



COMMONWEALTH OF AUSTRALIA

# Official Committee Hansard

## SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

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

**THURSDAY, 29 AUGUST 2002**

**CANBERRA**

BY AUTHORITY OF THE SENATE

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**SENATE**  
**COMMUNITY AFFAIRS LEGISLATION COMMITTEE**  
**Thursday, 29 August 2002**

**Members:** Senator Knowles (*Chair*), Senator Allison (*Deputy Chair*), Senators Barnett, Denman, Hutchins and Tchen

**Senators in attendance:** Senators Barnett, Mark Bishop, Boswell, Denman, Harradine, Heffernan, Knowles and Stott-Despoja

**Committee met at 3.32 p.m.**

**MATTHEWS, Ms Andrea Paulette, Director, Matthews Pegg Consulting, Consultant to NHMRC**

**MORRIS, Dr Clive Michael, Executive Director, COAG Implementation Task Force, National Health and Medical Research Council**

**PETTIGREW, Professor Alan George, Chief Executive Officer, National Health and Medical Research Council**

**CHAIR**—The committee is commencing its inquiry into the [Research Involving Embryos and Prohibition of Human Cloning Bill 2002](#). I note at the outset the comments in the Selection of Bills Committee report that the bill be referred to this committee to inform the Senate in its deliberations on the bill. The number of senators participating in this inquiry clearly demonstrates the widespread interest in receiving detailed facts to assist senators in making an informed decision on all the issues associated with the bill.

The committee will begin its public hearing program with an introductory briefing on the bill from the National Health and Medical Research Council. The committee has been asked to inquire into the bill, so I intend that this hearing should focus on the provisions of the bill. I would ask my colleagues that their questioning remain focused on the issues that are relevant to the bill and, to that end, I plan to proceed through the bill. If honourable senators wish to ask specific questions about it, may I respectfully suggest that they address their questions as we proceed through the bill.

I welcome Professor Pettigrew and representatives from the NHMRC. Witnesses are reminded that the giving of evidence to the committee is protected by parliamentary privilege and that you should not be asked to give opinions on a matter of policy. I invite you to make your presentation and to answer questions from senators.

**Prof. Pettigrew**—I thank the committee for the opportunity to appear before you to provide this briefing and to offer NHMRC's full support to the committee through your inquiry. The National Health and Medical Research Council was established by an order of the Executive Council of the Commonwealth government in 1936. The NHMRC has, therefore, over 60 years of experience in funding and promoting health and medical research, establishing the ethical framework for research to be undertaken within Australia and providing regulatory recommendations and advice to both Commonwealth and state governments.

On 5 April 2002, the Council of Australian Governments agreed to establish a nationally consistent legislative framework for the prohibition of human cloning and other unacceptable practices, and to regulate uses of excess ART embryos. COAG also gave the NHMRC

responsibility for the development and implementation of this important legislation and assigned to the NHMRC a regulatory function which few national bodies of a similar nature around the world have previously experienced. The NHMRC's involvement in the development of the [Research Involving Embryos and Prohibition of Human Cloning Bill 2002](#) did not, however, start with the 5 April 2002 COAG decision. Members will note from the detailed background briefing that we have provided to the committee that the NHMRC has been actively involved in the administration and support of the processes that led to these issues initially being considered by health ministers and then by COAG. The successful management of these processes by the NHMRC culminated in 12 weeks of intensive work after 5 April 2002 to undertake extensive consultation and develop the proposed legislation for introduction by the Prime Minister on 27 June, thereby meeting the deadline set by the COAG meeting. This work was undertaken in close consultation with Commonwealth and state and territory officials and many other people, as detailed in our submission to the committee. I would like to personally express my thanks and gratitude to my officers and all others involved in the work required in the preparation of this significant legislation.

Much of the debate surrounding the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 has revolved around the relative merits of adult and embryonic stem cell research and the question of whether excess ART embryos should be allowed to be used to obtain stem cells. However, it must be stressed that the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 does not regulate the use of stem cells. What the bill does do is provide for the first time in Australia a strong national framework for the regulation of research on excess ART embryos that would otherwise have been destroyed. The bill will, first of all, provide legally enforceable sanctions for human cloning and other unacceptable practises. It will provide a national licensing body that will consider all applications for a licence to work with excess ART embryos, whether those applications come from ART clinics, university research facilities or private companies seeking to develop the products of stem cell research for consumers. The bill establishes a system for the monitoring and enforcement of prohibited practises, including human cloning, and ensures that research on excess ART embryos is conducted within acceptable community standards and under the conditions of the licence granted, backed up by criminal penalties for any offences committed. Finally, the bill ensures that any member of the public who is interested in this issue will have access to relevant data, such as the number of projects involving excess ART embryos, the nature of these projects and the numbers of excess ART embryos that are used. The legislation establishes a comprehensive, rigorous, transparent and accountable system for the regulation of excess ART embryos. It will provide the Australian community with a level of regulatory certainty on these issues. I am confident that the NHMRC has the experience and expertise to take on the task envisaged by the Council of Australian Governments described in the legislation.

**Senator HEFFERNAN**—I am very new to this committee and so far I have only read the first few pages of your submission, but I have one question.

**Senator MARK BISHOP**—Before you do that, I missed the point made by Professor Pettigrew as to what the bill covered and did not cover. Do you mind repeating that for me, Professor Pettigrew?

**Prof. Pettigrew**—I am happy to repeat what I have said.

**Senator MARK BISHOP**—You said, ‘The bill does not regulate the use of stem cells and the bill regulates use of surplus ART embryos.’ Is that right?

**Prof. Pettigrew**—It regulates research and other practices involved in excess ART embryos.

**Senator MARK BISHOP**—Thank you.

**Senator HEFFERNAN**—The National Health and Medical Research paper on page 10 in paragraph 4 says:

One of the requirements included in the code—

this is the code about what practices are currently considered to be unacceptable—

is that clinics must comply with the NHMRC guidelines, including the requirement that they do not undertake any of the unacceptable prohibited practices detailed above.

What guarantees can you give that that does not happen?

**Prof. Pettigrew**—The clauses that you are referring to are contained in the ethical guidelines on ART. For ART clinics to be accredited to perform their work, it is the requirement of that accreditation that they comply with these guidelines.

**Senator HEFFERNAN**—How do you supervise that? How do you know when someone sneaks back and does a bit on the side?

**Prof. Pettigrew**—The state and territories have responsibility for that.

**Senator HEFFERNAN**—So you cannot make any guarantees?

**Ms Matthews**—You are quite right. One of the major drivers for a nationally consistent regulatory system was the absence of regulation previously. These guidelines are voluntary in nature. While there are indirect penalties that can be applied—

**Senator HEFFERNAN**—Thank you. I notice above that reference that there is some variation in the attitude of the states, that some have legislation and some have a voluntary code. At the present time, if I were to sneak back into a lab at night somewhere, I could get away with it and you would never know.

**Prof. Pettigrew**—The NHMRC would never know, that is correct.

**Ms Matthews**—At the present time there are only three states—

**Senator HEFFERNAN**—So there are no guarantees that it is not going on now?

**Dr Morris**—Even in those states where there is legislation in place there is no guarantee.

**Senator HEFFERNAN**—Thank you.

**CHAIR**—Remembering that I would like to proceed through the bill, I know that Senator Harradine has some overarching questions which probably should be put prior to going to the bill part by part. Are there any members of the committee who have questions specifically dealing with overarching issues before I call Senator Harradine?

**Senator STOTT DESPOJA**—I have some questions but I am happy to go through the bill first.

**CHAIR**—We are wanting to go through the bill, so if you have questions as we proceed, I ask all senators to ask those questions as we proceed, so that we do not jump backwards and forwards.

**Senator BARNETT**—I appreciate that Andrea Matthews is here with the NHMRC. Would you clarify the arrangement there so that we are in the know in terms of the consulting role that Ms Matthews is sharing with the NHMRC?

**Dr Morris**—The NHMRC has contracted Matthews Pegg Consulting to help with the preparation of some of the policy positions we have been working on and to facilitate the meetings we have had with the states and territories in developing the legislation.

**Senator BARNETT**—I am sure there is good reason and experience for that, but what is the history and background of Ms Matthews and the organisation that you have contracted?

**Dr Morris**—Prior to the NHMRC's involvement in developing the legislation, Matthews Pegg Consulting was contracted to help facilitate developing the reports for COAG's consideration on 5 April.

**Prof. Pettigrew**—That contractual arrangement had been entered into with the Therapeutic Goods Administration which had carriage of the matter prior to 5 April when COAG determined that the NHMRC should have carriage of the matter.

**Senator BARNETT**—Is it an organisational thing or is it for scientific advice? I have no idea what is going on.

**Ms Matthews**—Basically our firm specialises in the provision of advice on national legislative schemes. The firm has been involved previously in the development of the gene technology legislation, radiation and nuclear safety and complementary medicines—a range of national schemes. We were approached by the Therapeutic Goods Administration in advance of the National Health and Medical Research Council to assist them in the development of it and in negotiation with jurisdictions.

**Senator BARNETT**—Some of us are new members of the committee, so we are not familiar with some of that history and background. That is why we need help and assistance.

**CHAIR**—Ms Matthews is actually being quite modest. It would be fair to say that she has quite a long involvement in many of these scientific issues, on a consulting basis. It is not as though she has been plucked out of nowhere to advise on this.

**Senator MARK BISHOP**—So does Ms Matthews' firm bring a scientific perspective or a legal perspective?

**Ms Matthews**—Legal, predominantly—I am legally trained; I am admitted as a barrister to the Supreme Court of New South Wales. Members of my team have a scientific background, but we are not employed predominantly for our scientific advice on the issues.

**Senator HARRADINE**—But there was scientific advice, was there, from you?

**Ms Matthews**—Not scientific advice.

**Senator HARRADINE**—What sort of scientific advice was provided to the COAG prior to its meeting on the 5 April, and to the states? We are told by the states that we have to cop it sweet. I have written to the chair, who received the letter only today, asking for a copy of all the papers which were available to the members of COAG so that we can see on what basis it made its decisions.

**Dr Morris**—It is at the discretion of the Prime Minister and the Prime Minister's office whether or not to release that material prepared for COAG.

**CHAIR**—And that request has been made to the Prime Minister's office. We have not had an answer yet.

**Senator HARRADINE**—Thank you. In the preparation of your report to us, you have indicated a number of references, background papers and so forth. You did not mention the senate select committee on the Human Embryo Experimentation Bill. Were you aware of that committee's report?



**Dr Morris**—What is the date of that report? Is it 1983?

**Senator HARRADINE**—It is 1985 or 1986.

**Dr Morris**—We focused on the last 10 years. In developing this report at short notice, we looked over the last 10 years.

**Senator BARNETT**—Are you saying that, at this stage, none of the submissions that are referred to in attachment B, from the witnesses who appeared before COAG and before the NHMRC following the COAG decision, are available to this committee?

**Dr Morris**—The list at attachments A and B are not so much witnesses as people who were invited to attend consultations. Some of those people have given us written submissions, which were used to inform the consideration of the working group in developing the bill for introduction into parliament. In developing written reports of our consultations and in receiving written submissions, at no stage did we inform the participants that their written or oral submissions would be given to any other purpose but the purpose for which they were intended.

**Senator BARNETT**—Can I clarify: are we being denied the submissions that were put to your committee in the consultation process? There are a number of attendees set out in attachment C; the invitees are set out in attachment B. Is that information being denied to our committee?

**CHAIR**—Senator, a request has been made by the committee to PM&C for any relevant information. We do not have a response yet from PM&C.

**Senator BARNETT**—The first request related to the information prior to COAG's meeting on 5 April. This is post COAG, and it is the list of witnesses which appears here. Could you clarify in your response the list of attendees and their submissions to the NHMRC—which presumably you have used to prepare your submission today and on other occasions.

**Dr Morris**—I was just going to confirm that there were two requests. One request was for the information for COAG—the chair has clarified that—and then you were asking about the written submissions that we have received since 5 April in developing the legislation. As I was saying, our advice is that we cannot make that publicly available because we did not gather it for any other purpose than to inform our own group.

**Senator BARNETT**—Whose advice was that?

**Dr Morris**—That was our own internal legal advice.

**Ms Matthews**—I am not precisely sure of the nature of it, but I think the major issue was checking with the people who provided the submissions whether they were comfortable with us providing them to the committee.

**Senator BARNETT**—Is that your legal advice or other legal advice, Ms Matthews?

**CHAIR**—Internal legal advice for the NHMRC.

**Dr Morris**—The issue is publicly tabling the information. If you request the information, then it needs to be kept confidential. I think that is the issue.

**CHAIR**—So it could be provided in camera.

**Senator BARNETT**—So it is available?

**CHAIR**—No-one has ever said that it is not available. It is a case of whether or not the people who have provided this information are prepared to allow it to be used in a public

sense. It is now being suggested that that information can be provided to the committee on a confidential basis but that it not then be used in a public sense for reference.

**Senator BARNETT**—I am still slightly confused. Are we able to access the information—every single submission—that has been put to the NHMRC through your consultation process, as set out in your submission? Is that available on a confidential basis?

**Dr Morris**—What I said was that we would not be able to make that information publicly available without first seeking the permission of the people who gave us submissions. If you were to request it in camera, we could give it to you.

**Senator HARRADINE**—You had running instructions from COAG, didn't you? You had to stick by those. It would be important to know on what basis certain decisions were made. For example, in respect of the use of embryonic stem cells, how much reliance was put on submissions or information provided by Professor Alan Trounson or Professor Williamson? That would be very useful to know. It is no reflection on you, because you are concerned about the integrity of scientific research, aren't you?

**Prof. Pettigrew**—Certainly.

**Senator HARRADINE**—The examples that we have received recently seem to question that rather severely.

**Dr Morris**—Our task is to implement the policy position taken at COAG. You have requested the information that was provided to COAG, which has gone through the Prime Minister's office. We are unable to provide that information ourselves.

**Ms Matthews**—But we are clarifying at the moment whether we can.

**Senator BOSWELL**—Will your authority be investigating what Professor Trounson has distributed on the video and some of the research he quoted in the joint party room, in which he gave note of this research as supporting his position on embryonic stem cells when, in effect, it referred to germ cells, and that research had not been published? Is that something you will be taking up?

**Dr Morris**—That is beside the issue of the bill. We are here to give evidence on what is in the bill.

**Senator BOSWELL**—Who investigates that?

**Dr Morris**—I believe that the Prime Minister has asked for an explanation and people are expecting Professor Trounson to clarify his comments.

**CHAIR**—I remind honourable senators that the reason behind the reference of this bill was to assess the bill, not to quiz the NHMRC as to why they have made certain decisions. They have had to try to implement the decision of COAG, not to try to influence the decision of COAG. There is a difference there.

**Senator BOSWELL**—I take your point, Madam Chair, and it is a good one. I understand that they have had to implement the COAG decision. What I am concerned with is who investigates some of this information now. It is a simple question: who investigates the information that is clearly coming through that is untrue?

**CHAIR**—The Prime Minister has asked for an explanation of Alan Trounson's evidence, and I think it is fair to say that there has been some misrepresentation on both sides for which clarification has been sought. This is not the role of the NHMRC. Could I direct the committee to examination of the bill instead of justification of various decisions.

**Senator BARNETT**—Could I respond on two counts. I am not aware of misrepresentation of the science or ethics on one particular side only, and that is what the Prime Minister is investigating—that is my understanding. I would not want any allegations or aspersions levelled at the other side unless there was evidence of misrepresentation. I am only aware of an investigation by the Prime Minister's office with respect to Professor Trounson's alleged misrepresentation. Secondly, the reason I was asking the question—and it has been picked up by Senator Boswell—is that the submission that has been put to us by the NHMRC is based obviously on information and advice. You have talked to witnesses and listened to their views, and have read their submissions, and you are putting advice to us today. We have had serious allegations of misrepresentation in the last few days and the concern for the committee is whether some of that misrepresentation formed the basis of your deliberations, your views or your perspective on the bill. We need to validate the information before the committee. Otherwise, we are left not sure what evidence is correct and what evidence is not correct.

**Prof. Pettigrew**—In my opening statement I commented on the fact that much of the debate at the current time is about adult stem cells and embryonic stem cells. The legislation, as we have framed it following the COAG decision, has no direct comment or wording with respect to stem cells insofar as we were required to develop legislation which regulated the research environment using excess IVF embryos.

**Senator BOSWELL**—Could I get back to the basic question. It is a bill about the successful bid, who went through it and evaluated—

**Prof. Pettigrew**—The NHMRC was not involved in any way in the assessment.

**Senator BOSWELL**—That may be so, but who did evaluate it?

**Prof. Pettigrew**—I cannot answer that question, Senator. That was carried out by another portfolio.

**Senator BOSWELL**—Which portfolio carried that out?

**Prof. Pettigrew**—I understand it was the science division of the Department of Education, Science and Training. That is my understanding. I do not know if there are other parties involved.

**Ms Matthews**—We should clarify as well that we spoke to people in the development of the bill after 5 April. So in our discussions with them we have said, 'Look, the policy parameters have been set by COAG. We are interested in your perceptions of how we have done interpreting and implementing COAG's decision in terms of the bill. So, with those people, we did not have discussions about the relative merits of the use of excess ART embryos, or not. Rather, within the parameters of the COAG decision, we discussed whether the bill and particular provisions and definitions—those types of thing—address those issues.

**Dr Morris**—If I could clarify from what Senator Barnett was saying, the submission that we provided today is not based on submissions or evidence given by anybody else. It is an attempt to give background information on the processes which have gone on to date and a little bit of information on what is in the bill. As Ms Matthews said, in the consultations we have had to date, we provided the attendees with an exposure draft of the legislation and we limited the consultation to the exposure draft of the legislation, not to the peripheral policy issues. The policy parameters were already set for us.

**Senator HARRADINE**—Professor Pettigrew, you said—did I hear it wrongly?—that you did not mention embryonic stem cells at all.

**Ms Matthews**—That the legislation—

**Senator HARRADINE**—I am sorry; I was asking Professor Pettigrew.

**Prof. Pettigrew**—The request of the NHMRC was to develop legislation on the use of excess IVF embryos.

**Senator HARRADINE**—I thought you said just a minute ago that you had not said anything about embryonic stem cells.

**Prof. Pettigrew**—No, I didn't.

**Senator HARRADINE**—I was going to point out to you page 37 of the explanatory memorandum. Presumably this was prepared by you?

**Prof. Pettigrew**—Yes.

**Senator HARRADINE**—That says, 'ES cells have been reported to have potential to treat cancer, Alzheimer's disease, Parkinson's disease, paraplegia and other diseases.' Have you had reports of what number of people, including Professor Colin Masters, have said made that Alzheimer's claim? This is on page 37.

**Dr Morris**—Page 37 of the explanatory guide?

**Senator HARRADINE**—You have just put that in there without any information for us at all.

**Prof. Pettigrew**—Where is this, Senator?

**Senator HARRADINE**—This is on page 37 of the EM. What I am trying to get at is the question of academic integrity. Presumably the NHMRC is very concerned about the importance of academic integrity and of the good name of science. Surely we can ask you about the good name of science. We have seen examples in the recent week about what appears to be not an excellent scientific approach. I am aware of course that Monash University might deal with the matter, but your chairman is from Monash University, is he not, Professor Saunders?

**Dr Morris**—That is correct.

**Senator HARRADINE**—He is both chairman of the NHMRC and the Vice-Chancellor, isn't he?

**Prof. Pettigrew**—No, he is the Dean of Medicine.

**Senator HARRADINE**—I am sorry; he is the Dean of Medicine of Monash University. Indeed, your chairman of the research committee, Professor Anderson, who is also from Monash, would be very interested in that particular issue. Was it or was it not an improper use of information by Professor Trounson in respect of this particular matter?

**Prof. Pettigrew**—I am unable to answer that question, because I am not privy to the information that Professor Trounson presented in the joint party room. I have no evidence or information about it.

**Senator HARRADINE**—I have the actual document here that he was quoting from. It had not been published in a peer review journal.

**Dr Morris**—I do not know why you are asking us these questions.

**Senator HARRADINE**—I am asking you on what peer review journals you base your claim on page 37.

**Dr Morris**—We can probably give you the information sources that were used.

**Senator HARRADINE**—Peer review journals?

**Dr Morris**—We would have to take that on notice and find the information sources. The sentence says ‘ES cells have been reported to have potential to treat cancer, Alzheimer’s disease’ and so on. There are probably numerous reports in peer review journals that would say there is potential—I am sure we can find you some.

**Senator HARRADINE**—That in fact there have been cures?

**Dr Morris**—It does not say that; it just says ‘potential’.

**Senator BOSWELL**—How do you define ‘potential’?

**CHAIR**—Before we proceed, we have a minor technical problem in that Senator Boswell is not a participating member through Senate process. That can be rectified through the Senate. In the meantime, I seek the approval of the voting members of the committee to allow Senator Boswell to participate today. There are no objections; it is so ordered.

**Senator HARRADINE**—Could I go to the question of the number, in respect of the use of embryonic stem cells from the destruction of a human embryo for that purpose, and the numbers on the IVF, 70,000? How many of those are to be utilised? How many of them have you assessed would need to be utilised for the purpose of developing tissue for the cure of diseases, since you have mentioned it here?

**Dr Morris**—Firstly, when COAG met on 5 April they requested that the NRMRC report back to them within 12 months on the adequacy of supply of excess ART embryos because there was a lack of knowledge as to how many embryos would actually be made available. Although the number of 70,000 has been quoted widely, that number—

**Senator HARRADINE**—For ES cells?

**Dr Morris**—No. This is availability for research. I just wanted to say that the 70,000 in storage are not necessarily available for anybody. If they are in storage, then they are probably owned by the couple for whom they were created, and the couple have not yet made a decision.

**Senator HARRADINE**—I asked an absolutely specific question. How many are expected to be needed to be utilised for the cure of disease?

**Dr Morris**—Excuse me, Senator, I misunderstood your question. I do not think we could give you a number as to how many are needed. I do not know why you would expect us to know that.

**Senator HARRADINE**—Are you not aware of the official body for reproductive technology in South Australia?

**Dr Morris**—Yes.

**Senator HARRADINE**—Haven’t you read their web site?

**Ms Matthews**—The Reproductive Technology Council in South Australia?

**Senator HARRADINE**—Yes, the Reproductive Technology Council.

**Dr Morris**—We are aware that they have a web site, yes. We have seen their web site.

**Senator HARRADINE**—I am getting to the point. Most embryos in Australia will be used, according to the Reproductive Technology Council, for infertility research and not stem cell research. In fact, yesterday, Professor Hearn, at the vital issues conference, said a maximum of 200.

**Senator BOSWELL**—Is that a division?

**CHAIR**—Yes, it is a division. Could I just say, Senator, that the difficulty we have here at the moment is that you are putting questions to the NHMRC that are better directed to the scientists. The NHMRC are the ones who have simply implemented the decisions of COAG.

**Senator HARRADINE**—Yes, I understand that.

**CHAIR**—It is very difficult for the NHMRC to give answers that scientists are meant to be giving about the various merits of one way or the other.

**Senator HARRADINE**—But in their consultations, haven't they asked that question? Surely to goodness they have asked that question. That is a fundamental question. I am going through the rest of them as to why the rest will be needed.

**CHAIR**—I have to go. We need to suspend the sitting of the committee.

**Proceedings suspended from 4.09 p.m. to 4.14 p.m.**

**CHAIR**—Dr Morris, I think you were about to respond to Senator Harradine's question.

**Dr Morris**—Senator Harradine, could you please repeat your question?

**Senator HARRADINE**—I mentioned the reproductive technology department of the Department of Human Services in South Australia. They assess that the stem cell side of this is certainly not the big thing that is involved. The public have been told it is all about stem cells. But you have said, have you not, that the embryos are also for the derivation of stem cells, for examining the effectiveness of a new culture medium used in ART practice, for better understanding of embryonic development and fertilisation, to train clinicians how to cut up embryos, to examine gene expression patterns of developing embryos and improving ART techniques? Will there not also be toxicology studies on live human embryos and the testing of new drugs on humans rather than on animals? How many of the embryos are going to be used for all those purposes?

**Dr Morris**—The legislation seeks to take an even regulatory hand over all potential uses, so that each use will go through the same two levels of scrutiny—at the local human research ethics committee level and at the national level through the NHMRC licensing committee. Some uses, of course, would require more embryos than others. I cannot give you numbers on any particular use and I cannot tell you which use would gain the most embryos.

**Prof. Pettigrew**—The NHMRC licensing committee is specifically described in the legislation to take account of, in its own view, the requirement for undertaking the research on using human embryos before it issues a licence.

**Senator HARRADINE**—We are being asked to buy a pig in a poke if we do not know to what extent these so-called excess embryos are going to be used, and for what purpose. The public have been told that they are ES cells, and the explanatory memorandum is not much help along that line. That is why I am asking the question. Do you agree with the South Australian official organisation that, really, the majority of stem cells are not going to embryonic stem cells?

**Ms Matthews**—In the explanatory guide, we have tried to flag that, yes, the legislation regulates all uses of excess ART embryos aside from the exempt uses. That may include use of embryos from the derivation of stem cells or use of embryos for quality assurance training, as those uses are currently occurring in five jurisdictions in Australia. But as to how many are either currently being used in those jurisdictions without legislation or how many may be used in the future, we are not able to comment on that.

**Senator HARRADINE**—You have had no advice at all about that?

**Ms Matthews**—About how many are planned to be used in the future?

**Senator HARRADINE**—Yes.

**Ms Matthews**—No.

**Senator HARRADINE**—No advice at all as to how many it is thought would be used for the embryonic stem cell research?

**Ms Matthews**—Nationally, I would say that we do not know how many embryos people are intending to use should the legislation be passed. But one of the criteria that the licensing committee must examine is the number of embryos necessary to achieve the goals of the project, whether there is likely to be a significant advance in knowledge as a result of the use of the embryo and whether it could be reasonably achieved by using means other than embryos. That is one of the criteria that COAG set in terms of the matters that must be considered by the NHMRC licensing committee when they look at applications.

**Senator BARNETT**—This seems to be a bit of a touchstone point for the committee. I want to clarify what you have just said. You have received submissions and presentations from dozens and dozens of witnesses throughout Australia and you are advising us that you have never, in any of those submissions, received advice which says that a certain number of human embryo are required, in human embryo research, for curing purposes. That was the question that Senator Harradine asked—embryo stem cell research for cure purposes. You have advised us that you are not aware of that number.

**Dr Morris**—We can look through our submissions and see how many people gave us numbers, but as I said before, the object of our consultations was to inform the development of the legislation. As I was saying to Senator Harradine before, the NHMRC has been asked by COAG to provide it with a report on the availability of embryos, which will fully cover a lot of the issues that you are talking about. In relation to the legislation, I do not quite see where you are aiming.

**Senator BARNETT**—Yesterday, Professor Hearn provided advice that a maximum of 200 out of the 70,000-odd, in his expert view, would be required for human embryo stem cell research for cure purposes. We had a presentation from Professor Alan Trounson to the joint party room, indicating that he thought approximately 20, but at maximum 50. That was obviously not very many. You are advising that you cannot remember the number, or there were not any numbers put in the submissions in the full consultation process you have had all around Australia in the last couple of months?

**Dr Morris**—Senator, we have not been asking people for numbers. If people have provided numbers, that was not relevant to developing the legislation. What I am saying is that we can look through it.

**CHAIR**—Senator, that is not the role of the NHMRC in this matter. They were given criteria that they had to fulfil. They went out and got information on that and how the COAG decision could be implemented. What I am fearful of is that you are now starting to ask NHMRC for opinions about which they have no control. They have been asked to do a job.

**Senator BARNETT**—Madam Chair, the NHMRC have prepared the explanatory memorandum.

**CHAIR**—That is precisely right.

**Senator BARNETT**—They have made certain assertions in this explanatory memorandum, particularly at page 37, and presumably they have information and evidence to back up their assertions set out in the explanatory memorandum.

**Senator HEFFERNAN**—Could I ask whether you personally have read the submissions, or whether you got a consultant to read them for you?

**Dr Morris**—I have read most of the submissions.

**Senator HEFFERNAN**—You have read them all personally?

**Dr Morris**—I have seen them all. There are a considerable number of submissions,

**Senator HEFFERNAN**—Did you rely mainly on your consultant?

**Dr Morris**—We worked as a team on developing the submissions, summarising the submissions and going through the key issues which were raised in each submission. I have seen a significant number of them.

**Senator HEFFERNAN**—You have seen a significant number, but have you read them?

**Dr Morris**—I have read a significant number of them.

**Senator DENMAN**—Do you sit down as a team and discuss any controversial issues in the submissions? Is that how you do it?

**Dr Morris**—If you would like, I can take you through the process that we used in developing the legislation.

**Senator DENMAN**—That might be very useful, thank you.

**Dr Morris**—Following the COAG decision at the COAG meeting on 5 April and carriage of this task being given to the NHMRC, we reconstituted what had been called the COAG implementation working group. That is a working group made up of Commonwealth and state jurisdictions with officers from the health departments and the premiers' or chief ministers' departments of each jurisdiction, as well as officers from the Commonwealth, including the Department of Prime Minister and Cabinet. We organised a series of meetings in which to take forward the issues in developing the legislation.

Given the time available between the middle of April and the date when the legislation was to be tabled—the end of June—we developed a fairly detailed project plan, which included 10 days of consultation. We gave ourselves a target to develop an exposure draft of both the bill and an explanatory memorandum, including a regulation impact statement. We consulted with the states in developing lists of appropriate people in each jurisdiction with whom we could consult. We worked with the states in developing the legislation and that, of course, involved the Office of the Parliamentary Counsel, who did the drafting of the bill based on the drafting instructions that we developed through the COAG implementation working group. We also sent out letters of invitation to invitees in each jurisdiction and, in general, we invited every name that was provided to us by each jurisdiction to the consultations. The consultations occurred from the end of May to early June over a 10-day period, which gave us approximately three weeks to finalise the legislation for introduction to parliament.

**Senator DENMAN**—Thank you.

**Senator STOTT DESPOJA**—I have a general question before getting into the specifics of the bill. It relates to some of the discussions and the undercurrents here. There has been discussion sparked this week among senators and members, as a consequence of a presentation at a breakfast from Dr Prentice. He was asked if there were any researchers undertaking research on both embryonic stem cells and adult stem cells. I understand that he responded that he was not aware. I am wondering if you are aware of researchers in Australia. I believe Monash may be one institution where there are researchers undertaking research on both adult and embryonic stem cells.



**Dr Morris**—Yes, I believe there is at least one. Associate Professor Martin Pera is undertaking research.

**Senator STOTT DESPOJA**—Thank you.

**CHAIR**—I need to remind the committee that we are not here to evaluate the various methods of embryonic stem cell research versus adult stem cell research.

**Senator STOTT DESPOJA**—Thank you, Chair. It was just for the clarification of the committee because Senator Harradine was indicating that he believes that is in relation to animal stem cell lines.

**Dr Morris**—You asked about adult versus embryonic.

**Senator STOTT DESPOJA**—I asked generally, yes.

**Dr Morris**—A lot of researchers who are using animal embryonic stem cells may use human embryonic stem cells, or both. It is quite common to use animal models before using human models. In the scientific literature, the two seem to be quoted interchangeably. It is often difficult to know where the work was undertaken when it is reported in the literature or the media.

**Senator STOTT DESPOJA**—Maybe we can chase that up with Professor Pera.

**Senator BARNETT**—It is a fair question. Can you clarify for the committee what research is being undertaken in Australia in terms of the human embryonic stem cell research currently, and the adult stem cell research? Is that something that you can assist the committee with?

**Prof. Pettigrew**—In broad terms, the NHMRC is currently funding approximately \$10 million worth of research utilising stem cells. The vast majority of that is utilising adult human stem cells. There are two projects currently under way utilising human embryonic stem cell lines—that is, human embryonic stem cells that have been derived elsewhere.

**Senator BARNETT**—What are those projects and where are they?

**Prof. Pettigrew**—Both of those projects, to my recollection, are at Monash University.

**CHAIR**—We will now come back on to the bill, because the bill is not canvassing the various merits of adult versus embryonic stem cells. I ask honourable senators if we can go to the bill and work through the bill and direct specific questions in relation to the bill to the NHMRC.

**Senator BARNETT**—There are two questions that came up before. I would like clarification of the answer, through you, Chair. The first related to how many human embryos were required for human embryo stem cell research. Dr Morris, you were not sure because you had not had a comprehensive look at the submissions that were put. Could you take that on notice and come back to the committee with advice once you have reviewed the submissions?

**Dr Morris**—There are two questions there. The question of how many embryos would be required for embryonic stem cell research is a question that cannot be answered. It is one where we do not know where the science is up to. In relation to looking at our submissions and seeing if people did actually give us numbers, we are quite happy to do that.

**Senator BARNETT**—Can you advise us of the answer?

**Dr Morris**—Yes.

**Senator BARNETT**—The second question related to access to the submissions. What was the decision of this committee and/or NHMRC in regard to our access to the submissions that have been made to the NHMRC?

**CHAIR**—I thought Dr Morris was going to investigate as to whether—

**Dr Morris**—Yes; our position is that we could provide them in camera but we cannot make them publicly available.

**Senator BARNETT**—So from this committee's perspective they are available in camera?

**CHAIR**—If that is the wish of the committee. Is that the wish of the committee?

**Senator MARK BISHOP**—Why would they have to be in camera?

**CHAIR**—Because there has not been approval given by the people who submitted information to make it publicly available. The NHMRC is not in any position to be able to say that those documents are publicly available, and it is a huge task to ask them to contact each and every one of those people, whereas the NHMRC is offering to have it given to the committee on an in camera basis.

**Senator BARNETT**—Presumably, once we have reviewed them or once they have been made available in camera, we can always ask, via a letter or a phone call to the author of the submission, whether they could be made public if required.

**CHAIR**—If required, but with no public release of the whole or any part of the document until specific approval has been granted. Is there approval to be given for the committee to have those provided in camera? There being no objection, it is so ordered. I will now come to the bill. I want to proceed in an orderly fashion. If we are going to fly all over the place—

**Senator BOSWELL**—I do not know how we do that, because I have questions but I do not know which section of the bill they relate to. Can I ask a couple of questions?

**CHAIR**—Yes.

**Senator BOSWELL**—Thank you. Can the licensing committee licence research that will be done by overseas affiliates of the Australian organisation?

**CHAIR**—I point out to you that in the bill the licensing committee comes under division 3. You will be able to see in the contents of the bill where your questions probably slot in. Can we start at part 1 and ask whether there are any questions on the short title, the commencement, the object of the act and so forth, and move on to part 2, prohibited practices. I am sure, Senator Boswell, the questions you have will be able to be slotted in and you will see the various headings under which they will come.

**Senator HARRADINE**—Presumably on the provisions relating to commencement dates we would need to ask somebody other than the NHMRC.

**Dr Morris**—It depends on the question.

**Senator HARRADINE**—It is a simple one: why?

**Dr Morris**—In relation to the 28 days after royal assent?

**Senator HARRADINE**—Yes.

**Ms Matthews**—Our advice is from the Criminal Law Division of the Attorney-General's Department. Because those offence provisions carry significant criminal penalties, their advice was for commencement 28 days after royal assent.

**Senator HARRADINE**—I understand that.

**Senator BARNETT**—My questions relate to the legality of the bill, the legal advice that you have obtained on the enforceability of the provisions of the bill and how confident you are about the constitutionality of the bill.

**Ms Matthews**—The advice we have received from the Australian Government Solicitor has been that using a range of constitutional powers, as we do in clause 4, provides considerable coverage in relation to the legislation, but not complete coverage. Hence, there is a need for corresponding state and territory laws to confer powers on the NHMRC licensing committee to enable full constitutional coverage of all activities and persons in Australia.

**Senator BARNETT**—So that we all understand this, we pass this bill and then it would require each state and territory to pass its own legislation—

**Ms Matthews**—Corresponding laws.

**Senator BARNETT**—to confirm only the establishment of the licensing committee, or for other purposes? Can you expand, please?

**Ms Matthews**—How it works is that the NHMRC committee will be established and the legislation will commence operation. The constitutional powers of the Commonwealth—

**Senator BARNETT**—When you say the NHMRC committee, do you mean the licensing committee as set out in division 3?

**Ms Matthews**—That is right. That all takes effect six months after royal assent.

**Senator BARNETT**—Sorry, when you say six months after royal assent, it is within six months, isn't it?

**Ms Matthews**—Yes; then the committee can start issuing licences and the regulatory scheme begins. As the Commonwealth does not have a constitutional power specifically relating to this matter, we have used a range of constitutional powers to provide some level of coverage in relation to this legislation. Our advice is that the coverage is significant, because we are able to attract the trade and commerce power and corporations power, so we are able to cover organisations engaged in interstate trade and commerce and corporations. However, because the coverage is not absolutely complete, we cannot be guaranteed to catch individuals, for example, under the scope of this legislation. Our expectation would be that everyone would apply for licences, but if it came to the point where we initiated a prosecution and there was a challenge to the authority of the Commonwealth legislation over a particular person, it may be subject to High Court challenge because the constitutional coverage is not complete. That is the advantage of having corresponding state and territory legislation—it gives us complete coverage of all people and activities.

**Senator BARNETT**—So the state and territory corresponding legislation must reflect all of the provisions of this bill, or is it going to be different from this bill? Do you have a draft bill floating around?

**Ms Matthews**—Our advice from the states and territories at the moment is that they are likely to do it in one of two ways. Unfortunately, they do not have drafts. We have not seen a draft bill floating around at this stage. The two ways they would do it would be to either essentially mirror this legislation or apply this legislation. In other words, instead of establishing all of the licensing committee provisions, they would just say, 'It is an offence under this legislation to undertake anything covered here without a licence from the NHMRC licensing committee.' Effectively, it would be a shortened version of this bill that cross-references this bill. So there are two ways that they would do it: they would either essentially mirror this legislation or apply this legislation in their legislation.

**Senator BARNETT**—So you do not have a draft bill and you are not sure which alternative is the way to go, or have you got advice that both alternatives are watertight?

**Ms Matthews**—Different states may use different alternatives. For example, some jurisdictions with existing legislation would need to amend their existing legislation to reflect this. At the moment all jurisdictions have agreed to enact corresponding state legislation. Parliamentary counsels have been working together through the Parliamentary Counsels Committee around Australia to try to develop provisions that are as tight as possible to enable states to confer powers on the NHMRC committee.

**Senator BARNETT**—So at this stage we do not have any confirmation that it is watertight?

**Ms Matthews**—The state legislation is not drafted yet.

**Senator BARNETT**—You have the trade and commerce power and you have the corporations power. How is an individual covered under this legislation?

**Ms Matthews**—It would happen under the state legislation.

**Senator BARNETT**—At this stage, without any state or territory legislation, an individual is not covered by this bill?

**Ms Matthews**—It would depend on the activity being undertaken. For example, because we are using the international power as well, there may be some application. If they were doing human cloning, for example—

**Senator BARNETT**—You mean the external affairs power?

**Ms Matthews**—That is right. It is debatable whether that would cover them or not in the absence of conventions. But in terms of matters of international concern—

**Senator BARNETT**—Which convention is relevant?

**Ms Matthews**—At the moment, our advice from the Australian Government Solicitor is that there is no convention that can be directly relied upon to support this bill. However, depending on the particular circumstances of the case, it may be possible to argue that it is a matter of international concern in terms of the common law surrounding the power. In any event, there may well be conventions before too long on human cloning issues.

**CHAIR**—Senator Boswell, it is very hard to hear while there is another conversation going on.

**Senator BOSWELL**—My apologies. I understand that I am now a member of the committee. It has gone through the Senate, and they put it up to the Whip.

**CHAIR**—How is that for Senate efficiency!

**Dr Morris**—Excuse me, Chair. I am afraid I am needed in the House, but I will be back as soon as possible.

**CHAIR**—Thank you.

**Senator BARNETT**—The bottom line, from the committee's perspective, is that we cannot be sure that the legislation covers individuals—

**Senator HARRADINE**—Chair, is Dr Morris—

**CHAIR**—Dr Morris is required in the House of Representatives by the Prime Minister for the summing-up of the bill. Professor Pettigrew and Ms Matthews are able to continue to

provide answers to the committee. The timing of the House of Representatives summing-up is beyond our control, Senator.

**Senator HARRADINE**—It sure is.

**CHAIR**—As are most of the things that the House of Representatives do.

**Senator BARNETT**—I am just trying to get my head around it because we have to be upfront about this. You are saying that, unless the state and territory legislation is passed, certain provisions of the bill may not be constitutional, and certainly not with respect to individuals, and certain provisions of it may be voidable or voided by even corporations as well.

**Ms Matthews**—There may not be complete constitutional coverage, so that if a prosecution were taken under this legislation of an individual, for example, they may be able to initiate a challenge to that on the basis that the Commonwealth did not have complete constitutional coverage of them in the absence of any state and territory legislation—that is right.

**Senator STOTT DESPOJA**—Do you have a commitment from the states, or was there one under the COAG agreement, that would ensure that in that six-month transitional period the states would introduce complementary legislation, and are you confident that that deadline will be met?

**Ms Matthews**—The COAG decision was that the states would introduce corresponding state laws. In terms of timing, I am not aware of a commitment at premiers level about when they would propose to introduce legislation. Certainly at officials level there has been every intention to try to put the legislation forward and introduce within that six-month period, but I am not aware of commitments from premiers in terms of the precise timing for when they will be aiming for introduction and passage.

**Senator STOTT DESPOJA**—Insofar as there is a six-month period, I guess that is an arbitrary period, but it is one in which you think it is quite possible to have drafted and enacted complementary legislation?

**Ms Matthews**—A number of states have indicated at officials level that that is their intention.

**Senator STOTT DESPOJA**—But we have no guarantee?

**Senator HEFFERNAN**—If there were elections, and a whole lot of political paraphernalia got in the road, could that be two or three years in some states?

**Ms Matthews**—It could, potentially. There is some discussion about an intergovernmental agreement committing jurisdictions to certain time frames. Again, as an IGA, it is not legally enforceable.

**Senator HEFFERNAN**—In the meantime, if the horse bolted it would be a waste of time trying to shut the gate?

**Ms Matthews**—The difficulty is the absence of a specific constitutional power on which to rest this legislation. We have tried to gather together as many as we possibly can, but we recognise that that is not complete and that, yes, we are dependent on states introducing corresponding state laws to get absolute coverage.

**Senator HEFFERNAN**—Which means there could be a whole lot of political complications, depending on who had the balance of power in what camps?

**Ms Matthews**—Yes.

**Senator HEFFERNAN**—Very interesting.

**Senator BARNETT**—Do you have advice other than from the Australian Government Solicitor?

**Ms Matthews**—Not on the constitutional aspects, I do not believe.

**CHAIR**—Are there any further questions on part 1? We will go to part 2.

**Senator HARRADINE**—On human cloning, I noted that in your report to us—which we received today and which I have read through—you have suggested that the prohibition on cloning provisions of the Gene Technology Act and its regulations will no longer be needed. Is that right?

**Ms Matthews**—That is right. One of the components of this bill—schedule 1—is to repeal clauses 192B, 192C and 192D of the Gene Technology Act, if that was your question.

**Senator HARRADINE**—I have that in front of me, yes. Are you saying that the definition of cloning in the Gene Technology Act is the same as is being proposed here in this legislation?

**Ms Matthews**—No, they are not the same definitions.

**Senator HARRADINE**—What is the difference?

**Ms Matthews**—I do not have the gene technology one to hand.

**Senator HARRADINE**—I have. This piece of legislation, section 192B, which you are proposing to delete, says:

Cloning of human beings is prohibited—

And it goes on to give the prohibition. Section 192B(2) says:

Cloning of a whole human being means the use of technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical to the original.

I am not going to carry on that argument that we had on the gene technology legislation. I happen to believe we have missed out on the mitochondrial DNA, as we discussed at that time. But I do propose to raise the question as to how that is covered by this legislation. This legislation says:

A person commits an offence if the person intentionally—

and I do not know why it does not have ‘recklessly’ there—

creates a human embryo clone.

Does that mean the same thing in this legislation?

**Ms Matthews**—No.

**Senator HARRADINE**—What is the difference?

**Ms Matthews**—A human embryo clone is defined in this bill to mean a human embryo that is a genetic copy of another living or dead human. But, in order to address the concern that I think you flagged with the gene technology legislation, we have included an express provision saying that, in order to establish that it is a genetic copy of a living or dead human, it is not necessary to establish that it is an identical genetic copy, only that the set of genes has been copied to enable point mutations.

**Senator HARRADINE**—That is not the point to which I am trying to refer. I am trying to refer to the use of the words ‘of a whole human being’. The definition that is contained in this

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legislation, which talks about the cloning of human embryos, which says that a human embryo clone means a human embryo that is a genetic copy et cetera, says that that it is a human embryo. Is that covered, at this point, by the gene technology legislation? Would the gene technology legislation, at this point, ban the cloning of a human embryo?

**Ms Matthews**—I would probably have to take that question on notice and look again at the gene technology provisions. Certainly we have attempted to address some of the concerns that were raised in relation to the Gene Technology Act in this definition—

**Senator HARRADINE**—But it is very serious. I am surprised that you do not have that information for us.

**Ms Matthews**—I am not sure that I understand your question.

**Senator HARRADINE**—I am asking you specifically about the use of a full human being. In relation to a full human being, under gene technology, does that mean that at the point in the somatic cell nuclear transfer process where there is a fusion of the somatic cell with a ‘donated’ egg, when the pro-nuclei occur, that is a full human being?

**Ms Matthews**—In the gene technology legislation as I understand it, there is no definition of whole human being, so I guess it is subject to discussion about whether that incorporates an embryo, a cell, an egg or an egg in the process of fertilisation. We believe that that is clarified in this legislation. Underpinning it is the premise that a human includes a living or dead human embryo.

**Senator HARRADINE**—So why would you be abandoning that legislation? Clearly there is an entity which is human at that particular time because the RNA is present where it is not present in the gametes. I ask you the simple question as to why it is proposed that those provisions of the gene technology legislation be repealed. Are you saying that this legislation will ban the cloning of a human embryo for whatever purpose, whether it is for the purposes of developing to the implantation stage for the implantation of the embryo into the uterus and whether it is to ban the cloning of a human embryo for the purposes of growing that human embryo to the 14-day stage for the purposes of utilising it for drug testing or whatever? Is it all banned?

**Ms Matthews**—If I understand you correctly, my understanding is that during the Senate debate of the gene technology legislation it was clear that those prohibitions were inserted as a temporary measure until there was nationally consistent legislation comprehensively regulating these issues.

**Senator HARRADINE**—Yes, I am coming to that point.

**Ms Matthews**—We have redeveloped the definitions of human embryo cloning and we believe they are stronger than the gene technology legislation definitions currently are. Through the prohibitions we have addressed any type of human embryo cloning, be it through so-called therapeutic cloning, reproductive cloning, import or export of human clones, creation of human clones or implantation of clones.

**Senator HARRADINE**—You know the use of therapeutic cloning is frowned upon by the National Health and Medical Research Council’s ethics committee, don’t you?

**Ms Matthews**—Yes. That is my reference to the so-called therapeutic cloning. It is understood.

**Senator HARRADINE**—All of that could be undone in two years time, could it not, because the provisions in the legislation allow for a consideration of the provisions of the legislation in two years time by a committee that is picked by the National Health and

Medical Research Council and approved by the states. I am a bit surprised the Commonwealth parliament cannot get its nose in. It says that can be examined, including this cloning. So, really, in two years time that could open the way for human cloning.

**Ms Matthews**—But not without the agreement of this parliament.

**Senator HARRADINE**—Ah!

**Ms Matthews**—The report would be developed to COAG, commencing on the second anniversary of royal assent, concluding the report being given to COAG at the end of three years.

**Senator HARRADINE**—I understand. As the legislation says, it is to address the questions of scientific development at that time. What if at that time a scientist comes along and says, 'Look, I'm sorry. We've got histological incompatibility between the embryo taken off the IVF program and the DNA of the patient.' Under those circumstances the scientist may say—and I have no doubt will say—'We do want to clone. We need to take a somatic cell and do the processes of somatic cell nuclear transfer.' That is cloning. And there is a great push, because the immunosuppressants are not available at the present moment. So it is possible that this could open the way in two years time or thereabouts for human cloning.

**Ms Matthews**—It is certainly possible that scientists may put an argument to be able to do it, but scientists are not permitted to do it under this legislation, with the threat of a 10- or 15-year imprisonment term. In order for them to be able to do it in the future, the prohibitions on that particular practice would have to be repealed by this parliament. Under the legislation they would not be permitted to do it.

**Senator HARRADINE**—I am saying that it could open the way. Why don't you make that absolutely permanent? Everybody in the House of Representatives is saying that everybody agrees human cloning should be banned. Why are we opening the way, under this legislation, for that suggestion and recommendation to take place?

**Ms Matthews**—The legislation does not say that in three years the ban is lifted. All the legislation says is that the whole of the legislation will be reviewed within three years so people can put forward submissions in the same way that the House of Representatives committee looked at it, and there is discussion about the possibility of a parliamentary committee looking at it. The legislation would be reviewed but, should any changes be made to the legislation, that would obviously need to come before the parliament.

**Senator HARRADINE**—But wouldn't you agree that there is a possibility that the door might be opened at that time and you could get a suggestion by the scientists that, because of the histo incompatibility of the stem cells, you would need to do cloning?

**Ms Matthews**—I am not sure that I understand. Certainly scientists have raised the issue in the past, and I have no doubt they will raise it in the future. My thoughts are that there is a difference between that and what is prohibited and what parliament considers appropriate to prohibit either now or in the future.

**Senator HEFFERNAN**—You say there is a 15-year penalty. How are you going to supervise that? Are you going to have stem cell police? How the hell would you ever know it was not going on when it was going on? Answer that. How would you apply the law?

**Ms Matthews**—The legislation provides for the appointment of inspectors with monitoring powers and power to enter premises, inspect documentation, search and secure evidential material and that type of thing. Certainly, it is an issue that has been discussed: the difficulty of monitoring compliance—



**Senator HEFFERNAN**—It is dreamtime.

**CHAIR**—Senator Heffernan, please let the witnesses answer questions.

**Ms Matthews**—beyond reviewing documentation and reviewing laboratory practices in an attempt to establish whether an offence was likely to be committed or had been committed. The 15-year imprisonment term is, of course, at the discretion of the courts.

**Senator HEFFERNAN**—It would be a reasonable assumption, though, if you were a dedicated scientist who wanted to do something that you had to skirt the law to do. We have had a demonstration of the commitment of a certain individual who gave a false and misleading presentation to parliament to try to enhance his position. It would be a reasonable assumption that if that is a try-on, there would be other people willing to take the risk, and you would never catch them.

**Ms Matthews**—On the one hand that can be said of any criminal law: just because there is a law prohibiting murder does not mean we can stop murderers in all cases.

**CHAIR**—And it does not mean to say they are all caught.

**Ms Matthews**—That is right. I am saying that you are right, we can never have an absolute guarantee that it is never occurring. What we can do is have—

**Senator HEFFERNAN**—So it would be reasonable to assume that, if that happened and there was some sort of an outcome, then that would be part of the urging and lobbying that Senator Harradine refers to when in two years time the legislation is reviewed? If I was in the business, I would be at it tomorrow morning so that in two years time I had a case to put when they reviewed the legislation.

**Ms Matthews**—I cannot possibly speculate on the intentions of scientists or otherwise.

**Senator HEFFERNAN**—I am not asking you to.

**Senator HARRADINE**—In clause 15, why is the limit 14 days? Why not 13 or 12?

**Ms Matthews**—Fourteen days has been the number used in Australia under the reproductive technology—

**Senator HARRADINE**—I am asking the question: why 14 days? I do not mind who it being used by—

**CHAIR**—Ms Matthews is trying to give an answer. It might not agree with where you are coming from, but can we allow the answers to be given to questions? There is a lot of interruption.

**Senator HARRADINE**—I would prefer the NHMRC to be here.

**CHAIR**—But there is a lot of interruption where questions are being asked and the witness is being chopped off. Could we have a little respect in terms of asking the question and letting the witnesses answer?

**Senator HARRADINE**—I am sorry; I have not meant to be disrespectful by any means. I just hope that the National Health and Medical Research Council might have been able to provide an answer.

**Ms Matthews**—If you would prefer a response from the National Health and Medical Research Council, Clive will be returning shortly. We can keep the question until then or we can take the question on notice and I can ensure that he gets back to you with it.

**Senator HARRADINE**—In the absence of Dr Morris, I will continue to ask you: why 14 days?

**Ms Matthews**—My understanding is that the 14-day period has been used in ART clinics to date in terms of appearance of primitive streak. It is also part of the current code of practice. The Reproductive Technology Accreditation Committee Code of Practice sets 14 days, as do the NHMRC AHEC ethical guidelines on ART, which are also consistent with the UK, Canadian and US legislation on the issue. But I could not give you an in-depth scientific reason for why it is 14 days as opposed to 13 or 15 days. I can certainly seek further advice on that.

**Senator HARRADINE**—How does the primitive streak affect the status of the embryo?

**Ms Matthews**—In terms of the development of the embryo?

**Senator HARRADINE**—You mentioned the primitive streak. In what way does that alter the status of the embryo one way or the other?

**Ms Matthews**—I would have to seek further advice from a scientist or an ART clinic on the impact of the primitive streak on the development of the embryo.

**Senator HARRADINE**—But you have already said that there is no reason for 13 days. What about 15 days?

**Ms Matthews**—I cannot provide you with an answer on the scientific development of the embryo for 14 days over 13 or 15 days. As I said, I am aware of the 14-day rule in the RTAC and AHEC guidelines, ART clinical practice and international precedent. I am certainly happy to get some further information on that for you.

**CHAIR**—Senator Harradine, whether one agrees with it or not, this answer is representing the current accepted scientific practice. I feel that the question of why scientists decide that it is 14 days, 13 days, 15 days or however many days should be directed to the scientists. What the NHMRC has done—and I would certainly ask you to correct me if I am wrong—is implement that belief amongst the scientific community.

**Ms Matthews**—And the COAG decision, which referenced the 14 days and which was based on the AHEC ethical guidelines from 1996.

**Senator HARRADINE**—I think that it is proper that we know and that this committee is told by the peak body, the National Health and Medical Research Council. Never mind practitioners—as Dr Trounson has said, it is an arbitrary figure.

**CHAIR**—But the COAG meeting decided that they were going to adopt the 14-day precedent. The NHMRC were asked to implement the legislation as a consequence of that decision. There will be people coming to this committee to whom I believe this question would be more accurately directed. We should not be shooting the messenger in terms of those who have been given a specific demand by COAG to implement the legislation according to those specifications.

**Senator HARRADINE**—I understand the point you are making, but it makes it very difficult.

**CHAIR**—It is very difficult for the NHMRC to justify why COAG has said 14 days or for the NHMRC to say, ‘We think it should be something else.’ They are not the people who have made the decision.

**Senator HARRADINE**—I understand. Perhaps we can get some of the states.

**Senator STOTT DESPOJA**—I have some questions in relation to the penalties that are applied, whether it is the \$330,000 penalty for a corporation or \$66,000 for an individual in some cases. More generally, for the committee’s benefit would you tell us whether these are

based on international practice? Is there a reason for the figures and the prison terms that you have put in as penalties in relation to these offences?

**Ms Matthews**—They are predominantly based on domestic rather than international practice. The three provisions in the gene technology legislation have a 10-year term of imprisonment attached. I guess that is the closest equivalent in Commonwealth legislation, and it was certainly used as a gauge. In state legislation on these issues it varies between about nine and 15 years. We discussed it with the COAG implementation working group, the Commonwealth, states and territories. The states and territories sought advice from their areas—because they need to mirror this legislation—and we sought advice from the criminal law branch of the Attorney-General's Department, which looked at similar Commonwealth legislation. Of course, there is not very much like this, but the 10- and 15-year penalties were adopted on the basis of the gene technology precedent and existing state and territory legislation.

**Senator STOTT DESPOJA**—How do we compare internationally; for example, in comparison to what has been proposed in the UK and in other jurisdictions?

**Ms Matthews**—Regarding imprisonment terms, I could not say. The Canadians have recently introduced their legislation and I think it is 10 years, but I would have to verify. The US—

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

**Ms Matthews**—We can certainly get that information for you.

**Senator BARNETT**—The imprisonment refers to individuals, doesn't it? Based on the discussion we had earlier, without state and territory legislation the offences referred to in part 2 of up to 15 years would be unenforceable at the moment, wouldn't they?

**Ms Matthews**—The legislation refers to 'a person' but, through the combined effect of the Acts Interpretation Act and the Crimes Act, 'a person' also includes a corporation or body corporate. The Crimes Act provides that, where imprisonment terms are provided, you can have imprisonment for directors or whatever of those corporations and you can also translate the imprisonment terms into a dollar value or supplement them with a dollar value. That applies to both corporations and individuals, except that the dollar value for corporations is five times that for individuals. It is all detailed in the Crimes Act, and it is a bit confusing. There is a summary of it on page 15 of our submission. Basically, a court has the discretion to apply that imprisonment term, to supplement it with a monetary penalty or to replace it with a monetary penalty. The formula for working out the monetary penalty is included in the Crimes Act. It applies to corporations, individuals, organisations and body corporates.

**Senator BARNETT**—It has application but, based on the conversation we had earlier today, when it applies specifically to individuals rather than corporations it is unenforceable.

**Ms Matthews**—If an individual committed an offence under this legislation, a prosecution could be undertaken but it may be subject to challenge on the grounds that there is insufficient constitutional coverage in respect of that individual.

**Senator BARNETT**—Is the advice you have received so far from the Attorney-General's Department and wherever else that individuals are not specifically covered by the legislation?

**Ms Matthews**—In summary, the advice—I am obviously paraphrasing—is that there is considerable but not complete constitutional coverage, with one of the examples of particular susceptibility being individuals.

**Senator BARNETT**—We talked about the trade and commerce power and the corporations power, and we all know that they apply to corporations and entities. You specifically said that there were no conventions at the moment to which the external affairs power could be specifically referred. Therefore, an individual could avoid the offences.

**Ms Matthews**—That is right. There are limits to the constitutional coverage of the legislation.

**Senator BARNETT**—Okay, that is what I am seeking to confirm. The second point with regard to offences is, if these offences are so serious—15 years imprisonment or the equivalent financial penalty—why is there not some automatic de-listing or revoking of the entity's licence? It is all very well for a corporation to pay a penalty—and I am aware that there is a licensing committee that may look at the circumstances of the day—but why wouldn't you have, in a provision like this, automatic provisions to revoke licences for such serious offences as human cloning?

**Ms Matthews**—You could potentially have that. The prohibitions have been drafted so that they can apply to everyone, not just licence holders clearly, and the NHMRC has the discretion to suspend, revoke or cancel a licence. It does not expressly say that one must be cancelled in the event of one of the breaches at the front, but they have the discretion to do that.

**Senator BARNETT**—So why wouldn't you draft it like that? Is there a particular reason why you have not done it that way, or is that the way it has turned out? We are talking about human cloning here. Some of these offences are extremely serious and the actual corporate entity could end up paying \$495,000 for 15 years or around \$330,000 for 10 years. Whether it is in Australian dollars or international currency, for a major corporation that is, quite frankly, tiddlywinks, and they could continue to operate under this bill. There is no automatic loss of licence.

**Ms Matthews**—That is right, there is no automatic loss of licence. The public and the parliament would have very little confidence in a licensing committee that could continue to uphold a licence granted to someone who had been prosecuted for a criminal offence under the legislation. Our assumption had certainly been that the licence would be revoked by the NHMRC licensing committee. I think there would be hell to pay if the licensing committee allowed that to continue.

**Senator BARNETT**—That is left to the discretion of the committee, is it not?

**Ms Matthews**—That is right; technically it is up to their discretion.

**Senator BARNETT**—And we are looking at the bill here and trying to make it the best possible bill.

**Ms Matthews**—That is right.

**Senator BARNETT**—Chair, I have a question relating to part 1, which is on the legal matters, but it relates also to clause 56. I am happy to wait, but it relates to the discussions we had earlier about the states and territories, so it is up to you, Chair, if you are happy for me to ask that question.

**CHAIR**—You can proceed.

**Senator BARNETT**—It relates to clause 56 and the operation of the states and it links back to part 1 in terms of the authority of the states and territories. I have read the explanatory memorandum and I have read clause 56, and it seems to me that quite clearly we have got three states—Victoria, South Australia and Western Australia—that currently have provisions

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which regulate human embryo stem cell research and ART and other types of practices. Those three states have what you would refer to as more strict provisions in terms of the regulation of human embryo stem cell research when compared to this bill. I want to clarify if clause 56 in this bill can specifically override those three states.

**Ms Matthews**—The intent of clause 56 and our advice from the Australian Government Solicitor about the effect of clause 56 is that, yes, to the extent of the Commonwealth constitutional powers, that would override existing state laws that ban uses of excess ART embryos that damage or destroy the embryo. That is consistent with COAG's intention that there is a nationally consistent legislative scheme that allows the use of excess ART embryos subject to the licensing scheme.

**Senator BARNETT**—Correct me if I am wrong, but COAG did not specifically request the NHMRC or anybody else, in drafting the bill, to override those three states, or did they? If they did, can you provide or refer the committee to the provisions of the COAG agreement? As the chair said earlier, we are trying to implement something that is meant to be consistent with a COAG agreement, and I cannot find it in that agreement.

**Ms Matthews**—I could check, but off the top of my head I do not believe that the COAG communique expressly states that the Commonwealth legislation will override. It talks about a national legislative regulatory scheme, allowing the use of excess ART embryos subject to licensing. Again, I would have to check, but I am conscious that in the development of this legislation two of the three governments we are talking about—South Australia, Victoria and WA—before this bill was settled for introduction into parliament sought cabinet agreement on the Commonwealth legislation overriding the state law.

**Senator BARNETT**—Which two states?

**Ms Matthews**—I believe it was South Australia and Western Australia. I would have to verify that, and I am obviously not privy to the precise detail of that decision.

**Senator BARNETT**—So we are acknowledging that there are three sovereign states of the Federation of Australia and this legislation will override those states' laws with respect to human embryo stem cell research. Is that what you are confirming?

**Ms Matthews**—That is right. The intention of clause 56 is that the Commonwealth legislation would override the state prohibitions on the use of excess ART embryos.

**Senator BARNETT**—What I am asking is, where does it say that in the COAG agreement?

**Ms Matthews**—Our riding instructions were that there was to be a nationally consistent scheme that allowed the use of excess ART embryos. That is what we have implemented in consultation with states, territories and other Commonwealth agencies and the bill that we put to government for consideration before introduction.

**Senator BARNETT**—Who provides your riding instructions?

**Ms Matthews**—I should clarify between me personally, as Matthews Pegg Consulting, where clearly my riding instructions come from the National Health and Medical Research Council—

**Senator BARNETT**—Sure.

**Ms Matthews**—With the team, the parameters were set by COAG. We were implementing those in consultation with states, territories and Commonwealth agencies, and obviously in consultation with Minister Andrews, the responsible minister, and the Prime Minister's office.

**Senator BARNETT**—I will ask again. Of the NHMRC, who specifically provides your riding instructions? I cannot find it in the COAG agreement because I do not think it is there. So I am asking who provides your riding instructions that you will override three sovereign states of Australia with that legislation? Who would have given that instruction?

**Prof. Pettigrew**—I cannot comment on the legal side of your question, but the general point I would make is that we took the COAG communique as it was presented to us and developed the legislation from that point.

**Senator BARNETT**—But did somebody on behalf of COAG talk to NHMRC?

**Ms Matthews**—This issue was also considered directly by the government.

**Senator BARNETT**—The federal government?

**Ms Matthews**—While we were developing the legislation; that is right.

**Senator BARNETT**—So you think Kevin Andrews would have given those instructions, as the responsible minister?

**Ms Matthews**—I would have to double-check the exact sequence of events. There was government consideration of this issue. I would have to check whether it was cabinet consideration or whether it was minister-minister-party room. In implementing the COAG decision, we understood it to be the intent that there would be national consistency and therefore there would be override. We discussed that with state, territory and Commonwealth officials through the COAG implementation working group and states and territories got advice from their governments. We also put the issue and the two alternatives to this government, and the response was that we proceed with clause 56 as drafted in terms of introduction.

**CHAIR**—So there have not been any states that have waved their hands and said, ‘We bail out of this. This was not intended as part of the communique from the COAG meeting’?

**Ms Matthews**—That is right. At the level of officials, the communication has been that it should override. In terms of when the Prime Minister and Minister Andrews considered this, I could not say whether they discussed that directly with the relevant premiers.

**CHAIR**—The important issue is that none of those states at any time have said, ‘This does not apply to us as a direct consequence of that COAG communique.’

**Senator BARNETT**—Who is the COAG implementation working group?

**Ms Matthews**—It is Commonwealth representation from the health department, NHMRC, Biotechnology Australia and the Department of the Prime Minister and Cabinet, and it is representatives from the health departments and premiers and chief ministers departments from each state and territory.

**CHAIR**—Are there any further questions on part 2?

**Senator HARRADINE**—Is there any prohibition on the export or import of human embryos or human tissues at all?

**Ms Matthews**—There is a ban on the import and export of prohibited embryos. For example—

**Senator HARRADINE**—That is not really what I asked you.

**Ms Matthews**—Sorry. Your question was: is there a prohibition on the import and export of, I will assume, excess ART embryos?

**Senator HARRADINE**—That is what we are dealing with, yes.

**Ms Matthews**—No, there is not. Currently there are customs regulations that relate to export and there is also quarantine legislation. But, at the moment, there is import and export of embryos as people move from country to country. For example, someone might commence their ART treatment in England, might have some children and might want to continue their treatment here, so those embryos are imported into Australia.

**Senator HARRADINE**—Haven't you considered the commercial links between the Trounson centre and foreign companies in Singapore?

**Ms Matthews**—I am sorry. My understanding was that the question related to embryos. In terms of embryonic stem cell lines, yes, I understand that there were imported embryonic stem cell lines from Singapore by Professor Trounson's group. Beyond that, I do not feel in a position to comment on the nature of that arrangement, how it worked or anything like that.

**Senator HARRADINE**—I am simply asking you why there is not a general prohibition on the export and import of human embryos.

**Ms Matthews**—Do you mean human embryos or embryonic stem cells?

**Senator HARRADINE**—You have given one example which could presumably be in an exemption category, but I am asking you why there is no ban on this practice.

**Ms Matthews**—There are three points there. One, in terms of normal human embryos, as opposed to prohibited embryos, there is the application of the customs legislation, which includes—and I would have to check the precise provision—an exemption for the exportation and importation of embryos for ART treatment and bans without a permit export and import for other purposes. On the issue of the commercial trading of embryos, if that is your specific concern, the legislation does include an offence provision which bans the commercial trading in embryos.

**Senator HARRADINE**—I do not think it is necessary for Ms Matthews to say things that we already know on the commercial side. Of course, that is neatly covered in clause 22, which talks about a valuable consideration but does not include the payment of reasonable expenses. When you have a company with contacts in, say, Singapore, as in this case, there could be quite a huge payment of reasonable expenses involved. In fact, there is a commercial involvement, unless you strictly decide that you will not export or import human embryos. I would certainly like that to be taken on notice.

**Senator BOSWELL**—I will just expand on that. Presumably we have \$46.5 million and we are going to have research carried out on embryos, stem cells and whatever. Will the result of that research be able to be sent overseas to Singapore?

**Ms Matthews**—The results of the research would be able to be sent overseas. If you are talking about the embryonic stem cell lines and whether they could be sent overseas, yes, the embryonic stem cells could be sent overseas.

**Senator BOSWELL**—The embryonic stem cells could be sent overseas, and they can go to Singapore?

**Ms Matthews**—That is right.

**Senator BOSWELL**—Where they have very few ethical considerations, certainly far less than our standards. Is that what we are trying to drive at?

**Senator HARRADINE**—The other thing in regard to that is: who, in this whole process, takes out the patents? Are the embryos and their use not patentable by large biotech companies?

**Ms Matthews**—This legislation does not address the issue of patents—

**Senator BOSWELL**—So we have standards in Australia but, if you do not want to abide by those standards, you send them to Bangladesh and they can do what they like with them. Is that what it says, or does not say?

**Ms Matthews**—I am sorry, could you repeat your question?

**Senator BOSWELL**—We have standards in Australia—

**Ms Matthews**—That is right.

**Senator BOSWELL**—which you have set. But the results of the work in the laboratories can be sent to Singapore. Once they leave our shores and get over there, they can do anything they like with them, providing they meet Singapore's standards.

**Ms Matthews**—As I understand it, there are two issues there. Firstly, yes, in relation to embryonic stem cell lines, they can be imported and exported, consistent with the COAG communique, which provided that research with existing stem cell lines would be permitted to continue in Australia subject to observance of guidelines set by NHMRC and AHEC, which address the issue of import and export of stem cell lines. Secondly, the issues of commercial arrangements, gene patenting and IP arrangements between countries for exchange of resources, the issue of patenting intellectual property and commercial arrangements is not addressed in this legislation but is addressed through separate forums.

**Senator HARRADINE**—What sorts of forums?

**Senator BOSWELL**—What forums?

**Ms Matthews**—I am conscious that the ALRC is undertaking one review, and there is discussion about another one.

**Dr Morris**—I understand there are discussions about another government sponsored review of IP issues—

**CHAIR**—Can we just have one conversation, Senator Boswell?

**Dr Morris**—It is my understanding that there is currently discussion going on in relation to a second inquiry on intellectual property issues.

**Senator BOSWELL**—We are not voting on the inquiry. When this legislation goes through, as I understand it, Australia has certain standards to meet. The stem cells or any other product that results from the stem cell or embryo research can be transferred to Singapore, where the standards are not Australian. We can have a different set of standards in Singapore than in Australia. If you do not want to abide by the standards in Australia, you go to Singapore, or if you do not want to abide by those, you can go to Bangladesh. Is that correct?

**Ms Matthews**—The standards in this legislation relate to the circumstances under which stem cells may be derived from an embryo. So if—

**Senator BOSWELL**—No, no. Look—

**CHAIR**—Senator, please allow the witness to answer the question.

**Ms Matthews**—So if the stem cells are derived from the embryo in Australia, the Australian standards apply, not the Singaporean standards. If stem cell lines are subsequently sent to Singapore, the use of those stem cell lines is permitted in accordance with Singaporean law. In the same way, if stem cell lines are imported into Australia, the use of those is permitted and is not subject to this regulatory scheme.



**Senator HARRADINE**—I originally asked you whether there is a prohibition upon the import and export of human embryos. I am not talking about other matters just at the moment—I intend to go on with that. I am not talking about those embryos which have a ban on their creation. I am talking about the use of ART embryos, as you have got down here. Is there a ban on their import or export? Is there a ban on the import of so-called excess ART embryos in Singapore to Australia?

**Ms Matthews**—In answer to your question—

**Senator HARRADINE**—I am asking Dr Morris, if you do not mind.

**Ms Matthews**—Sorry; I understood you to be clarifying my response to the last question.

**Dr Morris**—Excuse me if I am repeating answers that have already been given, but it is my understanding that there is no prohibition on the import of ART embryos which form part of a couple's ART treatment program. That would be how they would come into the country. Other types of embryos are prohibited imports under this legislation—for example, an embryo created specifically for the purposes of research would not be allowed to be imported.

**Senator HARRADINE**—I deliberately said 'excess IVF embryos'. That is what we are talking about.

**Dr Morris**—What you are asking is whether, if a couple in another country had been through an ART treatment program and had designated embryos as excess to their needs, those excess ART embryos could be imported. Is that your question?

**Senator HARRADINE**—Yes.

**Dr Morris**—I do not think there is a prohibition against that. They would have to be used as excess ART embryos are in this country. The same qualifications would have to apply to them as apply to embryos created in this country in terms of consent.

**Senator HARRADINE**—There is an arrangement between Dr Trounson's organisation and Singapore whereby those embryos in Singapore are created specifically for research purposes as excess embryos, and they can be imported into Australia.

**Dr Morris**—The situation would be the same for an excess embryo whether it was imported or created in Australia. The same requirements would apply. The couple for whom the embryo was created would have to have provided written consent designating that that embryo was excess to their needs. Furthermore, they would have to consent to the research on the embryo.

**Senator HARRADINE**—In fact, you can have that consent or whatever in Singapore and import the embryos here.

**Ms Matthews**—You can import embryos into Australia but if you wish to derive stem cells in Australia you would need to comply with Australian law, even if it was in respect of embryos which had been imported.

**Senator HARRADINE**—The embryos are here, right?

**Ms Matthews**—The embryos are here, so they have to comply with the law here.

**Senator HARRADINE**—That means that the excess embryos could be cut up to obtain the stem cells or utilised in testing and screening of drugs?

**Ms Matthews**—Embryos imported into Australia could be used in Australia provided that use was in accordance with this legislation, so that there was a licence from the NHMRC

licensing committee, considering the number of embryos are likely to have significant advance in relation to consent.

**Senator HARRADINE**—Dr Morris, in relation to the screening of drugs—and I am talking about the commercialisation of this whole enterprise—you were talking about the IP discussions that are going to take place. You are really asking us to buy a pig in a poke. Are you not aware that there is considerable interest by pharmaceutical companies in the obtaining of human embryonic stem cells for drug screening and that that could be a major advantage? I am reading from a letter from the Minister for Industry, Tourism and Resources, Mr Macfarlane, to me.

**Dr Morris**—Senator, you have probably already been told this, but issues of IP and commercialisation are not covered in this bill.

**Senator HARRADINE**—So COAG did not mind if there is a huge amount of commercialisation involved?

**Dr Morris**—We cannot say.

**Senator HARRADINE**—So you were given absolutely no instructions at all about the commercial use of human embryos, whether it is for drug testing or all sorts of other things?

**Dr Morris**—We have been endeavouring to implement a nationally consistent scheme which applies an even regulatory hand to all users of ART embryos and to all people who may want to use those embryos. I do not believe the COAG communique made any pronouncements regarding commercialisation.

**Ms Matthews**—Beyond the ban on commercial trading in embryos for—

**Senator HARRADINE**—But the National Health and Medical Research Council has always been regarded highly as looking at science and the importance of science for the benefit of the people, and all the rest of it. I do not know that there are any or too many NHMRC grants that are determined on the commercialisation of the product, and I do not see in any of the committees the very substantial commercial interests and drug company interests that were involved in ticking off the \$46 million. Aren't the National Health and Medical Research Council concerned about the whole area of commercialisation of science and research?

**Prof. Pettigrew**—The issue of commercialisation of research is outside the scope of the legislation that we were asked to develop out of the COAG communique. To address your question, the link between research and commercialisation of research was a matter which was addressed very heavily in the Wells review of health and medical research in this country. The NHMRC have responded to the government's acceptance of most of the recommendations of that review. We have put in place certain activities which go to the point of helping to foster the development of research findings and dealing with intellectual property. As I have said to you at a previous meeting of this committee, the issue of balancing intellectual property matters with publication of research in learned journals is an issue which is a concern to researchers every day. It is a natural process these days in the normal course of research which is undertaken.

**Senator HARRADINE**—But you were not given any running instructions from COAG about this whole question?

**Prof. Pettigrew**—My understanding of the COAG communique—I have passed my copy across the table here—is that I do not believe that that communique made any reference to commercial issues, except in the case of what is included in the legislation with respect to

reasonable expenses where embryos might have been donated—to that extent. It does not deal with the intellectual property matters that you are alluding to in your question.

**CHAIR**—Bearing in mind that we were set to conclude this meeting at six o'clock, I move on to part 3.

**Senator BARNETT**—Section 25(2)(d) says:

(d) the use is carried out by an accredited ART centre, and:

(ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created; ...

Can you provide your views on what a diagnostic investigation will allow and give your confirmation that it would allow the destruction of a human embryo?

**Dr Morris**—This would be part of the treatment of a particular woman, through an approved ART treatment program. It relates to the diagnostic investigation of embryos where, in some cases, the embryos are not viable for a particular reason—that is, they have chromosomal abnormalities or they do not divide properly. There are a range of reasons why an embryo would not be viable. Only in some instances would it be beneficial to that woman's treatment to do an investigation on that embryo in order to improve the success rate of the next round of IVF treatment. An example of that is where, in some circumstances, the shell of a woman's ovum is tougher than in other women and, following fertilisation, the embryo does not divide. You cannot find that out without doing some investigation. If you find out why, there is a treatment you can do in order to stimulate division of the embryo for the next treatment. That is an example, but in all cases it is part of the IVF treatment of a woman.

**Senator BARNETT**—Dr Morris, my question specifically asked: would it allow the destruction of a human embryo?

**Dr Morris**—In some circumstances it might, depending on what the diagnostic technique was.

**Senator BARNETT**—Does that mean in some circumstances it would?

**Dr Morris**—If you like, yes.

**Senator BARNETT**—That is what I am trying to get at. A number of people have expressed concern to me about the use of the words 'diagnostic investigations'. So if it would allow the destruction of a human embryo in certain circumstances, we are saying that this ART centre is not required to be licensed like every other research centre and that they are an exempt use, under clause 25 of the bill. That could mean an indefinite number of human embryos could be used for research for whatever purpose the ART centre deemed appropriate. Is that a fair assessment?

**Dr Morris**—I do not think so. They could not be used in research because that is prohibited under the legislation.

**Senator BARNETT**—Would it be a fair assessment that it depends on their definition of 'diagnostic investigations'?

**Dr Morris**—It could only be undertaken as part of the ART treatment of a particular woman. You need to bear in mind that the embryo in question would be unsuitable for implantation into the body of a woman, which would automatically mean that it was not viable and it would probably die shortly anyway.

**CHAIR**—Would the woman need to give approval for that?

**Dr Morris**—Of course. It is part of her treatment and she would give approval.

**CHAIR**—It is her embryo?

**Dr Morris**—Yes.

**Senator BARNETT**—I will go down another track. Did you receive any advice—specifically from the Australian Health Ethics Committee—that the particular reference I am talking to, clause 25(2)(d), posed ethical concerns and was a loophole in the law?

**Dr Morris**—During the development of the bill for introduction into parliament, we consulted regularly with the executive committee of the Australian Health Ethics Committee. On one occasion, the members who were present questioned whether having an exemption would create a loophole, and on their behalf we raised the matter with Minister Andrews. I think he used it in his speech last night.

**Senator BARNETT**—So the answer is yes?

**Dr Morris**—Not exactly. They did not say, ‘This is a loophole.’ They questioned whether this would be a loophole. That was an opinion. In our consultative process in developing the legislation, we have consulted widely and they were one of the groups we consulted with.

**Senator BARNETT**—So the Australian Health Ethics Committee expressed concern and asked questions about whether clause 25(2)(d) was a loophole and whether the use of the words ‘diagnostic investigations’ was appropriate in such a clause?

**Dr Morris**—Could you repeat the question?

**Senator BARNETT**—The Australian Health Ethics Committee expressed concern and gave you some advice with respect to clause 25(2)(d). Can you advise us specifically what that advice was?

**Dr Morris**—I answered your previous question with what their advice was. It was a question that they were asking us which we passed on to the minister. In fact, this clause changed as a result of that interchange. I believe that it was made far more explicit that the embryo could not be suitable to be placed in the body of a woman and that it had to form part of the ART treatment of the woman for whom the embryo was created. So as a result of that interchange the clause was made more explicit as to what it covered.

**Senator BARNETT**—Are you saying that you took their advice and concerns on board and amended the clause?

**Dr Morris**—Yes.

**Senator BARNETT**—You said that it was then referred to the minister, as in Kevin Andrews. What was his response?

**Dr Morris**—That is what I am saying: the result of that interchange coming from AHEC to the minister was the clause in its current form.

**Senator BARNETT**—What was the minister’s response?

**Dr Morris**—His response was the form that you see now.

**Senator BARNETT**—So the minister supports 25(2)(d) subparagraph (ii)?

**Dr Morris**—You would need to ask the minister that.

**Senator BARNETT**—But you have just advised me that the minister’s response was 25(2)(d) subparagraph (ii).

**Dr Morris**—This is the bill following that interchange. We made the changes in consultation with the minister.

**Senator BARNETT**—This is a supplementary question, probably slightly related: who is the relevant minister for the bill?

**Dr Morris**—Kevin Andrews.

**Senator BARNETT**—For this bill, your confirmation today is that the relevant minister is Kevin Andrews?

**Ms Matthews**—We should clarify there that the relevant minister under the legislation would be the minister with portfolio responsibility for this legislation.

**CHAIR**—The bill was introduced by the Prime Minister.

**Ms Matthews**—The bill was introduced by the Prime Minister; but where there is a reference to a relevant minister in here, by reference to the Acts Interpretation Act, it is the minister with portfolio responsibility for this act, which we do not know until the passage of the legislation and delegation of legislative responsibilities.

**Dr Morris**—Also, the minister who introduced the legislation was the Prime Minister so the Prime Minister took carriage for the final iteration of the bill for introduction into Parliament.

**Senator BARNETT**—Chair, I think it is a fair question for all the committee members to know, and obviously we do not know at the moment. Under the bill, the minister—whoever the relevant minister is—has considerable discretion in certain respects. I think it would be appropriate for us to find out as a committee who is the relevant minister under the bill. NHMRC do not know the answer to that question as yet and neither do we.

**Dr Morris**—At this point, I do not think we can say who the relevant minister will be. That will be up to the Prime Minister to decide.

**CHAIR**—It is not the decision of the NHMRC; it is the decision of the Prime Minister.

**Senator BARNETT**—That is why I was asking, through you, Chair, because it is relevant for this committee to know which portfolio minister is going to be responsible for the bill. Is that not a fair question?

**CHAIR**—We can ask the Prime Minister, Senator.

**Senator BARNETT**—Thank you.

**Senator STOTT DESPOJA**—Is the NHMRC aware of concerns that have been raised by some ART researchers in relation to provisions in this bill, particularly provisions that may impact on ART or IVF research? Could you identify the provisions in the bill and outline what their likely scientific, medical and training impacts would be?

**Ms Matthews**—During consultations with ART clinics and over the last week as we have been getting requests from ministers and senators for advice, and they have obviously been getting advice from ART clinics, the major issues that have been raised have been in relation to some of the prohibited practices. There have been concerns expressed that the prohibited practices may be too restrictive and may prevent certain work that necessitates the creation of embryos—for example, work into ovarian cancer and related cancers, work looking at parthenogenesis and the creation of parthenogenic embryos, and research into cytoplasmic transfer. Certainly a range of issues have been raised by the ART clinics in respect of the prohibited practices.

In relation to the regulation of the use of excess ART embryos, probably the two biggest issues that have been raised by the clinics are concerned about the impact of the legislation on training and on quality assurance. They have expressed concern about requiring a licence for quality assurance and training which they are currently doing in five jurisdictions when in all jurisdictions they undertake training and quality assurance work. In five jurisdictions such training and quality assurance work can involve the destruction of or damage to the embryo. They have expressed concern that the legislation is overly restrictive in terms of its impact on their practices and the necessity for them to seek licences, including for work that does not involve the damage or destruction of embryos, particularly in relation to training and quality assurance projects.

**Senator STOTT DESPOJA**—Do you think they have valid concerns, particularly in relation to training? Are you concerned that the provisions could impact in a negative way on the work that they are doing?

**Ms Matthews**—Certainly the legislation will have an impact. From our perspective, in terms of implementing the COAG decision, it has been important that an even regulatory hand be applied and that there be logic and consistency both legally and ethically across different treatments of embryos. Our concern was, for example, if we have an exemption for training, that someone could then say, when they were deriving stem cells for research, ‘No, I was just training in the derivation of stem cells.’ All of a sudden, you have an enormous loophole; everyone is saying they are doing training, not research. Similarly, with quality assurance, it is very difficult to distinguish between quality assurance work and training work. When we looked at it, the point was that whether you were doing it for training, quality assurance or research the same ethical and legal issues were there. You still need proper consent, you still need to make sure that protocols have been observed and you still need to look at how many embryos are being used and for what purpose. That is why we have cast the scope of the legislation quite broadly—in order to encompass those things and apply treatment evenly to each of them.

**Senator DENMAN**—I have a general question. What mechanisms are in place to ensure that the NHMRC licensing committee is a balanced one?

**Dr Morris**—Firstly, the process of appointing the committee involves wide consultation, and in the regulations of the bill there will be bodies prescribed for consultation on the appointment of members. Secondly, the minister responsible will be required to consult with the states on all members, but a majority of states must agree to the appointment of the chair of the committee as well as the person with the expertise in the regulation of ART.

**CHAIR**—Are there any further questions on division 3?

**Senator BOSWELL**—Yes. Can the licensing committee licence research that will be done overseas or done by overseas affiliates of the Australian organisation? Do they have to abide by Australian ethical standards?

**Dr Morris**—The licences would apply to research undertaken in Australia. I do not believe they could apply to activities overseas.

**Senator BOSWELL**—So they do not have to abide by Australian ethical standards? I go back to my first, second or third question—I am not sure you were here. Take the case of some research work being done in the company laboratory that is receiving this grant, where the majority shareholding is held somewhere else. Can any work that is being done in said laboratory be sent overseas? And, if it is sent overseas, does it have to abide by Australian ethical standards?

**Dr Morris**—The licensing committee, in making its deliberations, needs to have regard for all NHMRC guidelines. The NHMRC's *National Statement on Ethical Conduct in Research Involving Humans* says, in clause 1.21:

Where research is conducted in an overseas country under the aegis of an Australian institution or organisation, the research must comply with the requirements of this Statement as well as the laws and guidelines of that country.

**Senator BOSWELL**—So we produce a product out of these ES cells, whether it be a stem cell, an embryo or any derivative of any of them, and the product is sent to Singapore. How do we know what happens over there? Who polices it? You are saying that if a product goes out of Australia to Singapore then it will have to be used in the same ethical way as it is used in Australia?

**Dr Morris**—In making its decision, the licensing committee would take into account issues which may be covered by clause 1.21 of the national statement.

**Senator BOSWELL**—Can I be specific, with a yes or no answer. If a product is assembled in a laboratory that has received this funding and it is sent to another country, do the same standards apply to that product as they do in another country?

**Dr Morris**—The licence would only apply to the work undertaken in Australia. If something is exported to another country, the laws of that country would apply.

**Senator BOSWELL**—So we could send these to Bangladesh, which really does not have any standards at all?

**Ms Matthews**—That depends on what we are talking of in terms of product as well.

**Senator BOSWELL**—I am talking about any product that comes out of this laboratory that is funded by this \$46 million—and it can go anywhere. We can set up anything here and send it overseas and you can do what you like with it.

**Ms Matthews**—This legislation does not regulate what can be done overseas—that is right—subject, obviously, to customs, quarantine and import/export regulations.

**Senator BOSWELL**—We are not talking about quarantine.

**CHAIR**—Senator, please do not interrupt when people are giving answers. It is very difficult. Ms Matthews, do you want to continue?

**Ms Matthews**—No, it is all right.

**Prof. Pettigrew**—May I add something which might help to clarify here? When a research laboratory in Australia applies for a licence, there is certain information that they have to provide to receive that licence. It is up to the licensing committee to determine—

**Senator BOSWELL**—That is what I am just asking.

**Prof. Pettigrew**—If there is a statement from the research laboratory that they intend to export the product, then it is up to the licensing committee to determine whether that should be licensed or whether there should be a constraint on the licence or a variation to the licence. You have used the term 'work', and I was going to ask you what you mean by the term 'work'?

**Senator BOSWELL**—Any product that is a derivative of an embryo or a derivative of a stem cell, or is an embryo or a stem cell. Once that leaves Australia then our standards do not apply, as I understand what you are saying.

**Dr Morris**—The licence that is provided by this committee only applies to the work that is undertaken under the licence.

**Senator BOSWELL**—Thank you. Ipso facto, if it goes overseas, no licence applies to it?

**Dr Morris**—Only the laws of a country where it is exported to.

**CHAIR**—We do not have jurisdiction overseas, Senator.

**Ms Matthews**—But even in Australia you do not require licensing for stem cell lines or products derived from stem cells. This legislation is about the actual use of that embryo in the derivation of the stem cells, rather than—

**Senator BOSWELL**—I am talking about the embryo, so that applies. How will the licensing committee ensure that no embryo research funding leaves Australia?

**Dr Morris**—The legislation does not apply to research funding.

**Senator BOSWELL**—You are the licensing committee.

**Dr Morris**—Yes, but having a licence is different to obtaining funds.

**Senator BOSWELL**—How do you? How does anyone? Who covers that?

**Prof. Pettigrew**—The research funds that are distributed by the NHMRC are administered by Australian institutions, and that is a condition of getting the funding. But some of the funding which might be applied through that institution can be applied under certain circumstances to research conducted in a foreign country, provided that is of benefit to health and medical research in this country. But the funds are administered through an Australian institution.

**Senator BOSWELL**—Then how can the NHMRC guarantee that no Australian taxpayers' money will end up subsidising research in other countries? Flowing on from your previous answer, can you give a guarantee? I do not mind taxpayers' money being used to promote research here, but I do not think we ought to subsidise Singapore or anywhere else. They are hard earned funds.

**Dr Morris**—All I can say is that question does not relate to the bill.

**Senator BOSWELL**—It must relate to someone. We just do not go and throw \$46 million up in the air and say, 'Grab it.'

**Dr Morris**—The NHMRC was not involved with that particular—

**Senator BOSWELL**—Who was involved in it?

**Dr Morris**—That was a grant through the Department of Education, Science and Training.

**Senator BOSWELL**—Can I bring up the case of the new \$46.5 million biotechnology centre of excellence, the Centre for Stem Cells and Tissue Repair. They say on the government biotechnic website document that one of their commercial partners is a company called ES Cell International Pty Ltd. This company is registered in Singapore, with Australian interests holding only a minority shareholding. The other shareholders are in Singapore and Israel, according to an answer given at estimates. What guarantee is there in this legislation that some of the funds going to the centre for embryo experiments will not end up in Singapore or somewhere else?

**Prof. Pettigrew**—I do not believe there is anything in this legislation which addresses that issue.



**Senator BOSWELL**—Senator Harradine, it appears that \$46 million of taxpayers' money can go anywhere, as long as we get a benefit in Australia.

**Prof. Pettigrew**—I am not in a position to answer the question on the details of the deed of agreement between the government and the institution which is managing that particular grant because the NHMRC is not involved in any way in that particular grant.

**Senator BOSWELL**—Who is?

**Prof. Pettigrew**—My understanding is that it is the Department of Education, Science and Training.

**Senator HARRADINE**—And industry, too. NHMRC was not asked.

**Prof. Pettigrew**—Exactly.

**Senator BOSWELL**—Can I ask this question, so I get it on the record. In what way will the commercial partners of the centre—a foreign majority owned company—benefit? Are there any licensing guidelines to deal with foreign ownership and research alliances?

**Prof. Pettigrew**—I do not believe that we are in a position to answer that question, I am sorry.

**Senator BOSWELL**—Who would answer that question?

**Dr Morris**—Those questions would be best directed to the departments responsible.

**Senator BOSWELL**—Will you be licensing research where ownership or benefit from the outcome or the intellectual property belongs in any way to a foreign owned company?

**Prof. Pettigrew**—I believe that is a very complex question and it is a hypothetical question—

**Senator BOSWELL**—No, it is not.

**CHAIR**—Just a moment, Senator. Please do not interrupt the witnesses when they are attempting to answer your questions.

**Prof. Pettigrew**—It is a hypothetical question in the sense that this regulatory regime has not yet been established, and we do not know the nature of the applications that will come forward for a licence, by the very nature of research being a forward looking activity.

**Senator BOSWELL**—But there is a company registered, ES Cell International. It is majority owned overseas.

**Ms Matthews**—The licensing committee will consider any applications made for uses of embryos within Australia. So if that company or any other wished to undertake the work in Australia, they would require a licence to do so, regardless of the ownership structure. But that is separate to the issue of funding.

**Senator BOSWELL**—I am sorry, I was distracted—somebody gave me a note. Could you say that again?

**Ms Matthews**—If any organisation in Australia wants to use an embryo to derive stem cells, they need a licence from the licensing committee, and that committee judges those applications in accordance with the criteria here rather than what their ownership or management structure is. That is a separate issue from the issue of funding, as Professor Pettigrew mentioned before, regarding the terms and conditions of funding and Australian involvement, that type of thing.

**CHAIR**—The former issue has nothing to do with the NHMRC.

**Ms Matthews**—That is right: the funding of the centre or ES Cell International.

**CHAIR**—That is why, Senator Boswell, the line of questioning is very difficult because you are asking the NHMRC to comment on things over which they have absolutely no jurisdiction.

**Senator BOSWELL**—Madam Chair, taking your advice, who should we be asking about this?

**CHAIR**—The different departments have been given to you by the NHMRC. If you are wishing to pursue that, then that is a different issue, but you are pursuing a line of questioning that cannot be answered by the NHMRC.

**Senator HARRADINE**—There is one point, though—just the point that you made: the licensing committee would not be able to set, as one of its benchmarks, whether or not the outcome of the research would be patented by whoever, whether it is a foreign company or a local one.

**Prof. Pettigrew**—The policy with respect to intellectual property management which the NHMRC operates under is that the intellectual property arrangements are to be determined by the administering institution. The implication of that is that NHMRC takes no direct interest in the intellectual property.

**Senator HARRADINE**—The administering institution includes?

**Prof. Pettigrew**—University, hospital, whatever.

**Senator HARRADINE**—Or a private company or an ART provider.

**Prof. Pettigrew**—We provide public funds for publicly funding institutions.

**Senator HARRADINE**—Yes, I understand that. So you have no control over those companies that are provided with a licence?

**Prof. Pettigrew**—The only control would be over the conditions and terms of the licence and the monitoring powers which are explained in the bill.

**Dr Morris**—As currently drafted, the licensing committee would not include in its consideration the commercial interests of the applicant. Those are the parameters that COAG decided.

**Senator BOSWELL**—Can I just ask this question, and you may refer it to another department: are there any guidelines that prevent the export of embryo products if they are to be used in a way inconsistent with the bill? I think you have answered this in countries where they allow therapeutic cloning, like Singapore.

**Ms Matthews**—That is right. Leaving aside the customs regulations, under this bill there is no prohibition on the export of the products of embryos, such as embryonic stem cell lines and other products.

**Senator BOSWELL**—On page 5, it says that the centre will be contractually bound to comply with all ethical codes and guidelines adopted by Commonwealth. What do the guidelines say about overseas commercial partners? I am referring to ES Cell International.

**Dr Morris**—Which document are you referring to, Senator?

**Senator BOSWELL**—The government's biotechnic web site, on page 5.

**Dr Morris**—I am sorry, I do not have that document.

**Senator BOSWELL**—Okay. I will put it on notice.

**Ms Matthews**—The other departments we mentioned would probably be able to give you a lot more detailed advice.

**CHAIR**—The officers have kindly agreed to continue the hearing for a short time, so I ask honourable senators to draw their questions to a conclusion.

**Senator BOSWELL**—I am right, thank you.

**Senator HARRADINE**—Who monitors the monitors? I do not mean that as a smart question. Seriously, if there is an application for a licence and the applicant is claiming commercial-in-confidence as part of the application, where is the transparency of the operation of the provisions in respect of the licensing committee? Where does transparency come into it for politicians or the public itself? They would be very interested in, for example, the circumstances for which the licence has been provided?

**Prof. Pettigrew**—I can tackle some of the elements of your question and my colleagues will probably tackle others. You asked at the very beginning about who monitors the monitors. In the legislation, the people who would be responsible for the on-the-ground monitoring will be responsible to the licensing committee and the chair of the licensing committee. We have not worked these procedures through yet, but obviously there would need to be regular reviews of activities in this regard. From there, the licensing committee, being a principal committee of the NHMRC, will be reporting to the council of the NHMRC. In addition, there are various other reporting requirements, as established in the bill, which prescribe reports that the licensing committee should provide both to parliament and to the NHMRC. In addition, certain data will be publicly available on the web site so that there is free access to relevant information.

**Senator HARRADINE**—I am concerned about the quality of the data to be provided on the web site, for example. How will you be affected by claims of commercial-in-confidence? I have run into that problem in other areas, unfortunately, and I do not want to run into that problem here.

**Dr Morris**—I think that the information that we make publicly available is the best that we can do, given the requirements of the Privacy Act and the obligations in handling commercial-in-confidence information.

**Senator HARRADINE**—But would you not agree that this is a matter of very severe sensitivity—if one can say ‘severe sensitivity’—amongst the public?

**Prof. Pettigrew**—We fully understand that sensitivity—it has been right through our deliberations in assisting with the drafting of this legislation. There are requirements, under section 44(1), set down as to the information to be made publicly available and then section 45 deals with confidential commercial information et cetera. So we have tried to be very careful in providing as much information as possible on the web site, as Dr Morris has said, consistent with all the relevant legislation which applies across these issues.

**Senator HARRADINE**—I have big question marks over section 44(4):

Information mentioned in subsection (1) must not be such as to disclose confidential commercial information.

It is a hard call, isn’t it, for the chairman of the licensing committee to balance the interests of the public and the interests of the applicant?

**Dr Morris**—In general, the information supplied under 44(1)(a) to (f) is the type of information that probably is not going to be commercially confidential. It will be other information that is commercially confidential.

**Ms Matthews**—At this stage we are not envisaging that a lot of information—particularly about the nature of the use, the conditions and the number of embryos—will be confidential commercial information. Clearly it would have to be assessed on a case-by-case basis, but certainly our intention is that all of that information be provided on the database. I think it would be very difficult for someone to establish that, for example, the number of embryos they were proposing to use was confidential information. But, as you say, it is certainly an issue for the committee.

**Senator HARRADINE**—Will that go up on the web immediately the report is made?

**Prof. Pettigrew**—That is correct. Can I also say that this is new legislation dealing with a very new situation, as you appreciate. The COAG agreement and the legislation provide for review of the legislation. So the issues you are raising are issues that clearly can be considered by this parliament in the context of the review of the legislation.

**Senator HARRADINE**—In subclause 36(4) it says that, in deciding whether to issue a licence, the NHMRC licensing committee ‘must have regard to the following ...’ and then gives the number of excess ART embryos likely to be necessary to achieve the goal et cetera. While we are talking about excess ART embryos, are you aware of the statement made to our committee—it is all déjà vu to me, I am afraid—in 1984 or 1985 by Dr Jensen of Sydney IVF that there was no problem for an IVF practitioner to increase the number of ‘excess embryos’?

**Dr Morris**—Are you asking about the number of excess ART embryos that may be created in an ART clinic?

**Senator HARRADINE**—Yes. This bill does not appear to me to prohibit that sort of practice; Dr Jensen said there was no real problem for an IVF practitioner to ensure a few extra embryos.

**Dr Morris**—I think you are right. The regulation of ART clinical practice is not covered in this legislation.

**Senator HARRADINE**—No, but it is largely a self-regulating regime. I asked the question so as to clarify that.

**Dr Morris**—It is our understanding that the number of embryos created for a treatment cycle for a particular woman is lower today than it would have been five or 10 years ago, due to improvements in ART practices. But we would probably need to look at data produced by the Australian Institute of Health and Welfare, which has been collecting statistics on these matters for a number of years. If you like, we can find out whether there has been a decrease in the number created.

**Senator HARRADINE**—I have that figure somewhere, but I cannot pick it out.

**Prof. Pettigrew**—May I make a further comment on the question you were asking. That is that another part of the COAG decision was that a review be undertaken with respect to providing advice on how to prevent the creation of excess embryos for research. That review will be undertaken over the next period. I cannot remember the exact timing of it, but it is due to commence or may already have commenced. That is a specific request from COAG to look into the issue, which you may be alluding to.

**Dr Morris**—Just to clarify that, COAG requested that report by 5 April 2003.

**Senator HARRADINE**—On the question of the licensing committee, I note that the membership of that committee is to be nominated by the NHMRC, provided it is approved by the states. I have questions about that, but I will not ask them now as it is getting late. I also

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have a question about accountability and so forth. I think that Senator Denman mentioned the question of the balance of such a committee. I am also adding a question on that, which is: what about the Commonwealth? Doesn't it also have a say? Presumably you would not necessarily see yourself, Professor Pettigrew, as necessarily reflecting government policy—there is a certain independence.

**Prof. Pettigrew**—The minister makes the appointments to the committee.

**Ms Matthews**—I think the reference is to the review—the NHMRC causes the review in consultation with the states.

**Prof. Pettigrew**—I misunderstood, I am sorry.

**Senator HARRADINE**—I think I did say the licensing committee. I am sorry—I meant the review committee.

**Prof. Pettigrew**—As you would be aware, the NHMRC is an independent statutory body. Clearly, when we are developing the situation for an independent review to be conducted, we would consult with relevant bodies before putting names forward.

**Dr Morris**—The minister responsible would definitely be involved in that decision.

**Senator HARRADINE**—Could I go to the key question, which is on the issue of the authority in South Australia—the Reproductive Technology Council—which on its web site said that in fact most embryos in Australia will not be used for stem cell research. How can this committee get a handle on what they are going to be used for? We have heard presumably authoritative statements from scientists recently that only a minute number of the available 70,000 embryos—something like half of one per cent or one per cent—will be used for the purposes of that stem cell research to cure disorders. How are we going to get handle on what the others are going to be used for? Presumably, according to that document, they will be used predominantly in the development of ART procedures and in experiments to teach new ART practitioners how to do things like carve up embryos for stem cell research or whatever and also for use in the testing of drugs. Can you suggest any way we can get a handle on that? The chair has correctly said that you have been given your riding instructions; you have had your consultation. I do not ask you to provide the information, but where do think we ought to get it?

**Prof. Pettigrew**—My understanding is that we do not have that information now. What this legislation puts in place is a licensing regime which requires people who wish to use excess ART embryos to put forward their information, for that to be assessed by an institutional ethics committee and for that to be then licensed by the NHMRC licensing committee. Then, out of that, data will be gathered as to the actual requirements for these excess embryos to be used in research.

**Senator HARRADINE**—I think Dr Morris did indicate that you might give us information that may be extracted from the consultation papers that you have.

**Dr Morris**—Yes, I undertook to look through the submissions that we have received to see if people have given us the numbers of embryos created or used.

**Senator HARRADINE**—Thank you.

**CHAIR**—Thank you, Professor Pettigrew, Dr Morris and Ms Matthews, for your time this afternoon.

**Committee adjourned at 6.25 p.m.**