officials.

Prof. Saunders—These were departmental officials. And it was convened by the NHMRC. I was the chair of the committee, but this was not an NHMRC function and it certainly does not carry the weight of AHEC or the NHMRC itself.

Dr Morris—Could I also say that the task which was assigned to the NHMRC was a narrowly defined task in that at the Australian Health Ministers Conference when this decision was made health ministers decided that they would work independently on ART legislation. But at the same time they said they wanted to work towards a nationally consistent ban on the cloning of human beings. So they almost split the two tasks to say that you could do a ban on the cloning of human beings without doing ART legislation, whereas the NHMRC would say that it should fit under ART legislation.

Ms ROXON—Has the NHMRC expressed a view that cloning or any regulation that there might be of various cloning techniques should fit within ART?

Prof. Saunders—That is our preferred position. Our preferred position is that it should be part of ART guidelines.

Dr Tobin—That is written into the 1996 guidelines and the 1998 report.

CHAIR—It is clear from your report that you castigate those states that have not done anything—mildly, I should say, but nonetheless you remind them. Professor Thomson, I thought you were going to say something about genetic identity and genomic copies.

Prof. Thomson—I guess this is wearing my hat more as a lawyer than as a deputy chair of AHEC.

Ms ROXON—If you guys wear any more hats, we are going to leave this discussion with no idea what your views are about anything.

CHAIR—Nonetheless, proceed.

Prof. Thomson—The focus on those definitional terms distracts from—and I am largely supporting what Nick Saunders has said—the possibilities of legislation that does not need to be confined to those narrow definitions. They are problematic. Science has now made it clear that human organisms, although called clones, are not genetically identical. There needs to be some language that indicates what is intended to be achieved or the kind of language that I think will end up being effective, but it will need to be supported by the usual approaches to the interpretation of legislation which are not necessarily confined to specific words.

Dr Tobin—Just on the matter of the production of another Professor Saunders, which I take it that people like Professor Antinori in Rome and a professor in the states say they are going to be able to do a large amount of, if we want to ban that activity—leaving aside research on embryos—and I wanted to do it, I would only have to ensure that the organism that I produced had some tiny genetic variability in order to avoid the ban. I cannot see how a ban expressed in any of that language could work.

Ms ROXON—Because of this difficulty in language and our being unsure where the science will go in the future, are we not left with no choice, if we want to prohibit such an activity, but to prohibit the purpose rather than the technology? I understood that there was a great deal of concern about prohibiting purpose rather than process. I do not see how you can avoid that, given these imperfections. Does AHEC or the NHMRC have any reason for thinking that a prohibition that looks at the purpose and endpoint rather than the particular technology is a problem?

Prof. Saunders—The council does not have a view, but certainly in discussions with the states this was a matter that was discussed. There was general support for the position that you are putting. I cannot tell you which countries but there is at least somewhere in the international arena specific reference in their legislation to the purpose of the experimentation as well as the other rules and regulations.

CHAIR—It is also probably fair to note that although they are not legislation the ART guidelines, in describing what are unacceptable practices, refer recurrently to purpose and intent.

Dr Tobin—I think there is another way you can go. You can talk of the more traditional notion of cloning in terms of asexual reproduction or you can talk in terms of production, reproduction or creation by means other than the union of egg and sperm. You can then add in transferring that entity into the uterus of a woman.

CHAIR—That is the Victorian legislation as I recall.

Dr Tobin—Yes, I had not really thought that out but I think you can go that way with the combination of those.

Ms JULIE BISHOP—I just wanted to get clarity on two areas. First—you might have answered this—do you have a position on research on excess embryos that would otherwise be discarded? Would you go so far as to say that it would be unethical not to use embryos that would otherwise be thrown away given that, as I understand it, aborted material is available for research?

Prof. Thomson—No, there is nothing other than what the 1996 guidelines say, and they focus on justifying research on embryos that will risk causing them harm or destruction under certain conditions. However, those conditions only refer to the future by reference to the need for there to be some significant promise of new knowledge.

Ms JULIE BISHOP—So you would not go as far as some of the evidence which has been put before us to the effect that it would be unethical not to use any embryos that would otherwise be thrown away?

Dr Tobin—In fact, there is quite a lot of reference in the 1996 guidelines to the acceptability of allowing embryos to succumb—that is the language that is used. And the emphasis goes into building in the conditions that would make research on those spare embryos ethically acceptable.

Ms JULIE BISHOP—And then just following on from that—and I am not sure if this point was answered—what is your position on the study of existing embryonic stem cell lines?

Prof. Saunders—We have discussed that and the position is we have no position. Technology has moved on since 1996 and we recognise that that is a matter that does need AHEC's attention, but we have been waiting—

Ms JULIE BISHOP—So there is no position.

Mr KERR—Except for the caveat—

Prof. Saunders—Yes.

Mr KERR—I am interested in following up the line that Senator Bishop raised about this issue of surplus IVF material—

Ms ROXON—Has Ms Bishop been promoted or demoted?

Ms JULIE BISHOP—Yes, what’s this ‘Senator’ business?

Mr KERR—Sorry about that.

Ms ROXON—We do have a Senator Bishop, but they do not share many views. They come from the same state.

Mr KERR—I cannot remember who indicated that there ought to be a particular caution around destruction of embryos, but as I understand it, any material that is not destroyed is destroyed. I mean, these embryos may be suffering silent torture in a fridge for an awfully long time. This may be a terribly immoral way to deal with them, but nonetheless, some years on, those that have not been utilised in reproductive use for IVF are in fact destroyed. Whether you wish to use kind language like ‘allowed to succumb’—

Ms JULIE BISHOP—Or thrown away, as I indelicately put it.

Mr KERR—Or whatever, they are killed; full stop. ‘Deaded.’ I just wonder where this sort of special approach to the destruction comes from, given that they are all going to be destroyed.

CHAIR—Just before you answer, Professor Saunders, you will not be discourteous to us if you need to go.

Prof. Saunders—I will stay as long as I can and then go. Thank you very much.

CHAIR—We understand that and I thank you for coming.

Prof. Thomson—I have asked Dr Tobin to answer because she was a member of AHEC at the time the guidelines were worked on. I know of them, but she has a deeper background in them and I defer to her knowledge.

Dr Tobin—The agreement that was reached on the substance of those guidelines was reached in spite of the fact that, behind them, there was a great diversity of ethical views and one of those points of diversity was on the very matter that you raise. Some of the members of that committee thought that allowing embryos to succumb was the equivalent of killing them—as you do—

Mr KERR—I am not arguing it is equivalent to killing them; I am just saying they are killed.

Dr Tobin—Some of the members of that committee thought that allowing embryos to succumb was equivalent to killing them. Some of the members of that committee did not think that. They saw a moral difference between deliberately bringing about the end of the life of the embryo and allowing it to succumb in the way that we often allow sick human beings to succumb without killing them. We saw that we did not need to settle that controversy and that we could get the agreement that we needed—if they were to be researched on, certain conditions needed to be met.

Mr KERR—I understand that, but it is not answering my question.

Dr Tobin—The point I am trying to make is that we did not need to reach agreement about the underlying—

Mr KERR—No, that is not answering the question. The question is this: given that you now have an outcome, you have an agreement—whatever the underlying arguments that were in the construct of that argument you can put aside—that allows IVF to proceed and it does actually mean that there is surplus material, and the actual practice is that that material dies, is killed, or is allowed to succumb—choose your language—at a point in time. Whatever arguments underlay it now cease to have any relevance, you can put them aside. That is occurring, and our inquiry will not affect that—it does not matter. Given that we now kill this material—or allow it to succumb, or what have you—that it has no viability, and whatever insult to its integrity that may have been occasioning concerns with people previously is going to happen, how does that then present us with an issue which says that its destruction is a component of any concern in relation to the set of issues that now confront us, because it is to be destroyed?

Prof. Saunders—I think the diversity of opinion, and it probably exists on both sides of this table, suggests that there is no absolute single answer to the question that you are asking. People will have different views about that, and I think those different views need to be recognised and valued. We have to find our way through the developments of new technologies and the new opportunities for treatment, accepting that there will be a range of views around the place.

Mr KERR—I understand. I am not trying to be provocative.

Ms JULIE BISHOP—Which would be a first.

Mr KERR—I am simply trying to isolate the issue which is essentially whether the moral conundrums, if any, have been resolved by a practical decision agreed to unanimously by your committee, and now implemented in practice. That means that the surplus material, at a point in time, is taken out of the laboratory system, and the practical effect is that it is dead tissue and it is thrown away. Having reached that conclusion, how can you have a specific argument about whether there is a moral dimension to its destruction, given that its destruction has been resolved through a previous process of determination and agreement, which you unanimously adhered to?

Prof. Saunders—I think there will be a range of views about that, accepting the fact that the end point might be death and how you reach that end point.

Mr KERR—How you kill them is—

Prof. Saunders—There would be a range of views around that, and I think I have heard people express those views.

Mr KERR—What are the moral dimensions on how you kill an embryo?

CHAIR—I understand the question that Duncan is raising, but I am going to assert my authority as chairman—

Mr KERR—Do you torch it over a Bunsen burner, or put it out in a storm in the Antarctic?

CHAIR—because we are not going to get an answer that satisfies everyone. We have about 11 minutes before this room is required by Foreign Affairs. There are a couple of matters that we can deal with. I will ask both of them and then see how far we can get. The first is the definition of ‘embryo’, which you raised in your original comments, Dr Tobin; and the second is the comment that AHEC had refused to use the terminology ‘reproductive cloning and therapeutic cloning’ because of the confusion which we have been grappling with for 18 months. Can you make a practical suggestion to us as to what terminology might avoid the ongoing confusion?

Dr Tobin—I would be happy to have a go at the first one. This is the way in which the science has moved on. We now know that there is a whole variety of ways in which you can create an embryo. I think if you are going to be talking about this you will need somehow to recognise that. You will need a definition of ‘embryo’ which is something like any entity, which has the organisation and developmental capacity of that entity that used in the old days to be formed by union of sperm and eggs. You are going to need a wider definition because the union of sperm and eggs is now only one way of producing an embryo. That was really my point.

CHAIR—We need terminology instead of reproductive and therapeutic cloning, particularly therapeutic cloning, because it means all sorts of things, which I have been saying ad nauseam.

Prof. Thomson—We grapple with that. It is something that focuses on cloning of human beings as opposed to cloning of parts of human beings, whether those are cells or something more than cells. That is a simple way of describing what in common parlance is understood. In the existing ART guidelines is we have sought to point out that there is conventional medical research language that is drawn on of non-therapeutic and therapeutic. That has quite a distinct history and meaning different from the way that language has been used in the present debate about cloning. That is at least where the confusion comes from. Given that it might be wise not to use that language at all—

CHAIR—If we use language something like the cloning of human beings for research purposes or cloning of human beings for purposes of implantation and birth, would that be—

Dr Tobin—Or in assisted reproduction.

CHAIR—Or assisted reproduction, would that be—

Dr Tobin—That would be better. There is one further thing I would like to add to that.

Ms ROXON—One of the things that have been troubling me is that everybody agrees that there is a broad range of views within the community or any committee. Whoever looks at it agrees there is a broad range of views, which everyone accepts. We live in this pluralist society. Why would a committee commissioned with the responsibility of overseeing the ethics of certain procedures prohibit something in circumstances where we know there is a broad range of views? If you are in a pluralist society and there is a broad range of views, why would you not say you want there to be some appropriate regulation but not seek to impose your particular view on other people? I accept that this is not answerable in a short time. If you do have a view on this, it would help me. This is one of the things that I have trouble resolving.

Dr Tobin—My way of answering that would be to say that there was that wide range of views on both of those committees. What we saw ourselves as doing was adopting a compromise position, a position that would not satisfy people at one end or the other but would protect the public interest by setting in place a set of regulations that would be broadly acceptable to the community. Could I add to that something which has not come up? It is drawing a little bit of a long bow to add it but this is my only opportunity to talk to you. This is my own thinking on the plane on the way down.

I think it will be pretty clear to you that I hope you recommend the continuation of the AHEC position. I have no idea what you are going to recommend. If you were to recommend something different from the AHEC decision, if indeed you were to recommend that it would be permissible to create embryos for research, I think it would be incumbent on you to build in a mirror image of the whole set of constraints on that activity that are built into the 1996 guidelines. Otherwise you would, de facto, be permitting the development of two kinds of embryos, one of which gets all the protections set out in those guidelines—that is, those that are going to be created for IVF programs, with someone who acts as custodian or guardian, someone who has got to give a consent, someone who may consent to research on them, limits on the amount of time, limits on the number that you can take and limits on what you can do with them.

If you were to recommend the permissibility of creating embryos for research, I think it really would be incumbent on you to build in a mirror image of that whole set of protections and, in particular, ensure that someone acts as custodian or guardian of this embryo and is in the position of giving consent or not to everything that is done to it. Otherwise I think that you would be recommending a position where the odd reckless scientist could act in ways that would be totally unacceptable to the community.

Ms ROXON—I understand your point, and I think it is a good point, but to say that there is only one type of embryo that is allowed to be created now because there are guidelines is really quite wrong. The states set up their own systems, and if a state wants to set up its system and say, ‘Actually, we do not give a damn what is said in that report, we can do it this way,’ we can have seven different systems in Australia.

Dr Tobin—That governs what goes on with public moneys, but I take your point.

CHAIR—We are going to have to finish up unless there are some urgent points.

Prof. Thomson—I just had one partly in response to that. One of the common themes throughout the 1996 guidelines and in the 1998 report about what decisions are made in relation to embryos is the involvement of the provider of the gametes—or the parents, if that is your preferred language. Certainly in relation to allowing embryos to succumb, their preferences are had regard to and their consent is required for research. That is one of the moral underpinnings that has been consistent throughout this debate and something that it seems to me even a committee that overlooks this practice and that contains a wide range of views is likely to regard as significant. That picks up Bernadette’s point that, where there is an asexual process, if you are consistent in your thinking about that kind of guardianship role that the providers or parents have of sexually produced embryos, then you might think it is an appropriate parallel and an appropriate moral position to have someone to consider the interests of that person.

CHAIR—Can I thank you all for coming along—and Professor Saunders in his absence. It has been very useful from my perspective, because I think it has helped to tease out what the actual AHEC position is which, as we have discussed, does allow in some circumstances non-therapeutic experimentation to occur in respective conditions, and that has been useful in itself. The other discussions contained some philosophical issues that we will probably never agree unanimously on, but that is beyond the task of the parliament, I suspect, and also of AHEC. There was just one technical matter, Dr Morris. You provided us with a copy of Dr Breen’s letter of 15 December. Do you have any objections if we accept that as an exhibit to the inquiry?

Dr Morris—With a rider—this was requested yesterday and I remembered your comments on it the night before. There is some language in it that—

Dr Tobin—There is one mistake in it on the third page, which we could very easily show you.

CHAIR—Just explain it. I do not know whether we would ever need to refer to it, but it is just that it arose.

Dr Morris—There are two sentences at the end of the third paragraph on the third page. They are the last two sentences in the long paragraph that begins with ‘The *Ethical Guidelines* and in particular ...’. The second last sentence states:

AHEC said that, in the matter of cloning and related technologies, the fundamental distinction was between the production by cloning of whole human entities (such as human embryos) and the production by cloning of the component parts ...

The next sentence says:

AHEC held that, whereas the latter has been an accepted part of medical and scientific research for over fifty years, the former should take place only in exceptional circumstances.

That is clearly not AHEC’s position. AHEC does not say that cloning should take place only in exceptional circumstances. AHEC says—

CHAIR—So we will delete that sentence.

Ms ROXON—What does AHEC say?

Dr Morris—AHEC says that non-therapeutic research should take place only in exceptional circumstances—

CHAIR—Which is what we have been through. I do not know that we need to rely on the questions being raised. You can provide us with a copy and the cleanest way for us is to have it as an exhibit should a question arise. Before I formally close, again I thank all of you for coming along and assisting us in this task. I am sure that it is not the end or the last word on cloning but, hopefully, we are contributing to an acceptable societal outcome. Thank you very much.

Resolved (on motion by **Mr Murphy**):

That the copy of the letter from Dr Breen, Chair of the Australian Health Ethics Committee, dated 15 December 2000, be accepted as an exhibit to the inquiry noting the clarification made by Professor Thomson.

Committee adjourned at 11.01 a.m.