The Senate

Community Affairs Legislation Committee

Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002

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Senator McLucas replace Senate Denman for the inquiry from 17 September 2002.

Senator Mason replace Senator Heffernan on 17 September 2002 from 4.45 pm until the Committee concludes its business on that day.

Senator Eggleston replace Senator Heffernan on 19, 24 and 26 September 2002.

Senator Bishop replace Senator Hutchins from 6.10 pm on 19 September 2002 until the Committee concludes its business on that day.

Participating members

Senator the Hon Eric Abetz	LP, Tasmania
Senator Mark Bishop	ALP, Western Australia
Senator the Hon Ron Boswell	NPA, Queensland
Senator Bob Brown** (from 27.8.02)	AG, Tasmania
Senator Geoffrey Buckland	ALP, South Australia
Senator Paul Calvert	LP, Tasmania
Senator Kim Carr	ALP, Victoria
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Senator Kerry Nettle** (from 27.8.02)	AG, Tasmania
Senator Marise Payne	LP, New South Wales
Senator Natasha Stott Despoja (from 22.8.02 to 17.9.02)	AD, South Australia
Senator John Tierney	LP, New South Wales
Senator John Watson	LP, Tasmania
Senator Ruth Webber	ALP, Western Australia

***** For matters relating to the Family and Community Services portfolio

^ For matters relating to the Health portfolio

** For the Committee's inquiry into the provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002

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LIST OF ACRONYMS

AHEC	Australian Health Ethics Committee
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers Conference
ART	Assisted reproductive technology
CNR	Cell nuclear replacement
COAG	Council of Australian Governments
DNA	Deoxyribonucleic acid
ES Cell	Embryonic Stem Cell
GMP	Good Manufacturing Practice
HREC	Human Research Ethics Committee
IVF	*In vitro* fertilisation
NBAC	National Bioethics Advisory Commission (USA)
NHMRC	National Health and Medical Research Council
NIH	National Institutes of Health (USA)
RTAC	Reproductive Technology Accreditation Committee
UNESCO	United Nations Educational, Scientific and Cultural Organisation

CHAPTER 1

INTRODUCTION AND BACKGROUND

Reference and inquiry

1.1 The Research Involving Embryos and Prohibition of Human Cloning Bill 2002 (the Bill) was introduced into the House of Representatives on 27 June 2002. On 21 August 2002, the Senate, on the recommendation of the Selection of Bills Committee (Report No.6 of 2002), referred the provisions of the Bill to the Committee for report by 24 October 2002.

1.2 The Selection of Bills Committee, in recommending the reference of the Bill to the Committee, provided the following reason for referral:

> To consult widely with various stakeholders in the community to inform the Senate in its deliberations on the Bill. The Senate last considered embryo and cloning issues in 1986.

1.3 The inquiry was advertised in *The Australian* on 28 August and 11 September 2002 and through the Internet. Submissions were also invited from a large range of groups and individuals, including representatives from the medical science research community (domestic and international, private and public); consumer and other health care groups; ethics groups and other community organisations. Due to the tight timeframe for the inquiry, the closing date for submissions was 13 September 2002, although the Committee continued to receive submissions throughout the course of the inquiry.

1.4 The Committee received 1851 public submissions, together with a large amount of additional material from witnesses at hearings and in response to questions on notice. The list of submissions and other written material received by the Committee and for which publication was authorised is at Appendix 1. The Committee held public hearings in Canberra on 29 August and 17, 19, 24 and 26 September 2002 involving some 52 witnesses. A list of witnesses who appeared at the public hearings is included at Appendix 2. Submissions that were received electronically and the *Hansard* record of the public hearings may be accessed through the Committee's website at www.aph.gov.au/senate_ca

1.5 This inquiry has been undertaken in circumstances where the political parties have given their Senators a 'free vote' on the Bill when it is considered in the Senate. Thus, in conducting the inquiry and in the preparation of the report, the Committee has been mindful that the purpose of the inquiry was primarily to gather information to assist Senators make an informed decision on the Bill. The report aims to balance the major issues and arguments relating to the subject of the Bill without attempting to formulate conclusions or recommendations that the Committee considers should be the prerogative of individual Senators in a 'free vote'.

1.6 The report has been structured in the following fashion. This background chapter refers to the inquiries, reports and debate that has taken place over nearly two decades leading to the introduction of the Bill. Chapters 2 and 3 discuss the scientific and ethical issues that underpin the Bill, chapter 4 considers the provisions of the Bill in detail and finally chapter 5 provides international comparisons, legislative or otherwise, on the subject.

House of Representatives consideration of the Bill

1.7 As noted above, the Bill was introduced into the House of Representatives on 27 June 2002. The Bill was debated in the House on 27 June and on 20, 21, 22 August and in the Main Committee of the House on 26, 27 and 28 August 2002 with 105 members participating in the debate.

1.8 On 29 August 2002 the House agreed after a lengthy debate to a procedural motion that divided the provisions of the Bill into two Bills, as indicated below:

- Prohibition of Human Cloning Bill 2002 consisting of, with associated amendments, the title, enacting formula and Parts 1 and 2 and clauses 56, 61 and 62 and the schedule of the Bill as introduced, and an activating clause.
- Research Involving Embryos Bill 2002 consisting of, with associated amendments, Parts 3, 4, 5 and 6 of the Bill, and also including with amendments the provisions of clauses 56, 61 and 62 of the Bill as introduced, and a new clause 55A.

1.9 The Prohibition of Human Cloning Bill 2002 was passed by the House of Representatives on 29 August 2002 and introduced into the Senate on 18 September. The Research Involving Embryos Bill 2002 was considered in detail on 16, 24 and 25 September and was finally passed by the House without amendment on 25 September.

1.10 With the two Bills created by the splitting of the original Bill passing in the House of Representatives without amendment, the provisions of the original Bill as referred to the Committee remain unaltered. For ease of reference, the Committee has referred in the report to the provisions by the clause number from the original Bill.

Inquiries, reports and debate on human cloning and embryo research

1.11 There have been a number of reports and inquiries since the 1980s in relation to human cloning and research involving excess ART embryos. The following is a brief summary of the major inquiries and reports and their outcomes.[1]

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1 The following section is largely based on information from *Submission* 23, pp.5-8 (NHMRC); Parliamentary Library Bills Digest No.17 2002-03, *Research Involving Embryos and Prohibition of Human Cloning Bill 2002*, pp.16-18; and House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*, August 2001.

Senate Select Committee on the Human Embryo Experimentation Bill 1985

1.12 The Senate established a Select Committee in October 1985 to consider the Human Embryo Experimentation Bill 1985, a private Senator's bill introduced by Senator Brian Harradine. The Committee's primary task was to consider for the purposes of the IVF program whether it was necessary or desirable to carry out research on relevant human embryos by manipulation, dissection or administration of drugs, and, if so, whether any guidelines could be formulated to govern such research. The Committee reported in October 1986.[2]

1.13 The Select Committee adopted the usage 'embryo' to refer to 'genetically new human life organised as a distinct entity oriented towards further development'. The Committee observed the distinction between experimentation of diagnostic and/or curative value and experimentation with no such value but undertaken to advance medical/scientific knowledge. The former it termed 'therapeutic experimentation', the latter 'non-therapeutic experimentation' with a further distinction 'destructive non-therapeutic experimentation' indicating that such experiments were, based on the state of knowledge at the time, so invasive as to inevitably cause the destruction of the subject of the experiment.

1.14 The Committee concluded that 'the respect due to the embryo from the process of fertilisation onwards requires its protection from destructive non-therapeutic experimentation'. The Committee also found that 'any supposed distinction between so called "spare" embryos and those created specifically for experimental purposes to be ethically unsound' and recommended that 'the concept of guardianship be adopted as the most appropriate model to indicate the respect due to the embryo in this context'.[3]

Development of the NHMRC/AHEC[4] Ethical Guidelines on ART

1.15 In October 1982 the NHMRC issued guidelines on the ethical aspects of research related to the use of assisted reproductive technology (ART) - *In vitro fertilisation and embryo transfer* as a supplementary note to the *NHMRC Statement on Human Experimentation*. In 1993 the Australian Health Ethics Committee (AHEC)

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2 *Human Embryo Experimentation in Australia*, Report of the Senate Select Committee on the Human Embryo Experimentation Bill 1985, September 1986, Parliamentary Paper No. 437 of 1986.

3 *Human Embryo Experimentation in Australia* (1986), pp.xiii-xiv. See also *Committee Hansard* 26.9.02, pp.226-7 and *Submission* 899 (Rev Prof Michael Tate AO) – Former Senator Tate was Chairman of the 1985 Select Committee.

4 The Australian Health Ethics Committee is a principal committee of the National Health and Medical Research Council. AHEC's primary functions are to advise the NHMRC on ethical issues relating to health and developing guidelines for the conduct of medical research involving humans. Other functions include the promotion of community debate on health ethics issues, monitoring the work of human research ethics committees and monitoring and advising on international developments in health ethics.

commenced a review of these guidelines, leading to the release in June 1996 of *Ethical Guidelines on Assisted Reproductive Technology*.[5] The Guidelines are still operative, although as discussed in chapter 4 they are presently being reviewed, and describe a range of prohibited or unacceptable practices. On the issue of research involving excess ART embryos the Guidelines allow the use of excess ART embryos for research that may damage or destroy the embryo, under exceptional circumstances.

1.16 In releasing these guidelines, AHEC identified the need for all States and Territories to introduce comprehensive ART legislation and recommended to the Commonwealth Minister for Health that ART legislation be enacted in those States and Territories which had not introduced such legislation.

1998 AHEC Report to the Minister for Health and Aged Care

1.17 In 1998, the Minister for Health and Aged Care, Dr Michael Wooldridge, requested AHEC to report to him on the scientific, ethical and regulatory considerations relevant to cloning of human beings. The report entitled *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings* was provided to the Minister on 16 December 1998.

1.18 AHEC recommended that the Government should reaffirm support for the UNESCO *Declaration on the Human Genome and Human Rights*, especially the article recommending the prohibition of the reproductive cloning of human beings; all States should legislate to limit research on human embryos according to the principles set out in the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*; all States should establish statutory authorities to regulate research on human embryos according to the principles set out in the NHMRC *Ethical Guidelines*; and the Minister should encourage informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques.

House of Representatives Standing Committee on Legal and Constitutional Affairs – 2001 Report on Human Cloning

1.19 In August 1999, Minister Wooldridge asked the House of Representatives Standing Committee on Legal and Constitutional Affairs to review the 1998 AHEC report *Scientific, Ethical and Regulatory Considerations relevant to Cloning of Human Beings*. The Committee undertook extensive consultations over a period of two years. Mr Kevin Andrews, the Committee Chair, has commented that 'at the core of the Committee's deliberations was the question: is there any benefit in conducting stem cell research or in the application of cloning technologies to human beings? If there is, what use of these technologies is permissible to achieve these benefits?'[6] The

5 www.health.gov.au/nhmrc/publications/pdf/e28.pdf

6 *House of Representatives Hansard,* 28.8.02, p.5747 (Mr Kevin Andrews).

Committee's report *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research* was released in August 2001.[7]

1.20 The majority of the Committee recommended:

- the enactment of legislation to regulate human cloning and stem cell research;
- that such legislation should include a ban on cloning for reproductive purposes combined with criminal penalties and loss of an individual's research licence; and
- the establishment of a national licensing body empowered to issue licences for research involving the isolation, creation and use of embryonic stem cells.

1.21 A minority of Committee members opposed any research which involved the destruction of human embryos and expressed concerns about the continued use of embryonic stem cells derived from embryos, whether in Australia or overseas.

1.22 The NHMRC indicated that the Bill introduced into Parliament is consistent with the majority report of the House of Representatives Committee – which is also consistent with the NHMRC/AHEC *Ethical Guidelines on ART* issued in 1996.

Gene Technology Act 2000

1.23 In December 2000, community concern regarding a lack of legislation in some States and Territories to regulate the cloning of human beings led to the amendment of the Gene Technology Bill 2000 in the Senate. Clauses were inserted in the Bill that ban human cloning, certain experiments involving animal eggs and certain experiments involving putting human and animal cells into a human uterus. These were intended as interim provisions while the Commonwealth, States, Territories and the NHMRC identified the most effective and comprehensive wording for a prohibition on human cloning and the creation of hybrid embryos.

1.24 The current Bill provides for such prohibitions and therefore repeals the sections that were inserted in the *Gene Technology Act 2000*.

Australian Health Ministers' Conference consideration of the issues

1.25 Australian Health Ministers have considered the issue of human cloning and research involving excess ART embryos from 1999, when the recommendations of the AHEC report prompted the Minister for Health and Aged Care to write to State and Territory Health Ministers urging them to consider the development of complementary legislation and regulation in the area of human cloning and ART.

1.26 Following that correspondence, the Australian Health Ministers' Advisory Council (AHMAC) and then the Australian Health Ministers' Conference (AHMC) considered the issues. In July 2000, AHMC decided that each jurisdiction would

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7 www.aph.gov.au/house/committee/laca/humancloning/report.pdf

independently legislate to regulate ART clinical practice, but agreed to work towards a nationally consistent approach for the prohibition of human cloning. Following AHMC's decision, Commonwealth, State and Territory officials worked together to prepare a detailed report outlining regulatory options for prohibiting human cloning, for consideration by Health Ministers. However, at the same time the issue was also placed on the COAG agenda.

COAG consideration and the 5 April 2002 communique

1.27 On 8 June 2001, the Council of Australian Governments (COAG) discussed assisted reproductive technology including human cloning and in a communique stated that the Council committed itself to achieving nationally consistent provisions in legislation to prohibit human cloning. It also agreed that jurisdictions work towards nationally consistent approaches to regulate assisted reproductive technology and related emerging human technologies. However, on this latter issue, Heads of Government were acutely aware of the need to engage the community on the matter and to ensure that all sectors of the community benefit fully from advances in medical science while prohibiting unacceptable practices.

1.28 COAG sought a report from Health Ministers by the end of 2001 on technical issues, with the aim of a nationally consistent approach being in place by all jurisdictions by June 2002. Health Ministers endorsed this approach at a meeting on 1 August 2001.

1.29 A technical report, *Human Cloning, Assisted Reproductive Technology (ART) and Related Matters*, was subsequently prepared by the Commonwealth in close consultation with officials from all jurisdictions and following consultation with experts in a range of fields including medical research, ART, ethics and law. Consultation was also undertaken with community and religious leaders as well as community groups. Both Health Ministers and COAG considered the report at concurrent meetings on 5 April 2002, although the Australian Health Ministers' Conference deferred any further consideration of the subject until after the outcome of the COAG meeting was known.

1.30 At the COAG meeting on 5 April 2002, the Prime Minister and all Premiers and Chief Ministers agreed that the Commonwealth, States and Territories would introduce nationally consistent legislation to ban human cloning and other unacceptable practices. A communique setting out the agreed outcomes of the discussions issued after the meeting stated:

> The Council agreed that research involving the use of excess assisted reproductive technology (ART) embryos that would otherwise have been destroyed is a difficult area of public policy, involving complex and sensitive ethical and scientific issues. Having noted the range of views across the community, including concerns that such research could lead to embryos being created specifically for research purposes, the Council agreed that research be allowed only on existing excess ART embryos, that would otherwise have been destroyed, under a strict regulatory regime, including requirements for the consent of donors and that the embryos were

> in existence at 5 April 2002. Donors will be able to specify restrictions, if they wish, on the research uses of such embryos.
>
> …
>
> The Council agreed that research involving the destruction of existing excess ART embryos be permitted under a strict regulatory regime to enable Australia to remain at the forefront of research which may lead to medical breakthroughs in the treatment of disease. It was further agreed that the regulatory regime governing the use of excess ART embryos that would otherwise have been destroyed will be reviewed within three years. Research would need to have approval from an ethics committee and be in accordance with NHMRC and Australian Health Ethics Committee guidelines.

The relevant sections of the communique dealing with human cloning, ART and related matters are reproduced in full at Appendix 3. The Committee requested access to the documentation that was presented to the Health Ministers and used as the basis of the report to COAG that informed COAG's decision on these issues. The NHMRC provided advice from AHMAC that while the decisions and resolutions made at AHMC meetings may be made publicly available, the agenda papers submitted to Ministers, which are often subject to Cabinet consideration, are not available for public information.[8]

1.31 The COAG Communique is not legally binding on the Commonwealth, the States and the Territories, but is an agreement which depends on the goodwill of each of the governments concerned. However, the NSW and Queensland Governments emphasised the importance of the fact that all States and Territories have worked cooperatively towards the development of nationally consistent legislation to fulfil the requirements of the COAG communique. Indeed, the State and Territory Governments pointed to the achievement of national consistency as a key principle in their acceptance of the Bill.[9]

1.32 The NSW and Queensland Governments' submissions expressed concern that the division of the provisions into two Bills was moving away from the COAG Agreement. However, the Prime Minister said in the House:

> What is in the COAG agreement is a series of principles, and this bill – or these bills, if you split it – gives effect to the COAG principles…I have advice that, by splitting the bill, you are not endangering the establishment of the regime agreed to at COAG, providing both bills are passed.[10]

This concern was not expressed to the Committee by any other States or Territories.

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8 *Committee Hansard* 26.9.02, p.254 (Senator Harradine). *Submission* 23, Additional information 16.10.02, p.4 (NHMRC).

9 *Submissions* 891 (NSW Government) and 1500 (Queensland Government).

10 *House of Representatives Hansard* 29.8.02, p.5809 (Mr Howard). The Minister's second reading speech for the Prohibition of Human Cloning Bill 2002 confirmed the Prime Minister's comments (see *Senate Hansard* 18.9.02, p.4324).

Development of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002

1.33 Between 5 April 2002 and the introduction of the Bill in June 2002, staff of the NHMRC worked with the Principal Committees of the Council, relevant Commonwealth agencies and all States and Territories to develop the legislation. The NHMRC emphasised to the Committee that it was the task of the Council to implement the policy position taken at COAG. The parameters for the legislation were provided by the decisions of COAG as set out in the COAG communique.[11]

1.34 An exposure draft of both the Bill and an explanatory memorandum was developed which became part of consultations undertaken by the NHMRC in each State and Territory. These consultations included discussions with experts in science, medical research, law and ethics and representatives from human research ethics committees as well as religious and community leaders.[12] The NSW Government submission refers not only to the Commonwealth consultations held in NSW, but also to in depth consultations with key stakeholders conducted by the Premier of NSW.[13] The NHMRC also took account of submissions made to the House of Representatives Standing Committee on Legal and Constitutional Affairs during its two year inquiry into human cloning and stem cell research, and written submissions received by the NHMRC on the draft Bill.[14]

11 *Committee Hansard* 29.8.02, pp.4-6, 9 and 26.9.02, p.246 (NHMRC).

12 The list of invitees for the consultations and actual attendees is included in the NHMRC *Submission* 23, Attachments B and C.

13 *Submission* 891, pp.4-5 (NSW Government).

14 *Committee Hansard* 29.8.02, p.9 (NHMRC).

CHAPTER 2

STEM CELL RESEARCH AND HUMAN CLONING: AN OVERVIEW OF SCIENTIFIC ASPECTS

Introduction

2.1 The fields of stem cell research and cloning are complex and rapidly developing areas of scientific endeavour.

2.2 There are a number of detailed and accessible accounts available of the science involved in these fields. In particular, the report of the Australian Parliament's House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*, August 2001,[1] provides a comprehensive introduction to human reproductive processes as well as to the specific technologies involved in stem cell research and human cloning.

2.3 Other sources of information for non-specialists are the National Health and Medical Research Council's (NHMRC) fact sheets,[2] and the National Institutes of Health (NIH), *Stem Cells: Scientific Progress and Future Research Directions*, June 2001.[3]

2.4 The Committee will not repeat in detail the information available from these sources. It seeks in this chapter to provide an overview of the technologies pertaining to stem cell research and human cloning, before outlining a range of the scientific concerns raised in evidence in relation to them.

Defining terms

2.5 In this section, the Committee seeks to define the terms and to outline the main areas of possible future scientific development in stem cell research and human cloning in such a way that the provisions of the Bills before the Senate and the ethical issues provoked by them can be properly considered.[4]

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1 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*, August 2001 [hereafter *Human cloning*].

2 These are available at http://www.nhmrc.gov.au

3 See US Department of Health and Human Services website, http://www.nih.gov/news/stemcell/scireport.htm (23 August 2002).

4 Department of the Parliamentary Library, Bills Digest No.17 2002-03, *Research Involving Embryos and Prohibition of Human Cloning Bill 2002*, p.4.

Stem cells

2.6 There are two types of cell which form 'the building blocks of the body'. They are called 'germ' cells and 'somatic' cells.

2.7 Germ cells are located in the ovary and testis, and are the cells from which sperm and eggs arise. All other cells types in the body are somatic cells. They are usually specialised for their roles as, for example, muscle cells or nerve cells in particular tissues or organs.[5]

2.8 The House of Representatives Human cloning report explained that 'all cells form initially from unspecialised cells. In the embryo, stem cells form the early tissues and organs. Under the influence of unknown genetic and chemical signals, cells become specialised and differentiated. Some stem cells are retained in most tissues or organs throughout life to participate in regeneration and repair'.[6]

Embryonic stem cells

2.9 After fertilisation of the human egg by sperm, the process of cell division in the embryo commences. By about the fourth day, the embryo consists of a ball of 32-64 cells, known as a 'morula'.[7]

2.10 By day five or six, the morula has developed into a 'blastocyst'. The blastocyst consists of an outer casing of cells and an inner cell mass.[8] The cells of the 'outer casing' are already committed to becoming placental tissue and have lost the ability to develop into other tissues and organs. The 'inner cell mass', however, is composed of embryonic stem cells and they become many or all of the specialised cells or tissues of the body.[9]

2.11 Embryonic stem cells can be removed from the blastocyst with a thin glass needle, or by a biochemical dissociation of the cells.[10] The removal of the embryonic stem cells from the blastocyst entails the destruction of the embryo.

2.12 The embryonic stem cells can be placed into a culture medium, where they can replicate and remain undifferentiated indefinitely. They can also be frozen and

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5 *Human cloning*, pp.16-17.

6 *Human cloning*, p.16; see also National Institutes of Health (NIH), *Stem Cells: Scientific Progress and Future Research Directions*, http://www.nih.gov/news/stemcell/scireport.htm (23 August 2002), p.ES-2.

7 *Human cloning*, p.13.

8 *Human cloning*, p.13.

9 *Human cloning*, p.20.

10 *Human cloning*, p.20.

stored, or grown in culture to differentiate into a wide range of specialised cell types or 'lineages'.[11]

2.13 Stem cells that have differentiated into specialised types, either spontaneously or in response to specific culture conditions, are called 'stem cell lines'. The Academy of Science has noted that:

> The research challenges are to identify and characterise the factors and conditions that maintain, expand and direct the lineages of the cell lines, to drive exclusive differentiation of cells into desired tissue types.[12]

Adult stem cells

2.14 An adult stem cell is an undifferentiated or unspecialised cell that occurs in differentiated tissue and is responsible for normal repair and replacement of that tissue.[13] Adult stem cells have been found in sources including bone marrow, blood, the brain, skeletal muscle, the pancreas, fetal tissue and tissue from the umbilical cord.[14]

2.15 Adult stem cells are able to make identical copies of themselves, or to 'self-renew', for the lifetime of the organism.[15]

2.16 It has been difficult so far routinely to identify adult stem cells from the majority of organs. They are also not easy to grow or maintain in an undifferentiated state in culture, because 'they naturally incline to become one or other more specialised cell type such as muscle, nerve or skin'.[16] However, in the past three years, there has been a major expansion in research on adult stem cells and there is a new understanding of their flexibility.[17] In particular, some evidence suggests that, given the right environment, some adult stem cells are capable of being 'genetically reprogrammed' to generate specialised cells that are characteristic of different tissues.[18]

Embryonic germ cells

2.17 An embryonic germ cell is derived from fetal tissue. As noted earlier, germ cells are located in the ovary and testis, and are the cells from which sperm and eggs

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11 *Human cloning*, pp.20-21; Australian Academy of Science, *Human Stem Cell Research*, 18 April 2001, p.12.

12 Australian Academy of Science, *Human Stem Cell Research*, 18 April 2001, p.12.

13 *Human cloning*, p.21; *Stem Cells: Scientific Progress and Future Research Directions* (NIH), p.ES-2.

14 *Stem Cells: Scientific Progress and Future Research Directions* (NIH), p.ES-2.

15 *Stem Cells: Scientific Progress and Future Research Directions* (NIH), p.ES-2.

16 *Human cloning*, p.21.

17 *Human cloning*, p.22.

18 *Stem Cells: Scientific Progress and Future Research Directions* (NIH), p.ES-3.

arise. Embryonic germ cells are isolated 'from the primordial germ cells of the gonadal ridge of the 5- to 10-week foetus'.[19]

2.18 Embryonic germ cells are like embryonic stem cells in that they have the capacity to differentiate into many or all of the tissues in the body. They are not, however, identical in their properties and characteristics.[20]

Embryonic stem cells and germ cells - The Trounson debate

2.19 The differentiation between different cell types, their derivation and properties (including developmental potential) is complex. That difficulties arise can be seen in the debate that arose following Professor Alan Trounson's presentation of the rat with a motor neurone lesion.

2.20 In a presentation to the Liberal/National parties that received widespread publicity, Professor Trounson referred to experimentation on a paralysed rat as an example to demonstrate that 'embryonic stem cells have been used to derive tissue for transplantation for the following major diseases/pathologies':

> Human ES cells directed into neural stem cells and motor neurone cells – when injected into the spinal column of rats with a motor neurone lesion (viral induced) – no muscle control at all below C6 (lower body) – were completely reversed (animals walked again and had control of bowel and bladder function) – potential application for human Motor Neurone Disease.[21]

A similar presentation was made in a Parliamentary briefing for National Science Week on Thursday, 22 August 2002.

2.21 Subsequent to the presentation it was established that the paralysed rat had been treated with 'differentiated germ cells from the early sex gland of a two month old aborted foetus'.[22] This led to much criticism of Professor Trounson for misrepresenting the science involved and misleading the politicians with the presentation. The Committee received many general comments echoing these views. A number of witnesses did provide specific comments relating to the Trounson presentation and the science involved.

2.22 Professor Peter Silburn, a clinical neurologist, told the Committee:

> The issue was used, and it was portrayed that this was an embryonic stem cell line from a human that was used to treat and cure–the word 'cure' was used–an animal with motor neurone disease. We have subsequently learnt

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19 *Stem Cells: Scientific Progress and Future Research Directions* (NIH), p.ES-2.

20 *Stem Cells: Scientific Progress and Future Research Directions* (NIH), p.ES-2.

21 The Case for Embryonic Stem Cells, notes for the presentation by Alan Trounson, p.5. The example is referenced to Kerr et al. Nature Medicine – On Line: August 2002.

22 *Submission* 1042, p.6 (Do No Harm – Dr van Gend).

> that when you actually look at that evidence, look at that statement, indeed they were not human embryonic stem cell lines. We also found out that these in fact were not published…We also found out that in fact it was not motor neurone disease and that the animal was not cured.[23]

2.23 The point of difference between a germ cell and an embryonic stem cell was commented upon by Dr Amin Abboud, a lecturer in medical ethics and health law:

> Listening to [Professor Trounson's] explanation of the differentiation between germ cells and embryonic stem cells reminded me–and I am not trying to be cynical–of what medieval theologians are often accused of: questioning how many angels can dance on a pinhead. There is a fundamental difference between a differentiated germ cell–it was a gonadal germ cell–and an embryonic stem cell, and I feel his explanation is wanting scientifically.[24]

2.24 Professor Trounson provided an explanation at the hearing of the terminology used in the presentation and the provenance of the research he quoted. He disputed that there is a 'fundamental difference' between the two types of cell:

> I use the term embryonic stem cells to describe embryonic germ cells. In doing so, I did not mislead members of parliament because the terms 'embryonic stem cells' and 'embryonic germ cells' are often used interchangeably…
>
> Embryonic stem cells from embryos are functionally indistinguishable from embryonic germ cells and will do everything that embryonic germ cells can do in terms of differentiation and tissue colonisation. Both represent human pluripotential stem cells derived from embryos and are quite distinct from adult tissue stem cells.
>
> Given the time available and the need to make several points about the potential benefits of embryonic stem cells, rather than give an extended lesson in cell biology, I used the term 'human embryonic stem cells' in a generic sense. This is not incorrect. It is perfectly reasonable to use a study on embryonic germ cells to support the argument for further research using embryonic stem cell lines derived from IVF embryos for treatment of some motor neurone disorders…
>
> I do not believe that I had any intention to mislead you or any other members of the parliament during that period of time. If I did, I apologise; it was certainly not my intention. I was trying to make an argument that this was the first time I had ever seen 'human embryonic stem cells' generically used in an animal in that way.[25]

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23 *Committee Hansard* 17.9.02, p.52 (Professor Silburn); see also *Committee Hansard* 24.9.02, pp.176-7 (Dr van Gend).

24 *Committee Hansard* 24.9.02, p.173 (Dr Abboud).

25 *Committee Hansard* 24.9.02, pp.136, 147.

2.25 Senator Jacinta Collins did not accept Professor Trounson's explanation:

> The public record shows quite clearly that in the question I asked you…I sought to understand the distinction between embryonic stem cells and those used in the particular case. Your response reiterated three times: 'No, they were embryonic stem cells.' This is what has given the media and others cause to believe that perhaps they were deliberately misled.[26]

2.26 Professor Trounson did however receive international support for his view. Professor Marilyn Monk, from the Institute of Child Health in London, submitted:

> His "error" was that he was not exact in that he did not make clear the derivation of the stem cell. The stem cells originally came from the gonads of an aborted post-implantation fetus rather than from the sub-population of cells of the pre-implantation embryo mentioned above. The point is that they are the same lineage of cells - the embryonic stem cells - just further 'down the line'. Both types of cells behave in similar ways in terms of their developmental potential.[27]

Properties of cells

2.27 For the purposes of this inquiry, the properties of cells that are of interest are those related to their capacity to 'differentiate' or 'specialise' into particular kinds of tissue.

2.28 'Differentiation' is the process by which an unspecialised cell, such as a stem cell, becomes specialised into one of the cells that make up the body. During differentiation, certain genes become activated and other genes become inactivated, meaning that the cell develops specific structures and performs specific functions.[28] For example, a mature, differentiated nerve cell has thin, fibre-like projections that send and receive the electrochemical signals that permit the nerve cell to communicate with other nerve cells.

2.29 In the laboratory, stem cells can be manipulated to become specialised or partially specialised cells and this is known as directed differentiation.[29] However, most of the cellular triggers and signals that determine how cells are differentiated to become, say, muscle, nerve or skin cells, are not understood.[30] Much of the research in

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26 *Committee Hansard*, 24.09.02, p.146 (Senator Collins).

27 *Submission* 1021, p.2 (Professor Monk). Dr Michael West who organised the collaboration in the US that led to the isolation of human embryonic stem cells made similar comments and advised that 'the terms were and continue to be used interchangably by some scientists' *Submission* 1083, p.1 (Dr West).

28 *Stem Cells: Scientific Progress and Future Research Directions* (NIH), p.ES-2.

29 *Stem Cells: Scientific Progress and Future Research Directions* (NIH), p.ES-2.

30 *Human cloning*, p.17.

this area is directed towards understanding how to control and direct cell differentiation or to identify the factors responsible for doing so.[31]

2.30 The kind of capacity that cells possess to differentiate into different kinds of cell is described by the concept of 'potency' or potential.

2.31 Totipotent cells can develop into a whole individual. The cells that possess this capacity are fertilised eggs and the individual cells of the embryo up to the 16-32 cell stage.[32]

2.32 Pluripotent cells have the capacity to develop into many or all the cells of the body, but cannot develop into whole individuals. The only known sources of human pluripotent cells are embryonic stem cells and embryonic germ cells.[33]

2.33 Recent research on adult stem cells indicates that they have the capacity to generate not only the tissue in which they are found, but to generate the specialised cell type of another tissue.[34] It is thought, however, that adult stem cells can differentiate into a more restricted range of tissues or organs than embryonic stem cells. They are thus described as 'multipotent' rather than 'pluripotent'.[35]

Cloning technologies

2.34 The Australian Academy of Science has defined 'cloning' as:

> the production of a cell or organism with the same nuclear genome as another cell or organism.[36]

2.35 As this definition makes plain and as the report into human cloning of the House of Representatives Standing Committee on Legal and Constitutional Affairs emphasised, cloning does not necessarily mean the replication of an entire individual.[37] It can mean simply the replication of a cell or group of cells.

2.36 Cloning occurs naturally in the 'asexual reproduction of plants, the budding of yeast in beer, the formation of identical twins and the multiplication of cells to repair damaged tissue in the normal process of healing'.[38] Cloning may also be achieved

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31 *Human cloning*, p.23.

32 *Human cloning*, p.17.

33 *Human cloning*, p.17; *Stem Cells: Scientific Progress and Future Research Directions* (NIH), p.ES-2.

34 *Stem Cells: Scientific Progress and Future Research Directions* (NIH), p.ES-3.

35 *Human cloning*, p.17.

36 *Human cloning*, p.19.

37 *Human cloning*, p.18.

38 *Human cloning*, p.18.

artificially.[39] At present, there are two artificial cloning technologies: embryo splitting; and nuclear transplantation, also known as 'somatic cell nuclear transfer'.[40]

Embryo splitting

2.37 The technology of embryo splitting involves fertilising an egg with sperm, and dividing the newly formed embryo into two or more individuals. In cases of identical twins this is the mechanism that occurs naturally, but it can also be performed in the laboratory. The individuals that result from this process, which is also known as 'fission', will be genetically identical to one another but not a clone of either parent.[41]

Somatic cell nuclear transfer

2.38 This technique was used to create 'Dolly' the sheep, and may be a technique used in developing stem cell therapies.[42] It involves removing the nucleus of an egg cell, which contains almost all of the genetic material in the cell, and replacing it with another cell nucleus. This second nucleus may be taken from any somatic cell, such as a skin cell or liver cell. In the case of Dolly, the cell was taken from the sheep's mammary gland.[43]

2.39 The enucleated egg and its new nucleus are fused using an electric current, and it forms a new embryo which is 'substantially' genetically identical to the organism from which the somatic cell was taken. In addition to the DNA from the somatic cell, this 'cloned' embryo would also possess very small amount of DNA attributable to the mitochondria in the egg cell.[44]

2.40 In theory, the cloned embryo may either be transplanted into a gestational mother and allowed to develop until birth, or it may be allowed to develop to the blastocyst stage when the inner cell mass or embryonic stem cells could be harvested, resulting in the destruction of the cloned embryo. In practice:

> the success of the somatic cell nuclear transfer procedure to form a viable blastocyst is approximately 1-2% of attempts made. The success of cloned embryos transferred to the uterus [of non-human mammals] resulting in live births is also of this order. The reasons for the many failures have yet to be fully defined. The efficiency of the procedure must be improved greatly

39 *Human cloning*, p.18.

40 Department of the Parliamentary Library Bills Digest No.17 2002-03, p.2.

41 Department of the Parliamentary Library Bills Digest No.17 2002-03, p.3.

42 *Human cloning*, pp.19, 23.

43 Department of the Parliamentary Library Bills Digest No.17 2002-03, p.2.

44 Department of the Parliamentary Library Bills Digest No.17 2002-03, p.2.

> before it becomes a viable technique, either for animal husbandry or for cell manipulation.[45]

2.41 Where the new embryo produced by a cloning technology is allowed to develop until birth, the term 'reproductive cloning' applies.

2.42 Where the new embryo is allowed to develop only so that its embryonic stem cells may be extracted, the term 'therapeutic cloning' has been applied. There is some dispute over the application of this term.

2.43 The term 'therapeutic cloning' derives from the potential application of the technology to the development of therapies. For example, through somatic cell nuclear transfer it is at least theoretically possible to create an embryo using the nucleus of a somatic cell from a patient. The stem cells that are subsequently extracted from that embryo are clones of the patient's own cells, and thus have the potential to grow into 'matching' or compatible tissue for the treatment of particular diseases. In other words, the purpose for which the cloned embryo is created is 'therapeutic' rather than 'reproductive'.

2.44 However, some have objected to the term 'therapeutic cloning' on the grounds that the relevant contrasting term should not be 'reproductive' but 'non-therapeutic'.[46]

2.45 The distinction between 'therapeutic' and 'non-therapeutic' scientific or medical research was made in the 1964 Declaration of Helsinki, and revised in Tokyo in 1975. This declaration was confirmed by the World Health Organisation and the Council for International Organisations of Medical Sciences as the basis for international guidelines for biomedical research involving human subjects.[47]

2.46 According to that distinction, 'therapeutic' research is research or practice carried out where the procedure is or is expected to be of benefit to the subject of the research. 'Non-therapeutic' research does not directly benefit the subject of the research, although it may be of benefit to others or to scientific understanding in general.[48]

2.47 The distinction was more recently affirmed by the Australian Health Ethics Committee in a statement by the Committee's chair, Dr Kerry Breen:

> Therapeutic interventions are interventions directed towards the wellbeing of the individual embryo involved and non-therapeutic interventions are interventions that are not directed towards the benefit of the individual

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45 *Human cloning*, p.22.

46 See, for example, *Submissions* 899, 981, and 987; *Committee Hansard*, 17.9.02, p.34 (Dr Juttner); *Committee Hansard*, 26.9.02, p.226 (Professor Tate).

47 See Senate Select Committee on Human Embryo Experimentation Bill 1985, *Human Embryo Experimentation in Australia*, September 1986, p.14 and Appendix VII.

48 See Senate Select Committee on Human Embryo Experimentation Bill 1985, *Human Embryo Experimentation in Australia*, September 1986, pp.14-16.

> embryo but rather towards improving scientific knowledge or technical application. Non-therapeutic experimentation includes both non-destructive procedures (which include observation) and destructive procedures…
>
> The more-recently-coined term `therapeutic cloning' collapses both (a) the distinction between therapeutic and non-therapeutic research on embryos and (b) the distinction between destructive and non-destructive experimentation on embryos. The creation of embryos specifically for research purposes, experimentation on those embryos and their subsequent destruction, etc. all fall under this term. It was because of the lack of transparency of the term `therapeutic cloning', because the term concealed rather than revealed these ethically-significant differences, that AHEC rejected its use.[49]

2.48 The cloning of an embryo in order to extract its stem cells for therapeutic application to others does not constitute a procedure 'of benefit' to the embryo.

2.49 The Reverend Professor Michael Tate, former Chair of the Senate Select Committee on Human Embryo Experimentation, observed:

> Language has now changed, and in a dangerous way that confuses the permissible ways in which to advance science in this area. Recently, 'therapeutic' has been simply opposed to 'reproductive'. This is because the question of cloning has become significant, and 'therapeutic', said to be advancing some knowledge that can have clinical or medical benefits immediately on the subject or, prospectively, on other embryos or human lives, is said to be undeniably good, whilst 'reproductive' experimentation is said to be still the subject of debate.
>
> I believe we need to emphasize again that the term 'therapeutic' is misused if applied to the intentional and deliberate destruction of the subject of the experiment. However, if this definitional argument has been lost by the media's contrasting of therapeutic with reproductive, nevertheless, within 'therapeutic', distinctions clearly need to be made.[50]

2.50 The Academy of Science supports therapeutic cloning as 'a possible way ahead for the production of appropriate stem cell lines if that turns out to be what is needed to produce them'. The Academy also supports a moratorium on therapeutic cloning advising that 'at the moment the position of the Academy is that it is unwise to close [therapeutic cloning] off as a possibility in the future'.[51] Professor Robert Jansen indicated that he was not opposed to what he described as 'somatic cell nuclear transfer, sometimes referred to as therapeutic cloning' saying 'no, not as a matter of principle. I accept that, because of perhaps incomplete understanding of the issues, a suspension of activity in that area for three years might be reasonable. I do not have

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49 AHEC/NHMRC: Position on Cloning and Related Technologies, dated 15 December 2000, *Senate Hansard,* 7.02.01, p.21477.

50 *Submission* 899, p.2.

51 *Committee Hansard* 19.9.02, p.14 (Professor White, Academy of Science).

strong views.'[52] The Juvenile Diabetes Research Foundation was opposed to a permanent ban on the practice, recognising 'that there is quite a considerable amount of research that has to be done before we get to the stage where therapeutic cloning may or may not be useful'.[53]

Potential applications of stem cell research

2.51 There are two broad two areas of research with possible clinical applications enabled by stem cell technologies. They are:

- research into cell therapies; and
- 'spin-offs' from that research including research into early embryo development.

Stem cell therapies

2.52 The potential applications of stem cell therapies, whose development may or may not make use of cloning technologies, are said to be wide-ranging and revolutionary. The House of Representatives Human cloning report stated that:

> The ability to control and direct cell differentiation or to identify the factors responsible for doing so, has enormous potential for new therapies in medicine and for new biomedical industries…The potential benefits include a complete revolution in the ability to treat acute and chronic diseases, including Alzheimer's, Parkinson's, diabetes and many others.[54]

2.53 There are two main types of cell therapy currently envisaged as potentially arising from stem cell research. The first involves replacing or transplanting damaged or diseased cells by tissue developed either from embryonic stem cells or from adult stem cells. The second involves developing drugs or other therapies that may trigger tissue to repair itself or prevent tissue degeneration.

2.54 Professor Alan Trounson, Monash Institute of Reproduction and Development and CEO (Designate), National Stem Cell Centre, told the Committee that:

> Future research with embryonic stem cells will allow us, firstly, to discover factors that influence and regulate tissue formation. This knowledge may be used to develop pharmaceuticals for tissue repair in the future. Secondly, it will help us understand the role of genes in development and tissue function and why some of those genes lose their regulators and are associated with cancer later in life. Thirdly, research will help us produce cells in abundance that may be used to regain tissue function in people suffering from diseases such as diabetes, Parkinson's disease, cardiovascular disease and cystic

52 *Committee Hansard* 26.9.02, p.208 (Professor Jansen).

53 *Committee Hansard* 17.9.02, p.76 (Ms Royles, JDRF).

54 *Human cloning*, p.23.

> fibrosis. Fourthly, research will help us develop new drugs using some specific cell types such as hepatocytes in the liver.[55]

2.55 Professor Trounson spoke of these developments as contributing to 'a new era of medicine', with a combination of cell therapies and conventional medicine available to treat disease.[56] Mr Robert Moses, Chairman of the Board, National Stem Cell Centre, spoke on the potential of stem cell research as 'identified throughout the world as one of the three or four new bioscience endeavours most likely to yield major advances in the development of medicines during the next 10 to 15 years'.[57]

2.56 Other evidence to the inquiry, however, seriously questioned these claims, saying that they were overblown and premature.[58] Professor Colin Masters, Professor of Pathology at the University of Melbourne with expertise in the study of brain diseases, Alzheimer's and other neurodegenerative disorders, questioned claims made about the potential of research with embryos to create therapies:

> My observations on the current stem cell debate relate to the misrepresentation which has occurred over the potential therapeutic benefits of stem cell therapies, especially in the areas of Alzheimer's disease, Parkinson's disease, motor neurone diseases and other causes (traumatic and non-traumatic) of spinal cord paralysis.
>
> I have been concerned that advocates of embryonic stem cells as a therapy have created false expectations in the mind of the general community. The difficulties in developing these cells for therapeutic purposes in the brain pose immense scientific difficulties which require much more developmental research. The real value of stem cells for drug discovery has been almost overlooked in the public debate.[59]

2.57 Dr Peter McCullagh advised the Committee that his career was spent studying immunological tolerance in the area of experimental transplantation. He said:

> I am appalled at the meretricious arguments and claims that have been presented for what can be done in relation to transplantation if this bill goes through and if the research that is foreshadowed by people appearing in favour of the bill proceeds…In fact, when one looks at the claims made for transplantation based on embryonic stem cell research, I suspect that you will not find a single published paper on transplantation by any of the main protagonists.[60]

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55 *Committee Hansard*, 24.9.02, p.135 (Professor Trounson).

56 *Committee Hansard*, 24.9.02, p.135 (Professor Trounson).

57 *Committee Hansard*, 24.9.02, p.137 (Mr Moses).

58 See *Submissions* 84, 87, 162, 614; *Committee Hansard*, 17.9.02, p.53 (Professor Silburn) and 19.9.02, p.95 (Professor Rowe).

59 *Submission* 87 p.1 (Professor Masters).

60 *Committee Hansard*, 24.9.02, p.156 (Dr McCullagh).

2.58 Dr David van Gend, a general practitioner and the Queensland spokesperson for Do No Harm, expressed the view that proponents of embryonic stem cell research in particular have misrepresented both the prospects of that research and the proven therapeutic success of adult cells.[61]

2.59 Professor Peter Rowe, Director, Children's Medical Research Institute, Westmead, Sydney, stated that he had been interested for the past 38 years in the prospects of genetic or cell therapy, particularly for the treatment of childhood inherited disease and developmental abnormalities. Nevertheless, he considered that 'at this stage, human embryonic stem cells have very little to offer'. Professor Rowe said that:

> I think the public…has been grossly misinformed as to the potential…I feel that there is a lot of work that could be done on human embryonic stem cells, but to what end? Because I do not think we are ever going to use them in any form of treatment, not in the next foreseeable 20 or 30 years, if even then.[62]

2.60 Professor Michael Good, an immunologist and Director, Queensland Institute of Medical Research, argued that there will be major difficulties with the therapeutic application of tissue grown from embryonic stem cells because of the problems of immunological rejection. He also claimed that there is no established 'proof of concept' or 'proof of principle' that human embryonic stem cells can be used clinically, and that successful therapies derived from adult stem cells are being overlooked in the 'hype' about embryonic stem cells.[63]

2.61 Professor Good agreed that embryonic stem cell research should go ahead in animals, in order to establish any 'proof of principle', but that in the meantime:

> when there is a limited amount of money for research in this country…why would we waste it on putting something into human embryonic stem cell research that, in my estimation, will never make it into a therapy.[64]

2.62 The Committee asked the proponents of embryonic stem cell research to respond to these criticisms. In general terms, the proponents agreed that it is unrealistic to expect 'overnight' or 'miracle' cures from either embryonic or adult stem cell research, but disputed the claim that there is insufficient 'proof of principle' to justify undertaking research into human embryonic stem cells.

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61 *Committee Hansard*, 24.9.02, p.177 (Dr van Gend).

62 *Committee Hansard*, 19.9.02, p.95 (Professor Rowe).

63 *Committee Hansard*, 19.9.02, pp.89-91 (Professor Good).

64 *Committee Hansard*, 19.9.02, p.97, 102 (Professor Good); on the need to establish 'proof of concept' in animal models, see also *Committee Hansard*, 19.9.02, p.99 (Professor Rowe) and p.100 (Professor Bartlett).

2.63 For example, Professor John Shine, Secretary, Biological Sciences, Australian Academy of Science, stated that:

> we all realise that, in this particular area, the goal at the end of the day is to take one of our own cells, a skin cell or a blood cell, put it into culture, multiply it up, add the appropriate growth factors and transfer it or reprogram it into a nerve cell to treat Parkinson's or a pancreatic cell to treat diabetes. That is the goal at the end of the day.[65]

2.64 'To get there', he acknowledged:

> the academy, and all of us as scientists, recognise that we have an enormous amount of information that we have yet to gain - a lot of knowledge we have to learn - about what triggers cells and how they reprogram themselves in this situation…[66]

2.65 Professor John Hearn, a developmental biologist and Deputy Vice-Chancellor, Research, ANU, supported research in human embryonic stem cells, but agreed that 'embryonic stem cells are still a very long way off application to therapy'. He said that:

> it is unhelpful to have unqualified statements and sometimes emotional statements about the promise of this field, where we are at a very early stage …It is quite wrong to expect…that in the next five to 10 years, in the normal course of science and the normal progress of clinical trials, there is going to be anything that resolves those problems.[67]

2.66 Nevertheless, Professor Hearn submitted that the study of human embryonic stem cells will be important for understanding how cells 'choose' to develop into different types of lineage and that this understanding will have the potential to underpin major new therapies and possibly major new drugs.[68] Professor Hearn also disputed the claim that proof of principle sufficient to justify proceeding had not yet been established in relation to this research.[69]

2.67 Associate Professor Martin Pera, Co-Director, Centre for Early Human Development, Monash Institute of Reproduction and Development, similarly agreed that this is a rapidly evolving area of research and that 'it would be very wrong for anyone in the scientific community to promise cures in a certain time frame'.[70]

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65 *Committee Hansard*, 19.9.02, p.115 (Professor Shine).

66 *Committee Hansard*, 19.9.02, pp.115-116 (Professor Shine).

67 *Committee Hansard*, 19.9.02, pp.114-115 (Professor Hearn).

68 *Committee Hansard*, 19.9.02, p.114 (Professor Hearn).

69 *Committee Hansard*, 19.9.02, p.122 (Professor Hearn).

70 *Committee Hansard*, 24.9.02, p.143 (Professor Pera).

2.68 He also, however, disputed the claim that there is no proof of principle underpinning the research. He said:

> In recent years we have seen proof of concept of treatment in animal models, using mouse embryonic stem cells in Parkinson's disease, diabetes, stroke, demyelination, severe combined immune deficiency and myocardial infarcation.[71]

2.69 Proof of concept studies using human embryonic stem cells or embryonic germ cells transplanted into mouse models are, according to Professor Pera, 'probably taking place in labs around the world now. It will certainly be taking place in ours within the coming year'.[72]

2.70 Dr Andrew Elefanty, Senior Research Fellow and Laboratory Head, Centre for Early Human Development, Monash Institute of Reproduction and Development, argued that, in any case, there are limitations on the extent to which proof of concept studies in animal models can validate human stem cell research. He stated:

> Whilst human and mouse embryonic stem cells do have many similarities, there are many differences in the growth and differentiation of these two species of cells. Although we strongly believe in the use of mouse embryonic stem cells as a complementary system…it is evident that the differences between the biology of mouse and human embryonic stem cells will limit the degree to which results in the mouse system can be extrapolated to humans.[73]

2.71 Very similar points were made by Dr Edouard Stanley, joint head of the embryonic stem cell differentiation laboratory at the Centre for Early Human Development, Monash Institute of Reproduction and Development.[74] In view of this argument, Dr Stanley concluded that 'there is no valid scientific justification for restrictions to be placed on the work using or generating human ES cell lines'.[75]

2.72 However, in addition to their general concerns about allegedly exaggerated claims and about the lack of proof of principle, critics raised a number of more specific questions about the likely feasibility and effectiveness of potential therapies deriving from human embryonic stem cell research.

2.73 In what follows the Committee outlines the scientific issues that arise from three key questions:

- feasibility of tissue transplantation;

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71 *Committee Hansard*, 24.9.02, p.144 (Professor Pera).

72 *Committee Hansard*, 24.9.02, p.144 (Professor Pera).

73 *Committee Hansard*, 24.9.02, p.138 (Dr Elefanty).

74 *Committee Hansard*, 24.9.02, p.139 (Dr Stanley).

75 *Committee Hansard*, 24.9.02, p.139 (Dr Stanley).

- the relative therapeutic effectiveness of adult compared to embryonic stem cells; and
- the relationship between cell therapies and disease processes.

Feasibility of tissue transplantation

2.74 The House of Representatives report on human cloning discussed two hypothetical cases designed to illustrate tissue transplantation therapies that might arise from stem cell research.

2.75 The first involved the treatment of Type 1 diabetes:

> Using somatic cell nuclear transfer, the nucleus of a somatic cell from a patient with the disease could be fused with an enucleated donor egg. The cell would develop into a blastocyst from which inner cell mass cells could be isolated and grown in culture with growth factors, as yet unknown, to develop into pancreatic islet cells that produce insulin. Because these cells came from and are genetically identical to the patient…they would not be rejected when transplanted back into the patient. There would be little or no need for immune-suppressing drugs, with their often unpleasant and serious side effects.[76]

2.76 The second envisaged that it may be possible to identify and isolate adult stem cells from a particular tissue or organ type, multiply and grow them in culture, manipulate them to repair any genetic or metabolic deficiency, and then transplant them back into the damaged organ with a view to its repair.[77]

2.77 The great advantage of the hypothetical cell therapies outlined above is that they seem to overcome the problems of immune rejection which are currently associated with the transplantation of donated organs. New tissue is grown either from an embryo created by somatic cell nuclear transfer using the patient's own somatic cell, or directly from the patient's adult stem cells. It thus already matches the tissue of the patient for whom it is intended.

2.78 In practice, however, there are a significant number of difficulties to be overcome before these hypothetical therapies can become a reality.

2.79 First, if the tissue is grown from embryonic stem cells, then it is only directly compatible with the patient's own tissue if the embryo is the product of a somatic nuclear cell transfer in which a somatic cell from the prospective patient is fused with an enucleated egg. Even leaving aside the fact that this technique is prohibited by the current Bill, it is unclear that it would be viable in any case.

2.80 As noted earlier, the rate of success in forming viable blastocysts from somatic cell nuclear transfer is in the range of 1-2% of attempts made. The

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76 *Human cloning*, p.23.

77 *Human cloning*, p.23.

inefficiency of this procedure would mean that a very large number of human eggs would need to be available for every treatment.

2.81 One concern raised in relation to this technology was that, because of the number of eggs required, any clinical application of this practice would necessarily be exploitative of women, for example that women may possibly be coerced in some way into providing their eggs for such purposes.[78]

2.82 A second concern focused on the impracticality of the therapeutic application of the technology. For example, the Caroline Chisholm Centre for Health Ethics submitted that:

> A large supply of human eggs will be required as this procedure is very inefficient; and, unlike preimplantation embryos, eggs are in very short supply…Treatments involving therapeutic cloning therefore, will not be readily available, will be very time consuming, labor intensive and, as are result, expensive. Thus, apart from ethical considerations, therapeutic cloning is, and will remain, problematic.[79]

2.83 The leader of the scientific team that first isolated embryonic stem cells at the University of Wisconsin-Madison has been reported as saying that therapeutic cloning would be 'astronomically expensive'.[80] Likewise, Dr Christopher Juttner, Medical and Executive Director, BresaGen Ltd,[81] told the Committee that his company:

> felt from the beginning that therapeutic cloning using human eggs as the recipients of an adult nucleus was never going to be possible because the success rates are so low that you would have to hyperovulate 10 women to get enough cells - say 100 eggs - to have a chance of getting one matching cell line. So that was practically impossible. We felt it was ethically unacceptable because these would be egg donors and it would not be reasonable to ask anyone to do that.[82]

2.84 If the problem of rejection of tissue grown from embryonic stem cells cannot be overcome by the method of somatic cell nuclear transfer, then other options need to be investigated.

2.85 One such option involves the creation of a multitude of stem cell lines, from which tissue can be derived. However, there are significant differences in scientific opinion about how many such stem cell lines would be required in order to 'match' the needs of all possible patients.

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78 See, for example, *Submissions* 211, 882, 981 and 1036.

79 *Submission* 280, p.4 (Caroline Chisholm Centre for Health Ethics).

80 *Human cloning*, p.39.

81 BresaGen Ltd describes itself as 'a publicly listed Australian company acknowledged as one of the three world leaders in the therapeutic application of human ESC [embryonic stem cell] technology'. *Submission* 1030, p.2 (BresaGen Ltd).

82 *Committee Hansard*, 17.9.02, p.34 (Dr Juttner).

2.86 BresaGen Ltd informed the Committee that, in its view, '600-1000 such therapeutic ESC [embryonic stem cell] lines will provide adequate immunological tissue matching for 90-95% of humanity across racial/ethnic groups'.[83] Professor Michael Good, by contrast, estimated that 'millions' of stem cell lines would be required for such matching. According to Professor Good:

> This is because we all possess near-unique tissue types and it is extremely rare to find stem cells with the identical tissue type to ourselves. In humans, the tissue typing molecules are encoded by 'HLA' genes and there are 5 main types…Each gene has multiple 'alleles' or variants…The number of different HLA alleles in a population, however, is thought now to be about 500 and the different alleles can be found in different permutations and combinations. There are literally millions of ways to mix and match the different genes. Collectively, these different 'HLA' genes determine our 'tissue type'.[84]

2.87 A second potential solution to the problem of immune rejection was also proposed in evidence by BresaGen Ltd. Dr Juttner told the Committee that BresaGen had been experimenting with the somatic cell nuclear transfer technique. Rather than putting an adult somatic cell into an enucleated egg, they had tried 'putting adult cells into an embryonic stem cell that had had its nucleus removed'. He said:

> It is not easy. We have worked on that for three years in mice. We have had the beginnings of some success.[85]

2.88 Dr Juttner noted that this technique produced cloned embryonic stem cells, but not cloned embryos. For that reason, he believed that it would not be prohibited by the current Bill and that 'it is likely, I think, that the Biotechnology Centre of Excellence will take up and expand this if it does indeed go ahead'.[86]

2.89 In terms of the feasibility of tissue transplantation, tissue cultivated directly from adult stem cells does not present problems of immune system rejection. Many submissions to the inquiry thus argued that research should focus on adult stem cells, because of the ready therapeutic applicability of tissue so derived.[87] However, other evidence indicated that the cultivation of tissue from adult stem cells presents its own difficulties.

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83 *Submission* 1030, p.1 (BresaGen Ltd).

84 *Submission* 614, p.2 (Professor Good).

85 *Committee Hansard*, 17.9.02, p.34 (Dr Juttner).

86 *Committee Hansard*, 17.9.02, p.34 (Dr Juttner).

87 See, for example, *Submissions* 86, 280, 359, 614, 866, 876, 880, 1042.

Therapeutic effectiveness of adult compared to embryonic stem cells

2.90 Adult and embryonic stem cells have different properties. These affect both their presumed effectiveness in different situations, and the ease with which they can be studied and used.

2.91 There was extensive debate in evidence about the relative therapeutic prospects of research into embryonic and adult stem cells. A number of submissions provided extensive bibliographies of research published in scientific and medical journals supporting the use of either adult or embryonic stem cells.

2.92 Proponents of adult stem cell research referred to their successful use in therapies including using brain precursor cells to treat stroke, the patient's own stem cells to treat cancer and to treat bone defects, and bone marrow cells to treat muscle, gut and retina. Experiments with animal models have led to published accounts of adult stem cell success in the treatment of conditions such as Diabetes, Parkinson's and spinal injury.[88] Proponents of embryonic stem cell research noted studies indicating their potential for treatment of a range of diseases including neurological, cardiac, cancer and other conditions.[89] Embryonic stem cell research is still in its infancy, whereas adult stem cell research has been performed for a number of years.

2.93 Professor Martin Pera told the Committee that:

> The excitement over the potential for human embryonic stem cell research relates to the unique properties of stem cells…These [embryonic] cells may be grown in the laboratory indefinitely in the primitive embryonic state, and they retain the key property of embryo cells from which they originate – pluripotentiality or the ability to give rise to any type of adult body cell. This combination of properties has not been documented in any type of adult tissue stem cell isolated to date.[90]

2.94 According to Professor Pera, these two properties mean that embryonic stem cells 'in principle represent a potentially indefinite renewable source of human tissue for use in research or in transplantation therapy to correct a range of debilitating and currently intractable medical conditions'.[91]

2.95 By contrast, adult stem cells are generally rare in the tissues in which they have been discovered, and they have not been discovered to exist in all tissue types. They are difficult to isolate and extract.[92] Finally, while some types of adult stem cell can be grown successfully in culture, there are others that cannot be. Associate Professor Paul Simmons, head of the stem cell program, Peter MacCallum Cancer

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88 *Submissions* 86, 480, 614, 1042, 1571.

89 *Submissions* 23 Ad info 13.9.02, 871 Ad info 17.9.02, 895, 1030 Ad info 24.9.02, 1292

90 *Committee Hansard*, 24.9.02, p.135 (Professor Pera).

91 *Committee Hansard*, 24.9.02, p.135 (Professor Pera).

92 *Stem Cells: Scientific Progress and Future Research Directions* (NIH), p.ES-3.

Institute, told the Committee that, for example, haemotopoietic stem cells cannot be grown in culture. He said:

> When one attempts to grow haematopoietic stem cells in culture, they actually lose their stem cell properties – they differentiate. Try as we might, we have not – and I have been actively engaged in this form of research for at least 10 years – found ways to retain their stem cell properties. They differentiate.[93]

2.96 Although, Dr Simmons said, he is 'a passionate, fervent believer in the use of adult stem cells':

> [t]here are limited numbers, and we cannot grow all the adult stem cell populations we would like. These I think are two important limitations of adult stem cells which, in fairness, the committee needs to take on board if it is to engage in a rational debate on the relative merits of embryonic and adult.[94]

2.97 Arguments raised in opposition to research on embryonic stem cells include that embryonic stem cells are not the only stem cell alternative, that they are undesirable from the point of view of therapeutic application, and that adult stem cells have already been used in a large number of successful therapies while embryonic stem cells have not – although embryonic stem cells have not yet been the subject of the same level of extensive research.

2.98 In support of the view that the identified properties are undesirable in the clinical setting, Dr Peter McCullagh observed that the judgement that a cell's capacity to differentiate into a wide range of tissue is advantageous 'is completely context-dependent':

> When one is contemplating the use of cells from any source for the purpose of clinical transplantation, it is essential that their capacity for differentiation after their introduction into a recipient patient has been reliably defined and that this capacity is confined to cells of a type which are normally present in the anatomical location into which it is proposed that they be introduced…The moral is that toenails are fine, in their place, but are not an asset in one's brain. If the end use of cells is to be transplantation to a sensitive location, an unrestrained capacity for differentiation is not an advantage.[95]

2.99 Evidence given to the Committee by Professor Good also suggested that pluripotency may not be an advantage:

> The embryonic stem cells are all called totipotent. They have enormous proliferative potential and they can differentiate into every single cell of

93 *Committee Hansard*, 19.9.02, p.92 (Dr Simmons).

94 *Committee Hansard*, 19.9.02, p.92 (Dr Simmons).

95 *Submission* 480, p.2 (Dr McCullagh).

> 200-odd tissues of the body. That is not an advantage; it is a disadvantage. Why would you want to put cells into a person which have the potential to change into other cell types that are not required? Those particular cells, due to their totipotential, can give rise to teratomas; that is, tumours formed by cells which can give rise to multiple tissues.[96]

2.100 Similarly, Dr Megan Best, representing the Archbishop's Social Executive Committee, Sydney Diocese, Anglican Church, described embryonic stem cells as 'wild stallions and adult stem cells as more like domestic horses'.[97] She spoke of experiments with embryonic stem cells showing that they have 'a very disconcerting tendency…to form tumours, which has not been seen to the same degree in adult stem cells'. She noted:

> that, even though stallions may be able to run faster, it was easier to bridle a horse; and that, even if adult stem cells were not shown to be quite as plastic as the embryonic stem cells, this may in fact be an advantage.[98]

2.101 In support of the argument that embryonic stem cells may not really be unique in terms of their pluripotentiality, witnesses cited two developments in recent research into adult stem cells.

2.102 The first of these involves the observation 'made in many laboratories' of the 'plasticity' of adult stem cells.[99] The term 'plasticity' refers to the previously unsuspected capacity of adult stem cells to give rise, not just to their tissues of origin, but to 'completely unrelated cell types and tissues'.[100] For example, it has apparently been shown that stem cells from neural tissue can differentiate into bone or muscle tissue, that stem cells from bone marrow can differentiate into neural, liver, or epithelial tissues, and into skeletal muscle and myocardium, and that skeletal muscle tissue can differentiate into bone marrow.[101]

2.103 The second research development used to support the argument that embryonic stem cells may not really be unique in terms of their pluripotentiality is found in the work of Professor Catherine Verfaillie, University of Minnesota.[102] This research was paraphrased for the Committee in the following terms by Dr Simmons:

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96 *Committee Hansard*, 19.09.02, p.91 (Professor Good).

97 Dr Best said that she was reporting the analogy used by Dr William Hurlbut, Stanford University, *Committee Hansard*, 24.9.02, p.159 (Dr Best).

98 *Committee Hansard*, 24.9.02, p.159 (Dr Best).

99 *Committee Hansard*, 19.9.02, p.92 (Dr Simmons).

100 *Submission* 1292. The submission provides journal references to articles in which these findings have been published. See also *Submission* 1030, Additional information 24.9.02.

101 *Submission* 1292 (Peter MacCallum Cancer Institute).

102 Catherine Verfaillie et al., 'Pluripotency of mesenchymal stem cells derived from adult bone marrow', *Nature* AOP, published online 20 June 2002, doi:10.1038/nature00870.

> It demonstrated the presence in adult human bone marrow of what appeared to be a population of adult pluripotent stem cells. They are cells that ostensibly have characteristics very similar to embryonic stem cells. That is, they could give rise to cells of all three germ lands - endoderm, mesoderm and ectoderm. They had the apparent advantage over embryonic stem cells in that they did not form tumours in the animal models these investigators were using.[103]

2.104 A number of submissions to the Committee referred to these recent research findings to justify the claim that research using embryonic stem cells is unnecessary, and that any therapeutic applications needed can be derived from adult stem cells.[104]

2.105 However, Dr Simmons expressed serious reservations about that line of argument. He noted, first, that many of the experiments purporting to demonstrate adult stem cell plasticity had not been able to be replicated by reputable researchers, and that the results of the studies have come to be challenged on scientific grounds.

2.106 In particular, he wrote:

> Some reported phenomena have been shown to be artifacts due to contamination of transplanted cells while other examples of conversion to other cell types appear to be due to *fusion* of different adult stem cell types leading to the generation of potentially unstable hybrid cells with shared properties of each founder cell type.[105]

2.107 According to Dr Simmons, then, 'it is to my mind not appropriate to use stem cell plasticity as an argument to not study embryonic stem cells. It is looking very much like adult stem cells are not as plastic in their developmental properties as was initially suggested by publications'.[106]

2.108 Similarly, while Dr Simmons agreed that Professor Verfaillie's research involved 'a very amazing observation', it has yet to be reproduced by any other laboratory. In any case, he said that he did not accept that it made research into embryonic stem cells redundant, and he noted that Professor Verfaillie herself had urged that research into embryonic stem cells needed to continue.[107]

2.109 In an interview in Melbourne on 28 August 2002, Professor Verfaillie reiterated that point, saying that:

> My message has always been, even though we're excited about the adult cells, that it's too early to say that they will replace embryonic stem cells to

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103 *Committee Hansard*, 19.9.02, p.93 (Dr Simmons).

104 See, for example, *Submissions* 86, 156, 280, 876, 880, 1046.

105 *Submission* 1292 p.2 (Peter MacCallum Cancer Institute).

106 *Committee Hansard*, 19.9.02, p.92 (Dr Simmons).

107 *Submission* 1292; see also *Committee Hansard*, 17.9.02, p.32 (Dr Juttner), *Submission* 477 and 1043.

> the point that our institution, the Stem Cell Institute, we actually recruited and investigated who has extensive experience in human embryonic stem cell work, so we're now in a position to do exactly what you mentioned, which is to parallel research and comparing and contrasting the two cell types.[108]

2.110 As intimated by Professor Verfaillie's remarks, there are two main reasons given by scientists for the need to continue research into both adult and embryonic stem cells.

2.111 First, it is too early to determine fully just what the potential applications of the two sets of stem cells are. Professor John Hearn emphasised that the focus on embryonic stem cells in humans is only four years old, and on adult stem cells even less than that.

> So our knowledge of whether adult stem cells or embryonic stem cells are going to deliver the best benefit, either in advancing knowledge or in advancing potential therapies, is still open to major question.[109]

2.112 In a similar vein, Professor Sue Serjeantson, Executive Secretary, Australian Academy of Science, stated that the Academy:

> considers that research is warranted across a range of sources of stem cells in the hope of developing tissue for use in repair of damaged tissues. We would all be very happy if we thought that scattered adult stem cells could be used for tissue repair. The ethical dilemma would then go away, with it being set aside. But we think, it is unlikely at this time that the different types of stem cells - whether derived from germ cells, blood cells, adult tissues or embryonic stem cells - will all have the same characteristics; we think it is unlikely that they will all have the same potential to develop into particular tissues.[110]

2.113 The second reason given in support of continuing research into both adult and embryonic stem cells relates to the possibility that advances in one field will spur advances in the other.

2.114 Dr Simmons, for example, referred to recent research done in laboratories at Harvard and Princeton which compares two adult stem cell populations with embryonic stem cells. The comparisons show that there are 'genes that are uniquely expressed in each stem cell population and there are genes that are expressed in all three populations'. Dr Simmons noted that this 'commonality of gene expression' may

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108 Transcript of interview with Professor Catherine Verfaillie, The World Today, 22 August 2002, http://www.abc.net.au/worldtoday/s656192.htm (30 September 2002).

109 *Committee Hansard*, 19.9.02, p.114 (Professor Hearn).

110 *Committee Hansard*, 19.9.02, p.120 (Professor Serjeantson).

imply that there are 'fundamental aspects in terms of stem cell biology that we could approach only through studying all three types of stem cell'.[111]

2.115 Given, he continued, that the heart of the matter is 'to understand and define pathways with differentiation that are responsible for derivation of the matured cell types that stem cells give rise to', then the comparison of completely undifferentiated cells such as embryonic stem cells with adult stem cells 'will inevitably yield secrets as to how adult stem cells work'.[112]

2.116 Another example of the possible complementarity of work in adult and embryonic stem cells was provided by Dr Andrew Elefanty. He noted that 'the recent very rare bone marrow derived multipotential adult stem cells', isolated in the mouse, grow only in the presence of 'the growth factor lift'. This growth factor, however, 'was identified and isolated because it works on mouse embryonic stem cells'. Dr Elefanty commented that:

> there is, if you like, an example already of the cross-fertilisation of those ideas, and that is part of the reason why we feel so strongly that both lines of research have to proceed in parallel.[113]

2.117 Professor Bob Williamson, Director, Murdoch Childrens Research Institute, and Professor of Medical Genetics, University of Melbourne said that:

> Many, including me, are primarily interested in 'adult' stem cell research because for the diseases we hope to treat (such as cystic fibrosis or thalassaemia), avoiding rejection is a very important issue. However, we need to learn how to use adult stem cells, and to treat them so that they become more 'pluripotent' and can grow more easily (that is, more like embryonic stem cells). In a sense, we need to learn from embryonic stem cells how to use adult stem cells better. There is also a chance that new developments in immunology may make embryonic stem cells less likely to be rejected, and if this is true, they may become more useful for childhood diseases. What I believe to be absolutely certain is that there are real benefits in allowing adult and embryonic stem cell research to proceed side by side in the same laboratories, so the experiments cross-refer and so that lessons can be learnt by comparing the two systems.[114]

2.118 This body of scientific opinion was echoed by Ms Sheila Royles, Spokesperson, Coalition for Advancement of Medical Research Australia and Chief Executive Officer, Juvenile Diabetes Research Foundation. She asked the Committee 'to support the pursuit of both adult and embryonic stem cell research', saying:

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111 *Committee Hansard*, 19.9.02, p.93 (Dr Simmons).

112 *Committee Hansard*, 19.9.02, p.93 (Dr Simmons).

113 *Committee Hansard*, 24.9.02, p.154 (Dr Elefanty).

114 *Submission* 1002, p.2 (Professor Williamson).

> We are at the start of the marathon; we have two strong runners, embryonic and adult stem cells. As yet we do not know which one is going to be capable of finishing or whether in fact they will cross the line together. Let's not make the decision to eliminate one of our strongest runners before we even start. There are many, many scientific questions yet to be answered. I urge you to support legislation and give our researchers the opportunity to see whether this area of research really can deliver the benefits that we hope…[115]

Relationship between cell therapies and disease processes

2.119 A third set of questions surrounding the clinical applicability of stem cell therapies raises the issue of the relationship between cell damage and disease processes.

2.120 In crude terms, the problem is that even if you were able to introduce compatible 'new' tissue to replace degenerated or damaged cells, the disease processes which caused the damage to the original cells might just turn on the 'new' tissue.

2.121 For example, Professor Bernard Tuch, Director, Diabetes Transplant Unit, Prince of Wales Hospital, spoke of the problems associated with the attempted transplantation of healthy pancreatic tissue into diabetics. He told the Committee of an experimental study involving twins:

> This is not stem cell work, but perhaps it can be used to explain. They did take half a pancreas from the twin that did not have diabetes and transplanted it into the person with diabetes. And of course the person with diabetes was no longer diabetic for two weeks, and then their diabetes recurred because of the self-destruct mechanism which causes type 1 diabetes.[116]

2.122 Professor Michael Pender, a neuroimmunologist, made a similar point in relation to Alzheimer's disease, saying that it 'is a global disorder of the brain and is highly unlikely to be amenable to any form of cell therapy at any time in the future'.[117]

2.123 Similarly, Professor Peter Rowe argued that:

> It is not even sure that Parkinson's disease is primarily caused by specific self-generated damage within the particular part of the brain which is responsible for producing the symptoms. It may well arise from a systemic

115 *Committee Hansard*, 17.9.02, p.71 (Ms Royles).

116 *Committee Hansard*, 17.9.02, p.41 (Professor Tuch).

117 *Submission* 84, p.3 (Professor Pender).

> disorder, and work has been done to suggest that that is the case. In which case, you put cells in and you get the same process occurring again.[118]

2.124 Nevertheless, evidence suggested that even if direct transplantation of new tissue is unlikely to cure certain diseases or conditions, research into stem cells may lead to other therapies. In other words, the concerns just outlined may constitute arguments against the prospects of the successful transplantation of tissue derived from stem cells, but not an argument against stem cell research per se.

2.125 For example, Professor Perry Bartlett, Head, Development and Neurobiology Group, Walter and Eliza Hall Institute of Medical Research, Melbourne, described research he has recently undertaken to isolate and purify neural stem cells, which are adult stem cells, in the adult brain. He then said:

> The reason that we went on to purify and find these cells was not to be able to transplant them but to be able to finally discover what molecules regulate these stem cells in you and me to make nerve cells, because the $64 million question – and the $64 billion therapy – is to have a drug that is able to stimulate those cells that reside in our own brains and that can make nerve cells to replace those cells lost in stroke, Alzheimer's disease, et cetera.[119]

2.126 Professor Tuch explained that research into a promising approach to treating diabetes is currently being undertaken on embryonic stem cell lines.[120] It involves not tissue transplantation but learning how to direct the patient's own cells, by developing genes or other agents that might turn non-insulin-producing pancreatic cells into insulin-producing cells.[121]

Other applications of stem cell research

2.127 Although most of the evidence to the Committee focused on the issue of cell therapies and tissue transplantation, some witnesses drew attention to other applications of stem cell research.

2.128 For example, Professor David de Kretser, Director, Monash Institute of Reproduction and Development, noted that significant advances in knowledge will necessarily arise from the process of developing tissue for transplantation. He said:

> Researchers seeking to define the conditions necessary to enable an embryonic stem cell to proceed down a selected pathway of development will identify numerous products with the capacity to create markets for new drugs or specific fluids and substrates to enable these cell types to be grown.

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118 *Committee Hansard*, 19.9.02, p.95 (Professor Rowe).

119 *Committee Hansard*, 19.9.02, p.94 (Professor Bartlett).

120 *Committee Hansard*, 17.9.02, p.37 (Professor Tuch).

121 *Committee Hansard*, 17.9.02, p.41 (Professor Tuch).

> Each of these has the potential to develop small but important industries to underpin Australia's future role in biotechnology.[122]

2.129 Professor de Kretser also expressed the view that this research would also greatly expand knowledge of the 'normal development' of a human embryo, and hence increase understanding of developmental birth defects.[123]

2.130 A large number of submissions to the inquiry expressed grave concern that 'other research' undertaken as a result of the passage of the Bill would include other destructive research on embryos, including the use of human embryos for drug or toxicology testing, and even for the testing of cosmetics.[124]

2.131 The Southern Cross Bioethics Institute detailed the possible range of embryo research and observed the majority of the research would not be related to stem cells:

> The broad range of uses to which embryos will be subjected are described, in part, in the *Explanatory Guide to the Human Cloning and Research Involving Embryos Bill 2002*…the following categories for the use of excess Assisted Reproductive Technology (ART) embryos were identified:
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> - for the derivation of stem cells;
> - for examining the effectiveness of new culture media used in ART practice;
> - for better understanding embryonic development and fertilisation;
> - to train clinicians in micro-surgical ART techniques;
> - to examine gene expression patterns of developing embryos; and
> - for improving ART techniques.
>
> To this list may be added:
>
> - toxicology studies on live human embryos, and
> - testing new drugs on humans rather than animals.
>
> Therefore, even within the context of the Bill it is recognised that human embryos will be used for purposes other than ES cell extraction, even though these uses have been largely ignored in the debate. The promotion of ES cell research in the emotive context of human suffering is being used as a beach-head to gain generalised access to human embryos, most of which will be destroyed for purposes like ART research, toxicology and drug testing.[125]

2.132 Professor Bartlett commented on the commercial motivation for some of the embryo research that would be allowed by this Bill:

> In fairness to companies like BresaGen, they are aware that therapy is 10 to 20 years away. Stem Cell International's CEO has said publicly that

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122 *Submission* 1041, p.4 (Professor de Kretser).

123 *Submission* 1041, pp.4-5 (Professor de Kretser).

124 See, for example, *Submissions* 419, 672, 765, 876, 880, 892, 987, 1015, 1020 and 1040.

125 *Submission* 892, Attachment pp.8-9 (SCBI). See also *Submission* 282 (National Civic Council WA).

> therapy, in their eyes, is 10 to 20 years away. So they have to generate some form of income along the way. To use stem cells for screening and diagnostic purposes is a perfectly understandable use of such cells.[126]

2.133 The Committee notes that the uses of embryos in ART practice and research which are allowed by the Bill are not new uses. The Bill brings under a national regulatory system uses and practices which are currently regulated under State legislation, in the case of Victoria, South Australia and Western Australia, and by NHMRC/AHEC guidelines and the requirements of the Reproductive Technology Accreditation Committee.[127]

2.134 In relation to the use of embryos in toxicology or drug testing, the Committee notes that a distinction needs to be drawn between testing on live embryos and testing on embryonic stem cells which have been derived in the first instance from an embryo and then grown into stem cells lines.

2.135 Dr Juttner, Medical and Executive Director, BresaGen Ltd endorsed the use of embryonic stem cell lines for that purpose, saying that 'I think [it] is actually a proper activity if it saves patients from being exposed to testing of new drugs'.[128] Dr Juttner noted, however, that he 'absolutely rejected' the concept of using embryos as such for drug testing.

2.136 The NHMRC advised that the Bill does not prohibit the use of embryos or embryonic stem cells for toxicology testing. In the case of testing on embryos, however, any such proposed use would require a licence from the NHMRC Licensing Committee.[129]

Summary

2.137 Research involving stem cell and cloning technologies is in its infancy.

2.138 Most scientists would agree that there is as yet insufficient experimental data to be certain either just how important research into stem cells is likely to be, or to be certain about the relative value of embryonic and adult stem cells for that research.

2.139 However, many agree that therapies derived from stem cell research have at least the potential to ameliorate currently incurable conditions, ranging from diabetes to spinal cord injuries to motor neurone, Parkinson's and Alzheimer's diseases.

2.140 In the next chapter, the Committee considers the nature of the ethical issues that arise in relation to this research.

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126 Committee Hansard, 19.09.02, p.99 (Professor Bartlett).

127 *Submission* 23, pp.16-17 (NHMRC).

128 *Committee Hansard*, 17.9.02, p.40 (Dr Juttner).

129 *Committee Hansard*, 26.9.02, p.257 and *Submission* 23, Additional information 18.10.02, p.5 (NHMRC).

CHAPTER 3

ETHICAL ISSUES

Introduction

3.1 The two main sets of ethical issues posed by the Bill before the Senate concern, first, the ethics of human cloning and, second, the ethics of destructive research on human embryos.

3.2 The Bill prohibits both reproductive and so-called therapeutic cloning, and makes it an offence to import a human embryo clone into Australia. The Bill provides for destructive research on human embryos under certain specified circumstances.

3.3 Evidence before the Committee suggests that there is near unanimous support for the prohibition on reproductive cloning, and very strong support for a prohibition or at least a moratorium on 'therapeutic' cloning.[1] This support is grounded in a strong consensus that such practices are 'ethically unacceptable'.[2]

3.4 That consensus in turn is based on both direct consequentialist considerations, such as the risk of creating abnormal or prematurely aged embryos or individuals, and on broader concerns such as the threat to concepts of identity and kinship, fear of eugenics, commodification of children and the implications for genetic diversity.[3]

3.5 There was almost no ethical disagreement expressed in evidence on the prohibition of human cloning. Concern was expressed about the legitimacy of the distinction drawn between reproductive and so-called 'therapeutic' cloning, and was discussed in the previous chapter.

3.6 There was, however, extensive debate about the ethical justifiability of the proposal that destructive research on human embryos be allowed to proceed. In what follows, the Committee outlines the main lines of ethical argument both for and against that research.

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1 The Australian Academy of Science, for example, supports 'therapeutic cloning as a possible way ahead for the production of appropriate stem cell lines if that turns out to be what is needed to produce them'. *Committee Hansard*, 19.9.02, p.124. However, it also stated that a 'moratorium for a few years on therapeutic cloning is a very reasonable road to take'. *Committee Hansard*, 19.9.02, p.116.

2 Hon. John Howard MP, Second Reading Speech, Research Involving Embryos and Prohibition of Human Cloning Bill 2002, House of Representatives, 27 June 2002.

3 See discussion of these issues in Department of the Parliamentary Library, Bills Digest No.17 2002-03*, Research Involving Embryos and Prohibition of Human Cloning Bill 2002*, Jennifer Norberry, Law and Bills Digest Group, 14 August 2002, pp.6-7.

3.7 It should be emphasised that the Committee's aim in this discussion is not to reach a definitive view on the ethical questions raised by the proposed research. It does, however, hope to contribute to a broadened or deepened understanding of the implications of the moral issues at stake.

3.8 To this end, the Committee attempts not simply to describe the different arguments put in evidence, but to analyse some of the implications of those arguments and to suggest what further questions may be raised by them.

Structure of argumentation

3.9 There are a range of arguments put for and against the ethical justifiability of permitting destructive research on human embryos. It will assist in clarifying the nature and status of these arguments, if some preliminary attention is given to their relationship with one another.

3.10 Imagine a proposal to perform destructive experimentation on an adult or child. Even if such experimentation promised great medical benefit, it would generate very little ethical debate. That is because for almost no one is it an open question as to whether it is morally acceptable to destroy an individual person for the sake of benefit to others.[4]

3.11 The heart of the ethical debate before the Committee is the question of whether or not the embryo enjoys the same moral status as an adult or child, and hence whether it is an open question that it may be morally acceptable to destroy a human embryo for the sake of benefit to others.

3.12 For those who think that the human embryo is morally equivalent to an adult or child, then acknowledging its moral status exhausts the question (in the negative) of whether it may be destroyed. Further reasons, either moral or scientific, may be adduced in support of the view that such experimentation is unacceptable, but these further reasons are not the decisive factors in the conclusion reached.

3.13 For those who think, however, that the human embryo under 14 days does not enjoy precisely the same moral status as an adult or child, then the nature of any further reasons for supporting or objecting to the practice becomes decisive.

Moral status of the human embryo

3.14 There are three broad ways in which the moral status of the human embryo may be considered. The Committee will consider how these views informed the

4 The Declaration of Helsinki, discussed in the previous chapter, states that 'In research on man [sic], the interest of science and society should never take precedence over considerations related to the wellbeing of the subject'. There are some consequentialist arguments in moral philosophy that would dispute that principle, but these do not have wide currency in the community.

evidence it received concerning the ethical justifiability of destructive research on human embryos.

3.15 The three views of the moral status of the embryo are that it possesses:

- no moral status;
- the same moral status as an adult human being;[5] or
- limited or different moral status compared with an adult human being.

No moral status

3.16 Very few argue that the human embryo has no moral status at all. Where it is argued, it often depends upon the idea that human moral status depends upon the properties of sentience or rationality.

3.17 For example, the Humanist Society of Victoria stated that:

> We do not regard early zygotes as humans: they lack the essential property of sentience, and in vivo, some 50% of these fertilised ova fail to implant and are discharged from the womb.[6]

3.18 This kind of argument was also made by Australian ethicist Peter Singer in evidence to the Senate Select Committee on Human Embryo Experimentation and more recently by Julian Savulescu, Professor of Applied Ethics, Oxford University, who has written:

> If we are fundamentally conscious minds, we do not begin to exist at least until the structures are present which could support consciousness. The Royal College of Obstetricians and Gynaecologist's Working Party produced a report on Fetal Awareness in 1997. It concluded that the structural development for ability to be conscious of pain is not present in the fetus before 26 weeks. Thus, the fetus does not achieve moral status before 26 weeks.[7]

3.19 As part of his argument that 'we' are fundamentally identified with our minds or that what really matters about us is consciousness, Professor Savulescu discusses the case of Tony Bland, a young man rendered permanently unconscious by the

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5 By the term 'adult human being', the Committee means to include human beings who are born as opposed to unborn. For the purposes of this usage, children and infants should be considered included in the term.

6 *Submission* 982, p.2 (Humanist Society of Victoria).

7 Julian Savulescu, 'The Ethics of Cloning and Embryonic Stem Cells as a Source of Tissue for Transplantation: Time to Take a Positive Approach to Law Reform in Australia', undated, p.8. See also *Submission* 899, in which the former Chair of the Senate Select Committee on Human Embryo Experimentation, the Reverend Professor Michael Tate, describes that Committee's rejection of the view presented by Professor Peter Singer. According to Professor Singer, 'a person could only be identified as such when consciousness and some capacity for moral discernment or decision making emerged'.

Hillsborough football disaster. Professor Savulescu notes that what justified the decision to withdraw artificial means of life-support from Tony Bland was that the fact of his permanent unconsciousness left him with 'no interest in remaining alive'.[8] By analogy, then, Professor Savulescu's argument is that an embryo which lacks consciousness likewise lacks any interest in remaining alive.

3.20 It is noteworthy, however, that although Professor Savulescu considers that Tony Bland's condition justifies the withdrawal of 'extraordinary' means to keep him alive, he does not propose that it licenses us to perform destructive experiments on him. In other words, a difficulty with this kind of argument is that it is seemingly too broad. It would mean, for example, that human beings who are comatose or severely mentally impaired would also lack moral status, and so would be available for destructive medical experimentation.

3.21 It seems then that absence of consciousness or sentience is not, by itself, sufficient to justify the withdrawal of *any* form of moral consideration for particular human beings.

3.22 Using the same analogy, then, a number of submissions to the Committee drew a moral distinction between the withdrawal of 'life support' from frozen embryos and destructive experimentation upon them.[9]

3.23 They argued, in other words, that there was a serious moral difference between allowing the embryos to 'die' or 'succumb', and destroying them by extracting their stem cells. For that reason, they maintained that the fact that the 'excess' embryos at issue 'are going to die anyway' is irrelevant to the argument.

3.24 For example, the St Vincent's Hospital, Sydney, questioned the claim that given the embryos are destined for destruction it is not unreasonable to use them for research:

> Of course it is true that in each case the embryo will end up dead. But just as there is a significant difference between the death of a person who is deliberately killed and the death of someone who dies from natural causes, so there is a significant difference between an embryo's being deliberately dismembered and its dying naturally. The embryos to be experimented upon will most certainly die by dismemberment. Dismembering them, rather than allowing them to succumb unviolated, merely ' adds insult to injury'.[10]

3.25 Mr Raymond Campbell from the Queensland Bioethics Centre described the difference between three different actions in relation to the nature of the decision on how to treat the human embryo:

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8 Julian Savulescu, 'The Ethics of Cloning and Embryonic Stem Cells as a Source of Tissue for Transplantation', undated, p.7.

9 See, among many, *Submissions* 282, 672, 685, 870, and 1026.

10 *Submission* 1483, p.2 (St Vincent's Hospital Sydney).

> …no matter what you are going to do with the embryo you are going to remove it [from the freezer]. If you are going to implant it, you are going to remove it from the freezer, allow it to thaw and allow it to begin to develop and then implant it. If you are going to use it for embryonic stem cell research, you are going to remove it from the freezer, allow it to thaw and allow it to develop–because they are not at the stage of having the cells that they are wanted for as stem cells, so they are allowed to develop further–and then the stem cells are harvested, destroying the embryo. If you are going to allow it to succumb, it is the same action. You remove the embryo from the freezer, put it back in the environment and it will begin to develop again. Then it will reach a stage where it can no longer survive in that environment and it will die if it is not implanted. I would suggest that they are three very different kinds of actions.[11]

3.26 The Committee notes that use of the analogy between unconscious embryos and comatose human beings suggests the following line of thought. Different acts are morally charged in different ways. The withdrawal of artificial life support from a human entity is one kind of morally charged act; destructive experimentation of a human entity is another kind of morally charged act. It is possible that the absence of the properties of consciousness or sentience may function to justify the first act, but not the second.

3.27 Some of the points that arise for consideration from this discussion then seem to be as follows:

- the enjoyment of consciousness is not the sole criterion upon which moral consideration of other human beings seems to be warranted;
- an analogy may be drawn between human embryos and comatose human beings insofar as they lack consciousness; and
- there is a question as to whether there are other similarities or differences between human embryos and adult human beings which mean that this analogy, by itself, is insufficient to justify equality of consideration.

Same moral status as an adult human being

3.28 A large number of submissions to the inquiry expressed the view that the human embryo possesses the same moral status as an adult human being, and thus that destructive research involving embryos is unacceptable.[12]

3.29 There are two basic stages in the argument that supports this view. The first stage involves establishing the biological 'fact' that new human life commences at fertilisation. The second stage involves being able to bring this biologically related entity into full moral fellowship with 'us'.

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11 *Committee Hansard*, 26.9.02, p.223 (Mr Campbell).

12 See, for example, *Submissions* 156, 211, 361, 427, 667, 868, 892, 981, 1003, 1017, 1028, 1037, 1046.

Commencement of human life

3.30 There is in fact little disagreement that the embryo is a human life and that its life commences at fertilisation. The difficulties arise in specifying exactly in what sense it is to be considered 'a life', and hence what significance should be attached to it.

3.31 In its discussion of the biological facts of the matter, the Senate Select Committee on the Human Embryo Experimentation Bill 1985 stated that:

> Two universally accepted attributes are that the fertilised ovum has 'life' and that it is genetically human (ie. it is composed of genetic material entirely from the species *homo sapiens*). It is also generally agreed that it is an entity (a centrally organised unit which has a purposeful independent function as opposed to an organ or tissues). It also has developmental potential (whether that may progress to little more than cleavage, or to birth and on to subsequent adulthood).[13]

3.32 Various submissions to the inquiry appealed to recent work in embryology to support the claim that a recognisably distinct and individual human life commences the moment the sperm enters the egg. For example, the Southern Cross Bioethics Institute stated that:

> Microscopic evidence and chemical changes to the egg and sperm mark the entry as decisive. No other defining moment can be identified as the start…From fertilisation onwards the self-organising behaviour of the embryo is evident, and is quite unlike ordinary processes of cellular replication by which cells multiply. The union of pronuclei - DNA already premixed as it were by meiosis during the formation of egg and sperm - leads to a new and unique amalgamation with a new composition unlike any other.[14]

3.33 The Caroline Chisholm Centre for Health Ethics submitted that:

> The genetic individuality or identity of the adult is practically the same as that of the embryo, who possesses the actual potential to develop and grow into an adult, given a suitable uterine environment. The zygote and the resulting adult are the same living being. The zygote organises itself into a multicellular embryo, fetus, infant, child and adult without ceasing to be the one and same living human individual.[15]

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13 *Human Embryo Experimentation in Australia*, September 1986, pp.8-9.

14 *Submission* 892, p.2 (SCBI); see also *Submission* 876, (Catholic Archdiocese of Melbourne).

15 *Submission* 280, Attachment p.2 (Caroline Chisholm Centre for Health Ethics).

3.34 The arguments in these submissions seem to assume that, having established that the embryo is a distinct human entity from fertilisation, it follows immediately that this entity is 'owed a duty of unconditioned moral respect'.[16]

3.35 However, the Committee notes that these views concerning the commencement of human life at fertilisation were accepted even by scientists who support some form of destructive research on embryos.

3.36 For example, Professor John White, Spokesperson on Human Cloning, Australian Academy of Science, agreed that a 'human entity' comes into existence with fertilisation. When, however, he was asked to agree that therefore this embryo was a 'human being', Professor White responded as follows:

> I am not sure I understand that declension. I said 'entity' because the view that I and many other people would take is that, in embryology and in the development of the human person – and, indeed, even theologically, in the implantation of a soul – it might well be a gradual process.[17]

3.37 In explaining his preference for the term 'entity', Professor White noted that:

> There are many overtones to the word 'being' that I would build into it, and perhaps you would build different ones in…But I am quite happy to agree to 'entity'.[18]

3.38 In essence, Professor White's distinction points to the fact that, although it may be relatively uncontroversial to identify the embryo as biologically human, that identification does not necessarily settle the question of the sense in which the embryo shares our humanity and hence of the significance to be attributed to it.

Shared humanity?

3.39 Arguments were presented to the Committee both for and against the view that the embryo shares our humanity in the morally relevant sense.

3.40 The view that the early embryo is not yet fully our moral fellow is often supported with reference to biologically significant 'marker' events in embryonic development.

3.41 There are four factors, in particular, which are often cited as grounds for authorising experimentation on the embryo up until 14 days. They are:

- totipotency;
- twinning;
- natural embryo loss; and
- primitive streak.

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16 *Submission* 280, Attachment p.2 (Caroline Chisholm Centre for Health Ethics).

17 *Committee Hansard*, 19.9.02, p.128 (Professor White).

18 *Committee Hansard*, 19.9.02, p.128 (Professor White).

3.42 Briefly, up until the 16-32 cell stage the individual cells of the embryo each have the potential, if placed in the right environment, to develop into separate individuals.[19] This capacity is referred to as the 'totipotency' of the cells. Also during the first two weeks of pregnancy, twins can be formed either as a result of the successful implantation of two fertilised eggs or as a result of the splitting of the single embryo.[20]

3.43 'Natural embryo loss' refers to the fact that it is estimated that up to half of all naturally formed embryos 'fail before the full establishment of pregnancy'. The House of Representatives report on human cloning noted that:

> The reasons for these failures are obscure and almost impossible to study in the human, but are thought to be due to genetic abnormalities in the embryo (about 30%), inadequate synchrony or development of hormonal signals between the embryo and the mother (about 30%), with the remainder due to unexplained causes.[21]

3.44 Finally, the 'primitive streak' refers to the alignment of cells that is formed at about the fourteenth day and that will go on to become the central nervous system. According to Professor White, that is the point 'where a discernible, bilateral symmetry is apparent in the early embryo in the cluster of cells – the first sign of a nervous system and of right-handedness and left-handedness'.[22]

3.45 In general terms, the argument for the significance of these biological features of the early embryo for the attribution of moral status is that it is only by the fourteenth day that we can be sure that the embryo is an identifiable individual, and will not be divided or naturally discarded.

3.46 Various objections are raised against this line of argument. In particular, the problem identified is that, given the essentially developmental nature of embryonic life, the insertion of a concrete point at which we suddenly begin to take that life morally seriously seems arbitrary.

3.47 The proposal that embryo experimentation should be allowed up until the fourteenth day was made by the Warnock Committee in the United Kingdom in 1984. Professor White acknowledged that 'in some sense' this 'might be arbitrary' and remarked that 'nevertheless a date has been fixed and a pragmatic arrangement for the treatment of early embryos has been arrived at both in law and in practice'.[23]

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19 *Human cloning*, p.17. The report on stem cell research by the House of Lords in the United Kingdom states that embryonic cells are totipotent up until the 8 cell stage. See *Select Committee on Stem Cell Research Report*, February 2002, Chapter 4, http://www.publications.parliament.uk/pa/Id200102/Idselect/Idstem/83/8305.htm

20 *Human cloning*, p.14.

21 *Human cloning*, p.14.

22 *Committee Hansard*, 19.09.02, p.127 (Professor White).

23 *Committee Hansard*, 19.09.02, p.127 (Professor White).

3.48 Critics of the 'fourteen day' line, have in fact cited the Warnock Report itself for evidence of the arbitrary nature of the point determined. The Report states:

> While, as we have seen, the timing of the different stages of development is critical, once the process has begun, there is no particular part of the developmental process that is more important than another; all are part of a continuous process, and unless each stage takes place normally, at the correct time, and in the correct sequence, further development will cease. Thus biologically there is no one single identifiable stage in the development of the embryo beyond which the in vitro embryo should not be kept alive. However we agreed that this was an area in which some precise decision must be taken, in order to allay public anxiety.[24]

3.49 If the view that the early embryo is not yet fully our moral fellow is argued with reference to biologically significant 'marker' events, the view that it is fully 'one of us' is often supported with reference to the dangers inherent in the systematic exclusion of certain classes of human being from the human moral community.

3.50 For example, the Southern Cross Bioethics Institute argued that:

> down through history there have been circumstances when personhood was denied to certain groups of people, usually for the purpose of withholding their basic human rights. For example, the *Canadian Indian Act 1880* states that 'the term person means an individual other than an Indian'. Within 5 years this changed. The *Canada Franchise Act 1885* states that '[a person] is a male person, including an Indian and excluding a person of Mongolian or Chinese Race'.[25]

3.51 The Catholic Archdiocese of Melbourne argued that:

> If [embryos] *are* tiny human beings then the fact that they are tiny is no more morally relevant than that they are black or white, Australian or foreign, boy or girl, at the beginning of life or soon to die. They are members of the human family…Reducing members of our human family to mere commodities or lab animals will ultimately be corrupting for us all.[26]

3.52 In a similar vein, the South Australian Branch of Do No Harm stated:

> An embryo is a member of the human family equal in status to any other…Experimentation on embryos is no different to experimenting upon any human being. The size or age of the human being does not alter their status as part of the human family nor does it determine (or diminish) their rights to protection under the law.[27]

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24 Senate Select Committee on Human Embryo Experimentation Bill 1985, *Human Embryo Experimentation in Australia*, September1986, p.28; see also *Submission* 892 (SCBI).

25 *Submission* 892, p.6 (SCBI).

26 *Submission* 876, p.5 (Catholic Archdiocese of Melbourne).

27 *Submission* 211, p.2 (Do No Harm, SA).

3.53 Dr Nicholas Tonti-Filippini developed a brief ontological argument on the nature of the human embryo:

> From the moment that the first cell is formed, a human embryo is an individual organism oriented to development to human adulthood, normally requiring only nutrition and a favourable environment for that development to occur, and whose inherited nature is formed by the human genome which carries the inherent radical capacity for rationality that is distinctive of human beings.[28]

3.54 An argument for the moral status of the embryo based on human rights conventions was also developed by Ms Rita Joseph. She argued in her submission that to pass this Bill would be to contravene international human rights law, saying that:

> This proposed bill will run directly counter to Australia's firm and repeated commitments to provide legislative protection for maternity and for all children before birth. This bill, if brought into law, will fail to comply with a whole raft of fundamental UN States' obligations under international human rights instruments to which Australia has committed and subsequently should honour.[29]

3.55 Dr Katrina Hallen also provided a long list of international human rights instruments which she claimed supported the right of human embryos to not be subjected to destructive research, including the Nuremburg Code, the International Covenant on Civil and Political Rights, the Universal Declaration on Human Rights and the Declaration of Helsinki.[30]

3.56 In considering the different kinds of argument for thinking that the early embryo shares fully in our humanity, and hence is deserving of the same moral protection as any other human being, the Committee notes the following points:

- the focus on biological markers is an attempt to isolate an 'objective' point at which a morally relevant difference in the embryo's development can be recognised;
- the application of 'anti-discrimination' and 'rights' arguments in favour of the embryo is an attempt to alter the perspective on the debate, such that the embryo can be 'seen' as vulnerable, as others historically have been, to our lack of recognition. The use of the language of 'family membership' or 'kinship' is significant here. From the perspective of these arguments, the identification of biological markers after conception is not so much the *identification* of 'objective' features but is an *expression* of a refusal of recognition or of kinship with the early embryo.

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28 *Submission* 86, Additional information 26.9.02 (Dr Tonti-Filippini).

29 *Submission* 1053, p.4 (Ms Joseph).

30 *Submission* 1301 (Dr Hallen); see also *Submission* 156 (Dr Orr).

3.57 It may be argued that behind this debate is a more fundamental question. That question involves the issue of what it is involved in, or what content can be given to claim that the early human embryo shares fully in the moral status we assign to adult human beings.

3.58 This issue may be further illuminated by considering the view of those who assign to the embryo some moral status, but one which is limited in comparison with the status assigned to an adult human being.

Limited moral status

3.59 The ascription of moral status is both constituted by and recognised through the responses or practices which attend particular relationships or which mark particular events.

3.60 For example, the ascription of full moral status to human beings is marked by, among other things, the prohibition on murder, the institutions of justice and by rituals of mourning and reconciliation. It is marked also by the fact that we are able to take seriously the notion of responding to another with respect or love, and of responding with remorse to the wrongs we do them.

3.61 The fact that it is difficult for some to take seriously certain forms of response to early embryos may arguably itself reveal that their moral status is more limited or is at least different from 'ours'. For example, embryos allowed to 'succumb' are not given funerals; donating parents are not considered to be abandoning their children; and there seem to be limits on the extent to which 'parents' mourn their unused embryos or to which scientists might intelligibly feel remorse for their treatment of them. These responses all seem to point to the difficulty for some of taking seriously the notion that embryos enjoy just the same moral status as 'we' do.

3.62 These considerations are not, of course, decisive. For some, the inability seriously to imagine these kinds of responses may be indicators of the failure of imagination or sensibility rather than of the 'status' of the embryo.

3.63 Nevertheless, these considerations seem to point to the possibility of there being a 'third way' between the denial of any moral status to the early embryo and the ascription of the same status as possessed by adult human beings.

3.64 According to this 'third way', the unborn belong in *a* sense to the human family and are deserving of *forms* of moral consideration. But this leaves open the question of just what forms that consideration must take.

3.65 The Committee notes that the Bill itself, and some of those who support it, implicitly adopt this third way.

3.66 Clearly some moral status is accorded to embryos. This shows itself in features such as the limitation on the age of the embryos to be used, the prohibition on the creation of embryos specifically for research, and the specification that the research to be undertaken must be serious and must not entail the unnecessary

destruction of embryos. Recognition of the moral status of embryos has taken the form of a policy of 'harm minimisation'.

3.67 Nevertheless the limitation of the moral status accorded to human embryos is revealed by the very existence of the Bill, which presupposes that the interests of adult human beings in the potential benefits of the research take precedence over any interests possessed by the embryos.

3.68 The Committee noted earlier in its discussion, that for those who think that the human embryo is morally equivalent to an adult or child, there can be no moral justification for allowing it to be destroyed for the benefit of others.

3.69 For those who think, however, that the human embryo under 14 days does not enjoy precisely the same moral status as an adult or child, then the nature of any further reasons for supporting or objecting to the practice becomes decisive.

3.70 In the remainder of the chapter, the Committee will outline the nature of the 'further reasons' given in evidence, both for and against destructive experimentation on human embryos. The nature of these reasons may be divided into two main categories, namely utilitarian or consequentialist, and other arguments.

Utilitarian arguments

3.71 The utilitarian argument in favour of engaging in stem cell research focused on the potential therapeutic benefits that might arise from it. These benefits, it is said, would accrue not only to the thousands of individuals suffering from a host of diseases and disabilities, but through them to their families and the whole community.

3.72 The benefits would be measured in terms of increased health and well-being, or 'quality of life', as well as in terms of cost savings to the community's health and welfare budgets.

3.73 Ms Sheila Royles, Spokesperson, Coalition for Advancement of Medical Research Australia (CAMRA) told the Committee that CAMRA believed that 'embryonic stem cell research holds one of the greatest hopes for finding a cure for hundreds and thousands of Australians with diseases and disabilities. We believe that these people should have the opportunity for a better quality of life and to not literally be protected to death by legislation'.[31]

3.74 Ms Royles outlined the scale of the potential benefit of research in the following terms:

> In terms of the key stats for some of these patient groups, one person dies of motor neurone disease every day - that is a larger number than AIDS - and the life expectancy is on average three to four years. One person is confined to a wheelchair every day in Australia, and there are 100,000 children and

31 *Committee Hansard*, 17.9.02, p.71 (Ms Royles).

> adults with juvenile diabetes in Australia who have to inject themselves two or three times a day just to stay alive. The cost to the community of looking after these people is many billions of dollars.[32]

3.75 James Shepherd, the 13-year old youth ambassador for the Juvenile Diabetes Research Foundation, spoke to the Committee of the personal cost of living with juvenile diabetes. Mr Shepherd said that he had lived with juvenile diabetes since he was five years old and that 'it has been quite traumatic for myself and my family':

> In the course of my life I have had approaching 7,000 needles and approximately 16,000 finger pricks, but that is just an external factor because it is more than anything mentally difficult to cope with diabetes. For example, there is always the looming prospect on the horizon of complications which can derive from diabetes, such as blindness, kidney problems and the increased chance of death due to heart disease, to name a few.[33]

3.76 James Shepherd went on to say that his diabetes 'affects everything I do. There is no break; there is no holiday'. He informed the Committee that:

> There are approximately 100,000 juvenile diabetics in Australia, and there are more being diagnosed each year. I think all of us deserve a chance for a cure. As Sheila said, the cure could lie in adult stem cells or embryonic stem cells or it could lie in one of the many other types of research, but I think that every possibility for a cure should be fully explored before it is banned completely. It is a hard thing to live with, and I think we have every right to a cure and any way that cure could be achieved should be fully tested before that window is closed.[34]

3.77 Mr Kevin Langdon, President, Motor Neurone Disease Association of NSW, made similar points on behalf of those suffering from motor neurone disease. He said:

> Imagine a disease which little by little robs you of the use of your arms, your legs, and even your voice. Imagine seeing the muscles in your body slowly waste away while your senses and intellect remain perfectly in order. The ability to feel emotion – love, anger, joy and bitterness – remains intact, but one has no way of expressing them.[35]

3.78 The disease, Mr Langdon said, profoundly affects not only the individual patient, but every member of the family. Dr Paul Brock, who also suffers from motor neurone disease, informed the Committee that:

> from the moment I am lifted out of bed in the morning until the bedclothes are pulled up over me every night, in order to live I am *literally* dependent

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32 *Committee Hansard*, 17.9.02, p.71 (Ms Royles).

33 *Committee Hansard*, 17.9.02, p.71 (James Shepherd).

34 *Committee Hansard*, 17.9.02, p.71 (James Shepherd).

35 *Committee Hansard*, 17.9.02, p.71 (Mr Langdon).

> on my wife, my two daughters aged 7 and 11, my team of carers, and a variety of devices. The physical, emotional, stressful and financial costs to me and my family cannot be expressed in words. I can no longer walk; nor hug my wife and daughters. I cannot eat without assistance. Nor use the toilet or have a shower unaided. An author of over 100 books, monographs, chapters, scholarly articles, and poems – I can now barely sign my name.[36]

3.79 The Committee also heard evidence from the Australasian Spinal Research Trust, represented by Mr Robert Turner, Honorary Chief Executive Officer, and Ms Johanna Knott, Director. Ms Knott expressed the view that, given the promise offered by research into embryonic stem cells, it would be unethical not to allow it to proceed. She said:

> Many hundreds of thousands of Australians suffer from serious or currently incurable diseases or conditions. In fact, one in eight suffers from neurological disorders alone. Twenty thousand plus people in Australia have severe spinal cord injuries, and that rate grows by one per day. Our government is supposed to do the greatest good for the greatest number of people, and I believe we have a moral responsibility to help others. But time is crucial. If scientists are forced to attempt to make adult stem cells behave like embryonic stem cells you could waste five years or more, and many people just do not have that time.[37]

3.80 In a similar vein, Dr Brock claimed that '[t]here is an ethical and moral imperative…to encourage scientifically rigorous and ethically responsible embryonic stem cell research in its virtuous pursuit of human healing'.[38] He objected to the common use, by opponents of embryonic stem cell research, of the assertion that 'the ends do not justify the means'. Dr Brock maintained that:

> what is central to the ethical and moral debate is the need to distinguish between *some* ends and *some* means. While there are some 'ends' that can *never* justify the 'means', there are some 'ends' that can *only* justify the 'means'. For example, when the Nazis tortured concentration camp inmates by injecting dangerous drugs for 'experimental' purposes and by removing body parts – this was evil. But when an anaesthetist administers dangerous drugs as part of an operation to remove a healthy kidney of a donor to heal a life by transplantation – this is good.[39]

3.81 James Shepherd, finally, exhorted Committee members to consider the arguments presented from the perspective that they themselves are potential sufferers of currently incurable conditions. He said:

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36 *Submission* 843, p.1 (Dr Brock).

37 *Committee Hansard*, 17.9.02, p.73 (Ms Knott).

38 *Submission* 843, p.2 (Dr Brock).

39 *Submission* 843, p.2 (Dr Brock).

> it is not often that people without diseases relate to us. The media commonly refer to us as 'these people who deserve a transplant', and stuff like that…Subconsciously people distance themselves. They think, 'That's them. I couldn't have that', whereas it is possible for anyone here to walk into hospital and walk out knowing that they have one of the diseases represented here. So the point should be made that we are just normal people who are unfortunate enough to catch these diseases; we are not a completely separate race of individuals.[40]

3.82 All of these witnesses clearly recognised that possible positive outcomes were in the future, rather than tomorrow. As Ms Knott said, 'I do not expect a cure tomorrow or even next year, and I do not intend to overstate the promise of research, but how can you overstate hope?'[41]

3.83 There were virtually no utilitarian arguments presented against engaging in stem cell research. One such argument was made by Dr Nicholas Tonti-Filippini who expressed concern that products from such research may eventually be used in developing bio-warfare technologies. He noted that 'pharmo-kinetic' research is currently being undertaken to identify 'genomic risk factors for pharmaceutical products'. However,

> This type of knowledge may well provide race specific information about the effects of bio-pharmacological agents and hence a bio-warfare use of the technology…The advantage of embryonic stem cell culture in this respect is their proliferative nature - their rapid replication and growth. It may well be that infectious or carcinogenic agents could be developed that were specific to particular genotypes based on research on stem cell differentiation studies.[42]

3.84 A number of other submissions to the inquiry raised matters that may be categorised broadly as concerns about the 'slippery slope'. Although this style of argumentation may be considered utilitarian, or at least consequentialist, the Committee will treat them separately in the next section.

Other arguments

3.85 A variety of other arguments were presented to the Committee, both for and against allowing destructive research on human embryos to proceed under the conditions specified by the Bill. In what follows, the Committee outlines these views and any rebuttals of them that appeared in evidence.

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40 *Committee Hansard*, 17.9.02, p.81 (James Shepherd).

41 *Committee Hansard* 17.9.02,p.73 (Ms Knott).

42 *Submission* 86, p.6 (Dr Tonti-Filippini).

Slippery slope

3.86 One concern expressed under this heading relates to the feasibility of limiting the embryos eligible for use to those deemed 'excess' from IVF programmes. The Anglican Diocese of Sydney stated that:

> If…we decide to establish an industry which is dependent on human embryos for laboratory material, we are establishing human embryos as a resource the demand for which may well continue. Requests for more human embryos, be they frozen excess ART embryos created after 5 April or fresh ones created specifically for research, will come before Parliament. The establishment of embryonic stem cell research in local biotech industries will invariably lead to requests for embryos which will meet current Good Manufacturing Practice (cGMP) safety requirements if therapeutic product development is to occur. These cGMP requirements are different from standards required in IVF programmes and are more stringent. Frozen excess ART embryos will never be adequate as a source.[43]

3.87 A second concern relates to the relationship between allowing destructive experimentation on embryos and future pressure to allow cloning. Although cloning is explicitly disallowed by the present Bill, evidence expressed concern that destructive experimentation is nevertheless the first step down that road. This concern is given weight by the fact that there has apparently been a gradual slippage away from parameters that surround the acceptable treatment of embryos since the IVF programme began.

3.88 For example, Dr Peter McCullagh commented that it 'seems rather perverse, in the light of the advocacy for use of the *resource* which embryos are now considered to represent, that advocacy for permission to develop embryo freezing techniques in 1982 was framed in terms of its benefit *to the embryo*'.[44]

3.89 Dr Joe Santamaria, a consultant physician and bioethicist, said that it is naïve to think that the present prohibition of cloning, on the grounds of its 'repugnance' to the community, will last. He said:

> If you pass the current legislation for the use of human embryos for experimental purposes (whether they are surplus or not), you have stripped all human embryos, however conceived, of any moral status. Once the law is activated, the procedures become normative and the community's innate repugnance is eroded.[45]

3.90 Similar points were made in the submission of Right to Life Australia Inc. A speech given by Ms Margaret Tighe, President, Right to Life Australia, at Monash University on 8 May 2002, noted:

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43 *Submission* 672, p.3 (Anglican Diocese of Sydney).

44 *Submission* 480, p.6 (Dr McCullagh).

45 *Submission* 1011, p.5 (Dr Santamaria).

> It has been interesting to observe the slow but steady advances of the lucrative reproductive technology industry since the birth of Melbourne's first IVF baby in 1980. The progress of that burgeoning industry has been an exercise in 'softly, softly, catchee monkey'! In these early days, it was all motherhood and apple pie. No experiments on human embryos said the scientists. No freezing and stockpiling of embryos. No selection and discarding of embryos to name but a few excesses. Yet one by one, these promises have been broken…[46]

3.91 Ms Tighe opined that:

> That is why, as surely as night follows day cloning of human embryos will be the next stage (only so called therapeutic cloning mind you) followed subsequently with seductive arguments and media campaigns designed to usher in reproductive cloning. It can always be justified by the hard case…And with a slick PR campaign to influence the gullible public into thinking it's cruel to oppose these measures because of the supposed good they might do, we will eventually see a cloned baby on TV.[47]

Conceptual loss

3.92 A number of submissions referred, in different ways, to the idea that permitting certain practices will lead, through their alteration of our concepts about human life and its significance, to the loss of certain possibilities or values.

3.93 For example, some submissions expressed concern that the failure to respect the 'human dignity' of the early embryo would lead to the erosion of fundamental respect for other human beings, particularly the most vulnerable. Dr Amanda Lamont asked:

> If today we decide to ignore the dignity of a baby in a test tube, what is there to protect the dignity of those deemed 'less fully functional' by our society tomorrow? *We* are the elderly generations of tomorrow, and those of us involved in this debate will be personally reaping the effects in our old age. Do we want to be allowed to die with dignity when our time comes, or would it be acceptable for our bodies to be used for experimentation while we are still half-alive, like the frozen embryos…?[48]

3.94 The Hon Graham Kierath argued that:

> Once we have made the irrevocable and frightening step to accept exploitation of, and experimentation on, human beings, there can then be no objection in principle to going further and further…Are we a society which protects the most vulnerable – the poor, the sick and the unborn, from the predations of those who are more powerful, more vocal or even dishonest?

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46 *Submission* 1003, Attachment p.2 (Right to Life Australia Inc).

47 *Submission* 1003, Attachment p.2 (Right to Life Australia Inc).

48 *Submission* 1010, p.2 (Dr Lamont).

> If so, then there is no way that experimentation, or the use of stem cells from, embryos, ie. tiny human beings, should even be contemplated.[49]

Commodification of life

3.95 Other evidence expressed concern about the potential of certain practices to cheapen our very sense of the significance of life. Submissions spoke in terms of the *commodification* or *instrumentalisation* of life.[50]

3.96 The Australian Catholic Bishops Conference criticised the capacity of IVF clinics to manipulate the numbers of 'excess' embryos produced and wrote:

> To so manipulate the production of human life is an affront to human dignity and fosters a view of life which is more akin to the embryo as 'property', able to be bought and sold as a commodity, than as a member of the human family…In short, the dominant paradigm promoted by the destructive, but commercially profitable, use of the 'frozen generation' is that of 'production – manufacture – commodification – commercialisation of life'.[51]

3.97 For some, the impact of this 'commodification' of the early embryo's life is already illustrated by the fact that parents are able to donate their 'excess' embryos for research. The National Civic Council (WA) argued that:

> The Bill is drafted on the assumption that human embryos are in a relationship to those for whom, or from whose gametes they were created, that is more akin to the relationship of owner to property than of parent to offspring.[52]

3.98 However, the Council said: 'Parents are not permitted under common law to make decisions for their children that are patently contrary to the life and welfare of their children'.[53]

3.99 The Reverend Professor Michael Tate, who chaired the Senate Select Committee on Human Embryo Experimentation in 1985, submitted that:

> The market model is such a dominant feature of our current world culture that sometimes it is difficult to appreciate that property is not the all determining concept governing relationships in human society…We certainly concurred…that the market model was quite inadequate in the case of this subject.

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49 *Submission* 1016, p.2 (Hon G Kierath, MP).

50 See, for example, *Submissions* 156, 359, 876.

51 *Submission* 981, p.2 (Australian Catholic Bishops Conference).

52 *Submission* 282, p.5 (National Civic Council (WA)).

53 *Submission* 282, p.5 (National Civic Council (WA)).

> The embryo is not 'property belonging to' gamete donors or either one of them. The 'property rights' of the provider of egg or sperm are exhausted on fertilization. At that point, guardianship arises, and would ordinarily be exercised by the intended social parents…[54]

3.100 The Committee received some evidence from the organisation, ACCESS Australia's National Infertility Network, however, which argued against the view that the willingness of parents to donate their embryos for research signifies a lack of respect or a crude commodification of life. ACCESS submitted:

> Those of us who have created embryos have grappled with the ethical and social implications of what to do with them because we must. They are ultimately our responsibility. Then we live with the decisions we make about them. We care about the fate of the embryos that were created to be our children, to see that their existence has had some meaning. We do not believe that to use them for research would be disrespectful, quite the contrary. For many couples, the opportunity to donate their embryos for ART research gives them some added meaning, as they contribute to scientific knowledge that will lead to improvements in ART practice and ease human suffering. No one else values or respects these embryos more.[55]

3.101 The submission emphasises that 'we value life and we value children, which is why we have been prepared to go through extensive investigations and treatment to try to create a family'.[56]

Community sentiment

3.102 The Committee notes further that concern about the conceptual or societal effect of allowing destructive research on early embryos does not appear to be reflected in general community sentiment.

3.103 The report of the Select Committee on Stem Cell Research in the United Kingdom noted that 'the question of research on human embryos has to be considered within the context of the law in the United Kingdom and the social attitudes it reflects'.[57] That context, the Committee noted, includes legislation permitting abortion in a relatively wide range of circumstances and an IVF practice which involves the discarding of a substantial number of surplus embryos. The Committee suggested that: 'It would be difficult to justify an absolute prohibition on the destruction of early embryos while permitting abortion in a relatively wide range of circumstances post-

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54 *Submission* 899, p.3 (Professor Tate).

55 *Submission* 1047, p.3 (ACCESS).

56 *Submission* 1047, p.3 (ACCESS).

57 House of Lords, Select Committee on Stem Cell Research Report, Chapter 4, p.5, http://www.publications.parliament.uk/pa/Id200102/Idselect/Idstem/83/8305.htm (16 September 2002).

implantation – indeed well after the emergence of the primitive streak and into the foetal stage of development'.[58]

3.104 In the Australian context, the Committee notes also that 72 per cent of Australians surveyed have indicated their approval of research using excess IVF embryos for the development of therapies, assuming the informed consent of donors.[59] Further, according to ACCESS, approximately 60 per cent of couples involved in ART treatment will choose to donate the embryos they no longer need for research.[60]

3.105 Dr Megan Best questioned the significance of these levels of community support, however, saying that:

> I cannot help but feel that the promotion of this bill by many proponents has been misleading and I wonder if destructive research on human embryos would be as widely accepted by the community if it were known that the purposes for which they will be used may turn out to be not life-saving but economical. (I am thinking of some pharmaceutical applications here).[61]

Holistic conception of the human condition

3.106 A final objection raised on conceptual grounds to the research concerns the damage done by refusing to integrate the experience of disease and disability into a holistic conception of the human condition.

3.107 Mr Erik Leipoldt informed the Committee that he has lived as a quadriplegic for almost 25 years. He wrote:

> People have an innate fear of disability, imperfection and mental and physical decay. We want to escape this human condition. But to really escape it would be to outgrow it by developing a more wholesome concept of it in our own minds. Wanting to control everything only leads to more unhappiness. Learning a balance between what can be realistically controlled and what is best learned to be lived with leads to a happier life…This means that we cannot expect embryonic stem cell cures to address the real causes of our suffering. We can start by acknowledging vulnerability and dependence as parts of the human condition, rather than overemphasise physical perfection and independence and apply them in our private lives and policies.[62]

3.108 Mr Liepoldt also argued that disability is being portrayed as a 'tragic condition' and used by those promoting embryonic stem cell research in 'an

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58 House of Lords, Select Committee on Stem Cell Research Report, Chapter 4, p.5.

59 Roy Morgan International conducted surveys in June and November 2001, showing that 72% and 70% of Australians approve the research. *Submission* 895 (CAMRA).

60 *Submission* 1047, p.4 (ACCESS).

61 *Submission* 419, p.2 (Dr Best).

62 *Submission* 301, p.1 (Mr Leipoldt).

irresponsible and opportunistic fashion' to set back the cause of ensuring that people with disabilities are 'accepted as equally valued members of society'.[63]

3.109 These 'tactics', according to Mr Liepoldt have implications for society's conceptions of 'normality' or 'a good life', and neglect the fact that the 'collective values and attitudes that our society applies to people with disabilities' are 'responsible for transforming much of the impairment to a disability experience'.[64] For these reasons, Mr Leipoldt said that he found it offensive to be used 'as a lobbying tool for the biotech industry'.[65]

3.110 Other evidence echoed these concerns, and drew the further conclusion that many people with disabilities or diseases are being manipulated into supporting embryonic stem cell research by scientists whose real interests lie elsewhere.

3.111 Dr Peter McCullagh, for example, spoke of the 'exploitation of highly vulnerable people living with disabilities',[66] while Dr David van Gend asserted that it was 'a bad thing' to say to the parents of a child who is paralysed that '[e]mbryo stem cells are your hope'. He said 'it is a false hope. You cannot do that to paralysed people nor to MS patients or Parkinson patients. You do not do that'.[67]

3.112 The Committee received evidence from other people with a disability or illness who objected to the destruction of human embryos. For example, the Disability Action Group said that:

> We…strongly object to the cynical exploitation of our disabilities by people who wish to carry out destructive research on human embryos. Arguments for such research, which we believe to be mostly unconscionable, must be made without gratuitously using us as human leverage…
>
> Furthermore, recent confirmation of the fact that "excess" embryos may be used as genetic material for drug testing puts people with disabilities in the invidious position of benefiting from others' destruction.[68]

3.113 Dr Christopher Newell, a bioethicist and academic who also has a disability, acknowledged his debt to medical science but also the harm that is proposed to the embryo:

> …I am a person with disability who, like so many, is alive today because of the developments of medical science.

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63 *Submission* 301, p.1 (Mr Leipoldt).

64 *Submission* 301, p.1 (Mr Leipoldt).

65 *Submission* 301, (Transcript of his talk on Radio National, 'Perspective', 5 September 2002).

66 *Submission* 480, p.8 (Dr McCullagh). See also, *Submission* 876.

67 *Committee Hansard*, 24.9.02, p.182 (Dr van Gend).

68 *Submission* 1598, p.4 (Disability Action Group); see also *Submissions* 1081, 1084, 1293.

> Medical science offers many potential benefits into the future but it is clear that there must be limits. One of the basic ethical principles directly derived from the Hippocratic tradition, affirmed in a variety of non-consequentialist philosophical and religious codes, is "first of all do no harm". It is clear that the proposal to use embryonic stem cells will provide a harm…[69]

3.114 The group Diabetics for Ethical Treatment objected to the stance of some patient advocacy groups:

> Some patient advocate groups which support destructive research involving human embryos are putting themselves forward as representing all patients with degenerative diseases, including diabetics. We categorically reject the right of these groups to speak for us…
>
> We firmly believe that an attack on the dignity and well-being of any group of human beings is an attack on human dignity itself. It is a profound insult to people with disabilities and illnesses, including diabetics, to presume that we are willing to accept therapies developed at the cost of other human lives.[70]

3.115 The Committee also received evidence, however, from people living with illness or disability which strongly disputed the claim that they had been manipulated or exploited into supporting embryonic stem cell research.

3.116 Mr Robert Turner, Honorary Chief Executive Officer, Australasian Spinal Research Trust, and the father of a quadriplegic son, indeed suggested that such claims were themselves patronising:

> Certainly, …one of the things they fight against is being talked down to like that as though they have not got the ability to discriminate between what is exploitation and what is not. When I take him out in a wheelchair…people talk to me instead of talking to him simply because he is in a wheelchair. This is symptomatic of that: 'They don't know what they're doing; poor fools. Somebody has their hand up their back manipulating them'. Nothing could be further from the truth.[71]

3.117 Ms Johanna Knott told the Committee that she was responsible for founding the Australasian Spinal Research Trust and that 'no-one could say I was manipulated into doing that'.[72] She said that:

> [F]or 10 years I have not been able to eat, wash, go to the bathroom or get dressed without someone else's help. Some people may be able to get used to living like that, but I am not one of those people. I have a keen interest in

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69 *Submission* 898, p.1 (Dr Newell).

70 *Submission* 1293, p.5 (Diabetics for Ethical Treatment).

71 *Committee Hansard*, 17.9.02, p.85 (Mr Turner).

72 *Committee Hansard*, 17.9.02, p.85 (Ms Knott).

> research, and I am deeply disturbed by any attempts to block scientific progress.[73]

3.118 She also advised the Committee that: 'The reality is that we do follow very closely, and we have done for a number of years, what research has gone on around the world, and I think we do have a good sense of what is credible and what is not'.[74]

Distribution of resources

3.119 Some submissions expressed the opinion that the money set aside for embryonic stem cell research could more profitably be spent on other research or services, and thus that the question of the ethical distribution of resources needs to be considered.

3.120 For example, Dr Christopher Newell stated that:

> If the Australian parliament really wanted to address the situation of Australians with disabilities those tear-streaked speeches would also be focusing on the significant unmet need for those of us with disability and our families. Likewise it would be focussing on putting its resources into community support and primary health care interventions which would also have a role in preventing and ameliorating disability. Sadly many of the interventions which would ameliorate the situation of people with a disability in Australia and overseas are not sexy or hi-tech.[75]

3.121 The Australian Family Association (Bayswater/Boronia Branch) expressed the view that the promise of results from research into embryonic stem cells is highly speculative, and that money should be provided only to more 'proven' research or services. The Association wrote:

> If adult stem cell research is where the genuine hope lies, then why are precious public funds being diverted away from it? With many programs ranging from abused women to drug addiction to Aboriginal health crying out for money, why would the Government be allocating our money to such a questionable line of research?[76]

3.122 Similarly, the Catholic Archdiocese of Melbourne questioned the validity of funding embryonic stem cell research at the expense of 'the ethically uncontentious but scientifically more promising avenues' of adult stem cell research.[77]

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73 *Committee Hansard*, 17.9.02, p.73 (Ms Knott).

74 *Committee Hansard*, 17.9.02, p.74 (Ms Knott).

75 *Submission* 898, p.7 (Dr Newell). See also *Submission* 1025 (Endeavour Forum).

76 *Submission* 983 (Australian Family Association (Baywater/Boronia Branch)).

77 *Submission* 876, p.2 (Catholic Archdiocese of Melbourne). See also *Submission* 981.

3.123 Often, questions about the allocation of funds were expressed in tandem with suspicion about the motives and commercial incentives driving the biotechnology industry in its support for embryonic stem cell research.[78]

3.124 The Committee received no evidence which analysed the actual distribution of research funds between different research priorities.

Autonomy argument

3.125 Some evidence argued that potential donors have the right to choose whether their embryos are used in research or not, and that the Government should not legislate to prevent them being allowed to make that choice.[79]

3.126 The Juvenile Diabetes Research Foundation stated its view that, assuming the appropriate ethical and scientific guidelines are in place, 'it should be the moral choice of those individuals that drive the donation of excess embryos into medical research'.[80]

3.127 Professor David de Kretser AO, Director, Monash Institute of Reproduction and Development, suggested that:

> For the opponents of this legislation we would propose the examination of the premise, already accepted by our society, namely that the parents of a child on a life support system that is about to be withdrawn are accorded the right to decide whether the organs of that child can be donated for transplantation. Surely the parents of an embryo, whose life support system is about to be withdrawn have an equal right to donate the cells of that embryo, potential transplants of the future, to generate embryonic stem cells.[81]

3.128 Ms Sandra Dill, Executive Director, ACCESS, Australia's National Infertility Network Ltd, exhorted the Committee to:

> acknowledge infertile couples – who have sought from the beginning to act in their embryos' best interests – by allowing them to make decisions according to their conscience. Fertile people in our community enjoy the right to act in their children's best interests; importantly, you will treat infertile people with the same respect by ensuring us corresponding rights to make decisions about embryos that once had the potential to be our children.[82]

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78 See, for example, *Submissions* 301, 359, 480, 876, 983.

79 ACCESS quoted former US Surgeon General, C. Everett Koop, who was personally opposed to abortion, but who argued that personal moral beliefs should not automatically be enacted into laws enforced by the State. *Submission* 1047.

80 *Submission* 896, p.2 (Juvenile Diabetes Research Foundation).

81 *Submission* 1041, p.6 (Professor Kretser).

82 *Committee Hansard*, 26.9.02, p.191 (Ms Dill).

3.129 Against this line of argument, however, Dr David van Gend from Do No Harm, argued that if widespread embryo research is allowed to go ahead, Australians will have difficulty exercising their right to conscientiously object or opt out of involvement. In this sense, the autonomy of those opposed to the research would be at risk.[83]

3.130 Dr Tonti-Filippini also expressed concern at the extent to which the autonomy of donors is protected in the Bill. He commented that donors would not know what would happen to their embryos or the stem cells derived from them, and said:

> there is no reporting back to the people who gave them in the first place. I just find the respect for autonomy–let alone respect for embryos and stem cells–to be appalling and a complete oversight in the structure of this.[84]

Scientific, economic and technological impact

3.131 A number of witnesses warned of the likely negative impact on Australian science and technology of the failure to pass legislation permitting embryonic stem cell research. That impact will, it is said, be caused by the fact that Australian researchers will be forced to continue their research in countries such as Singapore and the UK and by the loss of international research funding.[85]

3.132 For example, BresaGen, a publicly listed Australian company 'acknowledged as one of the three world leaders in the therapeutic application of Human ESC [embryonic stem cell] technology', wrote:

> We believe this legislation is critically important in maintaining Australia's current high scientific position in both ES cell research and assisted reproductive technology (ART). The change is important for the advancement of therapeutic opportunities for patient care and disease treatment, and for the progress of the Australian Biotechnology Industry.
>
> The passage of this legislation is essential in BresaGen retaining a significant presence in this country. BresaGen has overseas nodes, and failure of this legislation to pass will certainly force BresaGen to consider its Australian presence.[86]

3.133 Professor David de Kretser warned that the failure of the legislation would severely compromise the scientific prospects of stem cell research in Australia as well as emerging biotechnology industries. He noted that future research would require that stem cell lines be sourced from overseas, probably from commercial companies, and that these sources 'will almost certainly wish to retain some rights to any intellectual property generated by the research'. The consequence will be a substantial loss of

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83 *Committee Hansard*, 24.9.02, p.175 (Dr van Gend).

84 *Committee Hansard*, 24.09.02, p.165 (Dr Tonti-Filippini).

85 *Submission* 895, p.1 (CAMRA).

86 *Submission* 1030, p.2 (BresaGen Ltd).

control over the commercialisation of research done in Australia, which 'is not in Australia's long-term economic interests'.[87]

3.134 Professor Silburn, however, talked of his concern about the commercialisation of research 'as a scientist who is very committed to keeping public research in the public domain. I am not interested in commercialisation or patents. That is not the issue of what true science is about'.[88]

3.135 ES Cell International Pte Ltd noted that a 'political environment supportive of stem cell research is one reason why ESI has invested so considerably in Australia, and will be a significant factor in relation to our future investment decisions'.[89] Professor Alan Trounson, Deputy Director, Monash Institute of Reproduction and Development, and CEO Designate, National Stem Cell Centre, informed the Committee that the award of Commonwealth funding to the National Stem Cell Centre has enabled the recruitment of internationally recognised scientists to Australia. It is also the major reason 'for retaining one of Australia's most eminent adult stem cell researchers' who 'declined a very attractive offer to move to the USA in August 2002'.[90]

3.136 Professor Trounson also noted that:

> Presumably, if the bill is not passed, we will have to buy embryonic stem cells – if we are going to continue the research - from overseas. All the current embryonic stem cells are subject to some commercial restrictions and nearly all of them require that you return the intellectual property to that company. All of those companies are now majority owned overseas.[91]

3.137 Finally, Professor Bob Williamson, Director, Murdoch Childrens Research Institute and Professor of Medical Genetics, University of Melbourne, noted that the proposed legislation is already more restrictive than those regulating researchers in the UK, all non-NIH research in the United States, and Singapore. He said:

> I hope that we will be sufficiently in step with other OECD countries so that legislation does not disadvantage Australian attempts to create sustainable jobs and new therapies, and cause some of our research to move abroad.
>
> I also hope we will not be in the ethically dubious position of having to import the results of research that we ban in this country, to offer therapy to our children.[92]

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87 *Submission* 1041, p.5 (Professor de Kretser).

88 *Committee Hansard*, 17.9.02, p.52 (Professor Silburn).

89 *Submission* 1039 p.2 (ES Cell International Pte Ltd).

90 *Submission* 1043 (Professor Trounson).

91 *Committee Hansard*, 24.9.02, p.153 (Professor Trounson).

92 *Submission* 1002, p.3 (Professor Williamson).

3.138 Some witnesses expressed concern, however, that the economic interests of those involved directly in the research may be distorting the arguments in favour of stem cell research. Dr Brian Pollard claimed that comments from those with a stake in the embryo research industry should be considered against a range of pressures and motivating factors:

> It would be foolish…not to recognise that other motivating factors are also undeniably present, though they may never be made public, such as scientific intellectual satisfaction, scientific kudos from respected colleagues locally and internationally, advancement in status or employment and the potential for vast monetary gain.[93]

National legislation

3.139 Evidence to the Committee suggested that the passage of national legislation permitting research involving human embryos under specified circumstances might be the lesser of two evils. This is because, in the absence of a comprehensive national framework, the States would be free to enact their own legislation that could be less restrictive than the legislation before the Commonwealth Parliament.

3.140 The Queensland Government stated that the Council of Australian Governments had driven the pursuit of a nationally consistent framework in this area, because the kind of 'dual system of regulation such as that which exists in the United States' is not in Australia's interests. It considered that such a system sends inconsistent messages to the community, scientists and investors, and 'creates loopholes and safe havens for practices which are considered either universally abhorrent, unsafe or unacceptable'.[94]

3.141 Professor Martin Pera warned that, defeat of the legislation would both restrict the ability of Australian scientists 'to remain at the forefront of embryonic stem cell research', and 'return us to an unsatisfactory position in which contradictory piecemeal regulations govern embryo research in the various states and territories'.[95]

3.142 Four of the biotechnology companies involved in embryonic stem cell research in Australia are members of AusBiotech Ltd, a company which describes itself as 'at the edge of acadaemia and industry'.[96] The Executive Director of AusBiotech, Dr Anthony Coulepis, told the Committee that:

> All four companies have said quite clearly to us that they believe they are at the cutting edge. If this legislation does not go through, they are first of all going to turn to their states - which is why we believe that the senators who are concerned about this legislation would be less concerned if there were

93 *Submission* 685, p.3 (Dr Pollard).

94 *Submission* 1500, p.1 (Qld Government).

95 *Committee Hansard*, 24.9.02, p.135 (Professor Pera).

96 *Committee Hansard*, 19.9.02, p.120 (Dr Coulepis).

national legislation which then controls what we do in the country, as opposed to allowing the country to go its own way. One of the cautions we are getting from our stakeholders is that national legislation will give us that degree of unity to be able to say how we can control this better. So the companies are saying, 'If this does not go through, we will first turn to our states. If we cannot get any relief from our states, we are going to go offshore'.[97]

97 *Committee Hansard*, 19.9.02, pp.121-122 (Dr Coulepis).

CHAPTER 4

THE BILL

4.1 The provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 (the Bill) as referred to the Committee were not altered by the House of Representatives procedure of dividing the provisions into two separate bills. This chapter will discuss the provisions of the Bill in the order they were originally introduced.

Part 1 - Preliminary

4.2 Clause 2 provides that the various provisions take effect on various specified dates. Clauses 25 to 27 dealing with offences will commence 6 months after the day on which the Bill receives Royal Assent. Clause 25 provides that a person must not use an excess ART embryo unless that use is an exempt use or is authorised by a licence. Clause 26 provides that a person must not use a non-excess ART embryo unless it is part of an ART program carried out by an accredited ART centre. Clause 27 provides that a person must comply with any conditions of a licence.

4.3 The explanatory memorandum explains that the delay of commencement for these clauses is to allow time for the establishment of the new NHMRC Licensing Committee and for applications for licences to be made. During this 6-month transitional period researchers and others will continue to have to comply with existing State legislation and the NHMRC *Ethical Guidelines on ART* (1996).[1]

4.4 The delay will also allow States and Territories to introduce complementary legislation and, where necessary, repeal existing provisions of State legislation that ban the use of excess ART embryos.

4.5 Clause 3 sets out that the object of the Bill is to 'address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos'. This provision gives a general understanding of the purpose of the legislation and sets out general aims and principles that are intended to help users interpret the detailed provisions of the legislation.

4.6 Several submissions expressed dissatisfaction with this objects provision, preferring an express reference to be made to the various ethical considerations and international conventions.[2] For example, the Australian Catholic Bishops Conference submitted that:

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1 Explanatory memorandum, p.3.

2 For example, *Submissions* 1, 156, 282, 285, 981, 1031, 1033 and 1053.

> There ought be basic, preambular provisions which at least refer to some ethical parameters, such as found in the Victorian and WA legislation, and/or taken from the Declaration of Helsinki. This may assist some members of the licensing committee to focus on appropriate ethical considerations and provide a source for further ethical reflection.[3]

4.7 The definitions contained in Clause 7 of the Bill were commented upon in a number of submissions.

4.8 Several submissions noted that the Bill contains no specific definition of 'embryo'[4]. Instead, it defines the terms, 'chimeric embryo', 'human embryo', 'human embryo clone', 'hybrid embryo', 'prohibited embryo' and 'excess ART embryo' by reference to the undefined concept of an 'embryo'. These submissions argued that the circularity in these definitions created uncertainty as to the fundamental scope of the Bill. Possible meanings for the term 'embryo' were proposed in a number of submissions including the Catholic Archdiocese of Melbourne which suggested that:

> ***embryo*** means a cell whose self-directed development is begun by the fertilisation of an ovum by a sperm, or such an organism as it subsequently develops, or any cell or organism produced in another way which has a similar developmental potential in favourable conditions.[5]

4.9 Other submissions were concerned with the definition attributed to a 'human embryo'. Subsection 7(1) of the Bill defines a 'human embryo' as a 'live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means'. Dr Tonti-Filippini advised the Committee that:

> In fact an unfertilized ovum also has two pro-nuclei. […] Thus the first appearance of two pro-nuclei is actually prior to fertilisation with the appearance of the ovum.
>
> This problem could be rectified by adding the words 'after sperm penetration' following the word 'pro-nuclei' in the definition of 'human embryo'.[6]

4.10 An alternative view was offered by Professors Jansen and Pera, and Dr Pope, who each told the Committee that unfertilised eggs do not have 2 pro-nuclei. Dr Pope and Professor Jansen outlined the difficulties in defining an 'embryo'. Professor Jansen advised that:

> Defining embryos is problematical in many ways, not least of which is that embryo-like development can arise from an egg without fertilization at all.

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3 *Submission* 981, p.15 (ACBC).

4 For example, *Submissions* 86, 870, 876, 884, 981 and 1061.

5 *Submission* 876, p.11 (CAM). *Submissions* 981, p.16 (ACBC); 86, p.2. (Dr Tonti-Filippini); and 870, p.10 (Qld Bioethics Centre) endorsed or proposed substantially similar definitions.

6 *Submission* 86, p.2 (Dr Tonti-Filippini).

> The pronuclear stage, at which the presence of 2 pronuclei generally indicates fertilization of the egg by a single sperm (there are exceptions), lasts only a few hours and might be missed by observers.
>
> In summary, there is no easy way of defining an embryo and defining an embryo as having or having had 2 pronuclei is neither necessary nor sufficient in principle and also has additional limitations in practice…
>
> Incidentally, pronuclei can form from parthenogenesis and from self-fertilization, which appears to be what happens in the natural initiation of an ovarian germ cell tumour such as a dermoid cyst, the commonest ovarian tumour in young Australian women, research into which will be jeopardised as an unintended consequence of the legislation.[7]

4.11 Dr Pope made similar comments noting that:

> The definition of an "embryo" is quite difficult as it is based on an individual's religious and moral opinions of when life begins. Scientifically, I feel an embryo is defined when the embryonic genome is activated at around the 8 cell stage. Syngamy is often used as a marker for an embryo. This is the time at which the 2 pronuclei fuse and the cell divides into two cells. This marker does overcome the concerns relating to failure of 2 pronuclei oocytes/zygotes to divide.[8]

4.12 Professor Pera added a note of caution indicating that 'many definitions use the point of syngamy meaning mixing of the maternal and paternal chromosomes, but this is a difficult point to determine experimentally'.[9]

4.13 The Catholic Archdiocese of Melbourne also commented on the definition of 'human embryo clone':

> The reference in this definition to "genetic copy" is problematical given that clones created by the 'Dolly the Sheep Technique' are not precisely 'genetic copies' of the genetic parent from whom the nucleus was taken. This is because some genetic material from the egg donor survives in the cytoplasm even after the nucleus is removed to be replaced with the nucleic material from the genetic parent.[10]

4.14 However, the explanatory memorandum explains that Subclause 7(2) clarifies that the definition will cover the case of somatic cell nuclear transfer.[11] The Subclause provides that to establish that a human embryo clone is a 'genetic copy' it is sufficient

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7 *Submission* 897, Additional information 15.10.02 (Professor Jansen).

8 *Submission* 1001, Additional information 15.10.02 (Dr Pope).

9 *Submission* 873, Additional information 11.10.02 (Professor Pera).

10 *Submission* 876, p.11 (CAM).

11 Explanatory memorandum, p.6.

that the set of genes in the nuclei of the cells has been copied and it is not necessary that the copy is an identical genetic copy.

4.15 The Catholic Archdiocese of Melbourne and Dr Tonti-Filippini submitted that the definition could still permit a variety of forms of asexual reproduction, that is, embryos formed other than by fertilisation. While they noted the ban on this activity provided in Clause 12, they submitted that the Bill could still allow fertilisation using genetically altered sperm or ova.[12]

4.16 They also submitted that the definition of 'hybrid embryo' would seem to allow researchers to create an organism that was part human and part animal by fusing segments of the human nucleus with segments of an animal nucleus. They addressed this issue by suggesting that:

> ***Hybrid embryo*** means an embryo which contains genetic material substantially derived from an animal source and genetic material substantially derived from a human source.[13]

Part 2 - Prohibited practices

4.17 Part 2 of the Bill contains a number of offences relating to human cloning and the creation and use of human embryos.

4.18 The Committee received several submissions that addressed the terms of these offences generally. For instance, the Australian Catholic Bishops Conference suggested all of the offences in Part 2 be extended to include acts or omissions that are done recklessly, noting that only the offence created under Clause 21 (importing, exporting or placing a prohibited embryo) currently includes this element.[14] In all other provisions in the Part, a person will not commit an offence, despite the fact that they have engaged in the offending conduct, if they did not intend, but were merely reckless as to whether, they acted in the offending way.

Human Cloning

4.19 Clause 8 of the Bill makes it an offence to intentionally create an embryo that is a genetic copy of another human, that is, a human embryo clone.

4.20 As discussed in chapter 2, current technology presents two methods of cloning–nucleus substitution and embryo splitting. Nucleus substitution (also known as somatic cell nuclear transfer) basically involves removing the nucleus from an egg cell, and substituting the nucleus of another cell. Embryo splitting is a technique of fertilising an egg with sperm, and dividing the newly formed embryo into two or more. The Bill provides that it is an offence to intentionally create a human embryo

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12 *Submissions* 876, p.11 (CAM) and 86, p.2 (Dr Tonti-Filippini).

13 *Submissions* 876, p.11 (CAM) and 86, p.2 (Dr Tonti-Filippini).

14 *Submission* 981, p.16 (ACBC). The NHMRC responded to this point in additional information dated 18.10.02.

clone, whether by either of these methods or by any other method that may be developed in the future.

4.21 However, the offence does not apply where a human embryo is created by the fertilisation of a human egg by human sperm. In this way, where a human embryo created by assisted reproductive technology spontaneously divides into two or more identical embryos (commonly known as identical twins, triplets, etc.) no offence is committed under Clause 8.

4.22 Clause 9 creates an offence for intentionally placing a human embryo clone in the body of a human or the body of an animal. The Queensland Bioethics Centre submitted that this offence should be much broader, to instead prohibit all uses of a human embryo clone.[15]

4.23 Clause 10 creates an offence for intentionally importing or exporting a human embryo clone. It was submitted that the offence created under Clause 10 should be extended to apply to all products derived from a clone. In the absence of this further restriction, those submissions suggested that the Bill may be circumvented by the importation of products derived from a human embryo clone.[16]

4.24 Dr Clive Morris, of the NHMRC advised the Committee that:

> There would be a prohibition on the import or export of prohibited embryos under the legislation. In relation to the import of embryos which are not prohibited embryos–that is, embryos which are part of an IVF program or embryos which were part of an IVF program and which perhaps have been declared to be excess–if they are part of an IVF program then the import or export would be for the purposes of the IVF program. If they were embryos which were declared to be excess to an IVF program, to import them for other purposes–for example, research–under the Quarantine Act you would, firstly, need to get an import permit from the Director of Quarantine. You would also need to get a licence from the NHMRC Licensing Committee…
>
> In relation to the import and export of embryonic stem cell lines, there is general legislation relating to the import and export of tissue.[17]

4.25 Dr Morris also advised the Committee that there is no prohibition in the Bill on a person from taking stem cells from a human embryo and then selling them for profit overseas:

> The legislation does not extend to the use of stem cell lines…The use of cells derived from any tissue would be permitted to be sent overseas…[The legislation] does not prohibit any uses of embryonic stem cell line.[18]

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15 *Submission* 870, p.10 (Qld Bioethics Centre).

16 *Submissions* 86, p.3 (Dr Tonti-Filippini); 876, p.14 (CAM); 981, p.16 (ACBC).

17 *Committee Hansard*, 26.9.02, p.262 (Dr Morris).

18 *Committee Hansard*, 26.9.02, p.256-257 (Dr Morris).

4.26 Ms Matthews, a consultant to the NHMRC added:

> The Customs regulation provides that approval must be sought in certain circumstances for the export of tissue…
>
> It would not prevent it; it just provides that a permit is required for the export under certain circumstances.[19]

4.27 Mr Rocco Mimmo, of Don't Cross the Line spoke about the possibility that disaggregated embryos are being stored either in Australia or overseas. He suggested, that if this were the case, 'it would seem to me that the bill itself would not prevent the importation of such material to Australia'.[20]

4.28 Clause 11 provides that it is no defence to any of these offences that the human embryo clone did not survive, or could not have survived.

4.29 The maximum penalty for each of these offences is imprisonment for 15 years, though the explanatory memorandum notes that a court may, at its discretion, either supplement the imprisonment term with a monetary penalty or convert it into a monetary penalty.[21] The NHMRC explained that:

> While the Bill only mentions imprisonment terms, the effect of this is the same as if monetary penalties had also been included. This is because of the operation of the Commonwealth *Crimes Act 1914*. The *Crimes Act 1914* provides that if a piece of Commonwealth legislation includes an imprisonment term then this can be converted, by the courts, to an equivalent monetary penalty or a combination of imprisonment term and monetary penalty, in accordance with a formula included in that Act.[22]

Other prohibited practices

4.30 The Bill also creates a number of offences relating to the creation of human embryos and other prohibited activities.

4.31 Clause 12 provides that an offence is committed when a person intentionally creates a human embryo by a process other than fertilisation, or develops an embryo that has been created in such a way. This ensures that if such an embryo was imported into Australia (an offence under clause 21) it could not be developed by the person who imported it or by any other person without an offence being committed.

4.32 The explanatory memorandum explains that a human embryo intentionally created outside the body of a woman must only be created by the fertilisation of a human egg by human sperm. As such, an embryo must not be created by embryo

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19 *Committee Hansard*, 26.9.02, p.262 (Ms Matthews).

20 *Committee Hansard*, 24.9.02, p.181 (Mr Mimmo).

21 Explanatory memorandum, p.7.

22 *Submission* 23, p.15 (NHMRC).

splitting, by nucleus substitution or by any other technique that does not involve fertilisation of a human egg by human sperm.[23]

4.33 The NHMRC noted that some IVF clinicians have argued that, since parthenogenesis (where an unfertilised egg starts to divide in the same manner as a fertilised egg) may be a causal factor in the development of ovarian tumours in Australian women, the clause may jeopardise research into the cause of these ovarian tumours. The NHMRC advised the Committee that:

> The Bill does not impose a different regulatory approach from that which currently applies under the requirements of the Reproductive Technology Accreditation Committee (RTAC), the NHMRC's Ethical Guidelines on ART and existing legislation. Under the existing system of regulation, embryos may only be created for the purposes of ART treatment and the creation of parthenogenetic embryos for research is not allowed.
>
> The Bill will not prevent research on ovarian tumours, ovarian tissue or human eggs, or the investigation of disease models and proof of concept research using animal models.[24]

4.34 Subclause 13(1) makes it an offence for a person to intentionally create a human embryo outside the body of a woman, unless it was created in an attempt to achieve pregnancy in a particular woman. That is, it is an offence to create human embryos specifically for other purposes such as for use in research or to derive embryonic stem cells for potential therapeutic use. However, the explanatory memorandum explains that this is not to limit the creation of multiple embryos in ART to bring about a pregnancy in a particular woman or to prohibit the creation of embryos that may not be ultimately used, and so become excess.[25]

4.35 Professor Jansen, of Sydney IVF, considered that this provision could restrict the research currently undertaken by IVF clinics. He claimed that the Clause:

> …prevents the fertilisation of eggs in the investigation of a scientific question unless the embryo is for the particular woman whose egg it is…
>
> It will not necessarily be in the interests of that person but it will be in the interests of infertile women generally. There are several areas where these questions are very important for improving IVF. I should preface this by saying that the area where IVF fails to make an impact on socially important infertility is the infertility that occurs in women as they get older, well before the menopause, and which is from the mid-30s and on.[26]

4.36 In response to this argument the NHMRC noted that:

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23 Explanatory memorandum, pp.8 and 9.

24 *Submission* 23, Additional information 15.10.02, p.5 (NHMRC).

25 Explanatory memorandum, p.9.

26 *Committee Hansard,* 26.9.02, p.200 (Professor Jansen).

> Research involving the *in vitro* fertilisation of human eggs, when this is not carried out in conjunction with the ART treatment of a particular woman, is not allowed in Australia under existing legislation nor the NHMRC's Ethical Guidelines on ART, which are required to be observed as a condition of accreditation of ART clinics by RTAC. The proposed legislation does not alter this situation.[27]

4.37 Subclause 13(2) clarifies that the prosecution (and not the defendant) bears the evidential burden in relation to an offence under Subclause 13(1).

4.38 Clause 14 provides that a person commits an offence if they intentionally create or develop a human embryo containing genetic material provided by more than two persons. In particular, the explanatory memorandum explains that this will prohibit the ART technique of cytoplasmic transfer, which involves the transfer of the cytoplasm (the part of the cell outside the nucleus) from one egg to another. Under this procedure mitochondrial DNA (which is thought to have no impact on the physical characteristics of a child) from a third party would be introduced into a recipient patient's egg.[28]

4.39 However, the explanatory memorandum acknowledges that cytoplasmic transfer has been reported to be particularly valuable in assisting older women to achieve pregnancy. Professor Robert Jansen submitted to the Committee that, while the efficacy of the procedure has not yet been proven, it should be further investigated and that Clause 14 'is a significant set-back for improving the fertility of women over 35'. Professor Jansen added that:

> …the alternative to a probably unimportant admixture of non-coding mitochondrial DNA to the genome is to donate an entire nuclear and cytoplasmic genome (in the form of egg donation), disenfranchising the woman from all genetic endowment to her children.[29]

4.40 The NHMRC commented that:

> Cytoplasmic transfer is a relatively new and controversial technique, which involves the injection of cytoplasm from a healthy donor egg into a recipient patient's egg. Because of the presence in the cytoplasm of mitochondria, which contains small amounts of DNA, embryos created through cytoplasmic transfer will have DNA from three separate people. The clinical safety and efficacy of this practice has not, to date, been established and therefore the impact of the third party mitochondrial DNA is not known.
>
> The Bill implements the cautious approach adopted by COAG by banning the creation of an embryo that contains genetic material from more than two

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27 *Submission* 23, Additional information 15.10.02, p.5 (NHMRC).

28 Explanatory memorandum, p.10.

29 *Submission* 897, p.6 (Professor Jansen).

> persons. This is subject to review within three years when more may be known about the safety and efficacy of this technique.[30]

4.41 It is an offence under Clause 15 for a person intentionally to develop a human embryo outside the body of a woman for more than 14 days, not including any time that the development is suspended (e.g. while the embryo is frozen). This means that human embryos created by ART must be implanted, stored or allowed to die (if unsuitable or excess) before the 14th day of their development. It is standard ART clinical practice for embryos to be implanted when they have reached between three and seven days of development. The explanatory memorandum explains that this Clause must be read subject to Clause 12, which provides that a human embryo created by embryo splitting or nucleus substitution, cannot be created or developed to any stage.[31]

4.42 The NHMRC advised that the 14-day limit is based on a clear policy direction in the COAG Communique and is consistent with Australian and international standards. The NHMRC explained that Clause 15 conforms with:

- NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996);
- Reproductive Technology Accreditation Committee (RTAC) Guidelines;
- South Australian legislation (*Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995*);
- Western Australian legislation (*Human Reproductive Technology Act 1991*);
- United Kingdom legislation (*Human Fertilisation and Embryology Act 1990*); and
- proposed Canadian legislation (Bill C-56).[32]

4.43 In addition, the NHMRC provided further information on the scientific evidence that determined 14 days as the appropriate time to mark the offence for inclusion in the Bill. It advised the Committee that:

> The prohibition on maintaining an embryo *in vitro* for longer than '14 days' is based on scientific evidence, which indicates that beyond 14 days development *in vitro*, an embryo is unlikely to have the capacity to implant in a woman's uterus.
>
> *In vivo*, the second week of embryonic development is marked by continued blastocyst development and implantation. Rapid growth and differentiation of the extra-embryonic tissue leads to development of the placenta. During the second week the cavity within the blastocyst and the inner cell mass, consisting of embryonic stem cells that form the embryo, begin early differentiation. Implantation is necessary to ensure the viability of the

30 *Submission* 23, Additional information 15.10.02, p.6 (NHMRC).

31 Explanatory memorandum, p.11.

32 *Submission* 23, Additional information 13.9.02, p.15 (NHMRC).

> embryo and has normally completed by the end of the second week (14 days).
>
> If implantation occurs, this is shortly followed by the next phase of embryonic development known as gastrulation. The term gastrulation describes the series of events that leads to the formation of the trilaminar (three layered) embryo and is characterised by the appearance of the 'primitive streak'.
>
> Hence, guidelines for clinical practice in the application of ART require that embryos must be implanted, stored or allowed to succumb before the 14th day of their development.[33]

4.44 As discussed in chapter 3 there is dispute over this point. For example, several submissions argued that there was no real significance behind the 14-day limit, and that this period was purely an arbitrary line drawn by the UK Warnock committee.[34] Dr Gregory Pike of the Southern Cross Bioethics Institute told the Committee that:

> The Warnock committee also acknowledged that it was dealing with a continuum of development and that 14 days was indeed an arbitrary time and that it had to choose for extrinsic rather than intrinsic reasons on a time– 'to allay public anxiety' was the wording used by the Warnock committee, yet it is a scientific fact that it is a continuity of development. We are talking about quite an arbitrary point of time. Arguments based on twinning or the appearance of the primitive streak are in my view quite thin.[35]

4.45 Under Clause 16 it is also an offence to use precursor cells taken from a human embryo or a human fetus to intentionally create a human embryo, or develop an embryo so created. A precursor cell is one that has the potential to develop into a human egg or sperm. This provision will prevent the situation where a child may be born never having had a living genetic parent.

4.46 Clause 17 prohibits the alteration of a human genome that is intended to be heritable, that is, able to be passed on to subsequent generations. This would ban germ line gene therapy, which modifies the genome of embryo, egg or sperm cells that would then be passed on to subsequent generations. However, the GeneEthics Network advocated that this prohibition should also apply to all non-heritable gene manipulations in embryos, arguing that the repeal of sections 192B, 192C and 192D of the *Gene Technology Act 2000* 'may leave a legislative vacuum unless this is done'.[36]

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33 *Submission* 23, Additional information 13.9.02, p.16 (NHMRC).

34 Baroness Mary Warnock was invited by the UK Government in July 1982 to chair a Committee of Inquiry into the 'social, ethical and legal implications of recent, and potential developments in the field of human assisted reproduction'. The report of that committee is the *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (1984).

35 *Committee Hansard*, 17.9.02, p.35 (SCBI).

36 *Submission* 1843, p.1. (GeneEthics Network).

4.47 It is an offence under Clause 18 if a person removes a human embryo from the body of a woman, intending to collect a viable human embryo. This bans the practice of 'embryo flushing' where viable embryos are removed after fertilisation has taken place *in vivo*.

4.48 Clause 19 makes it an offence to intentionally create a chimeric or hybrid embryo. The explanatory memorandum explains that this provision prohibits the creation of transgenic human embryos, but not transgenic animals, which are regulated under the *Gene Technology Act 2000.*[37] However, the GeneEthics Network submitted that:

> The claim that such procedures are regulated under the *Gene Technology Act 2000* as a genetically modified organism is not strictly correct. Transgenic animals are categorised as Notifiable Low Risk Dealings by the OGTR [Office of the Gene Technology Regulator] and need only be notified to the office. They are not assessed, monitored or regulated by the OGTR provided they remain in enclosed environs.[38]

4.49 Clause 20 prohibits the placement of:

- a human embryo into an animal;
- a human embryo into the body of a human, other than a woman's reproductive tract;
- an animal embryo into a human for any period of gestation.

4.50 Under Clause 21 a person commits an offence if they import, export or place in the body of a woman, a prohibited embryo (broadly one prohibited under Clauses 12 to 19), where the person knows, or is reckless as to whether, it is a prohibited embryo. The current practice of importing or exporting embryos (created by fertilisation of a human egg by human sperm) for the ART treatment of a particular couple, will be permitted to continue, subject to other legislation such as the *Quarantine Act 1908* and the *Customs Act 1901*.

4.51 Clause 22 prohibits the commercial trading in human eggs, sperm or embryos. A person commits an offence if they give or receive valuable consideration (not including reasonable expenses) for the supply of human eggs, sperm or embryos. Valuable consideration is not limited to monetary rewards and includes any inducement, discount or priority in the provision of a service. Reasonable expenses may relate to the costs of collection, storage or transport. However, as noted earlier, the Bill does not prohibit commercial trading in embryonic stem cells.

4.52 The Committee heard evidence from Professor Michael Good and Professor Peter Rowe, that excessive handling fees had been offered within the United States to

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37 Explanatory memorandum, p.13.

38 *Submission* 1843, p.2. (GeneEthics Network).

escape provisions equivalent to Clause 22.[39] In response to this suggestion, the NHMRC advised the Committee that:

> The legislation prohibits the giving or receipt of valuable consideration for the supply of a human egg, human sperm or human ovum. Valuable consideration is further defined to include any inducement, discount or priority in provision of a service, and it is intended that this would include such things as a handling fee.[40]

4.53 Many submissions supported the creation of this offence. BresaGen added that Clause 22 should be strengthened to further reduce any risks of financial inducement to donate embryos for embryonic stem cell research. In particular, BresaGen suggested that the following two points from the United States NIH guidelines for embryonic stem cell research be included:

> (a) the donors must recognise that any ES cell lines resulting from embryo donation may result in the development of cell therapy products which may be used for human therapy;
>
> (b) if this should happen, the embryo donors should have no commercial rights to financial benefit from these products.[41]

4.54 Dr Megan Best of the Anglican Church, Sydney Diocese informed the Committee that:

> We would like clarification on the buying and selling of stem cells and embryos. We were looking at the Canadian legislation–which is similar to this bill–and it has limitations on payments for embryos or stem cells, direct or indirect. Researchers are asked to disclose actual perceived or potential conflicts of interest to the equivalent of the NHMRC. Copies of contracts between researchers, institutions and industry sponsors and any relevant budgetary information are provided to the licensing body so that any actual or potential conflict of interest can be detected by examination of these documents.[42]

4.55 Although the current Bill does not directly address the issue of intellectual property rights in relation to human embryos and stem cells, this was an issue that was repeatedly raised during the course of this inquiry.[43]

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39 *Committee Hansard*, 19.9.02, p.104 (Professors Good and Rowe).

40 *Committee Hansard,* 26.9.02, p.246 (Dr Morris); see also *Submission* 23, Additional information received 16.10.02, p.6 (NHMRC).

41 *Submission* 1030, p.12 (BresaGen).

42 *Committee Hansard*, Tuesday, 24 September 2002, p.170 (Dr Best).

43 For example *Submissions* 37, 100, 282, 285, 362, 480, 540, 614, 805, 869, 871, 872, 880, 981, 1012, 1027, 1030, 1031, 1035, 1041, 1072, 1074, 1099, 1239, 1250, 1263, 1300, 1409, 1484, 1542, 1561, 1600 and 1833.

4.56 Biotechnology Australia submitted to the Committee that one reason existing embryonic stem cell lines are insufficient for continued research and further development of therapies is that many existing stem cell lines are subject to patent protection, restricting researchers' freedom to operate. It identified that this inability to gain access to cell lines is likely to hamper scientists' work in this field.[44]

4.57 *Australian Biotechnology News* has since reported that:

> Singapore-based company ES Cell International (ESI) is changing the marketing strategies for its human embryonic stem cell lines because of researchers' reluctance to part with intellectual property. The company is dropping its previous demand to share in any IP flowing from research using its lines and instead is attaching a straight dollar value to the lines…
>
> The company does not believe its cell line sales will contravene any clauses on the Bill on research into human embryonic stem cells being readied for debate in the Senate. The Bill does outlaw trade in human embryos but that is not the same thing as human embryonic stem cells.[45]

4.58 Many submissions suggested that the regulation of embryonic stem cell research was being driven by the prospect of profits that could be derived under a patent. Those submissions claimed that the potential for scientific and medical advances, which may also exist in adult stem cells, was secondary to the financial bounties that could be secured by asserting intellectual property rights that may only be claimed over embryonic stem cell lines.[46] Professor Silburn also commented in the Committee hearings that patents inhibit the sharing of research information.[47]

4.59 Dr Warwick Neville argued that the commercial emphasis of the Bill provides a flawed basis for research. He suggested that:

> Firstly, empirical research suggests only a weak correlation between patent rights and innovation. Secondly, there is substantial doubt whether the traditional equilibrium that patent law seeks to strike between private monopoly and public accountability works to maximise innovation in the biomedical field. Thirdly, patent law is centred on economic or market values and has difficulty dealing with ethical and social issues.[48]

4.60 Others opposed the commercial control and exploitation of embryonic stem cells on the grounds that they represent a fundamental biological resource. For

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44 *Submission* 1263, p.7 (Biotechnology Australia).

45 *Australian Biotechnology News,* vol.1 No.29, 4 October 2002, p.5.

46 For example *Submissions* 37, 100, 282, 285, 362, 540, 869, 872, 981, 1027, 1031, 1049, 1250, 1409, 1484, 1487, 1542 and 1600.

47 *Committee Hansard,* 17.09.02, p.52 (Professor Silburn).

48 *Committee Hansard*, 26.09.02, p. 215 (Dr Neville, ACBC).

instance, Stem Cell Sciences suggested the adoption of the European Union's Ethics Group recommendation to prohibit patenting of unmodified human stem cells.[49]

4.61 In addition, Stem Cell Sciences advocated the establishment of a National Stem Cell Bank, within an independent government organisation, to distribute human stem cell lines to researchers. This would be similar to the recent United Kingdom announcement to establish such a bank, operating independently of research institutions and commercial organisations.[50]

4.62 However, others saw the creation of such a bank, in the IVF context, as the very reason as to why there are many excess embryos in existence today. They asserted that a bank of embryonic stem cells would itself promote the creation of further embryos.[51] Professor Michael Good submitted that for any stem cell collection to be comprehensive many more embryos would need to be created:

> To make such a tissue bank from 'all human ES cell lines' would be virtually beyond the bounds of possibility. Furthermore, women would have to undergo super-ovulation in order to provide the large number of eggs that would be needed to generate such a vast bank of cell lines.[52]

Part 3 - Regulation of certain uses involving excess ART embryos

4.63 Broadly, the Bill provides that a human embryo may only be used in the course of routine IVF practice, if the couple for whom the embryo was created decide that it is excess to their needs, and the use is an exempt use, or a use that has been licensed.

Interpretation

4.64 Clause 23 defines a number of terms for the purposes of Part 3 of the Bill. In particular, the clause defines an 'accredited ART centre' as one accredited by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia. The GeneEthics Network expressed their opposition 'if this were to take over the legally mandated roles of statutorily established organisations such as the Vic Infertility Treatment Authority' adding that '[v]oluntary self-regulation is not appropriate here'.[53]

4.65 Clause 24 defines an 'excess ART embryo' as a human embryo that was created by assisted reproductive technology and is excess to the needs of those for whom it was created. Furthermore, those people must have determined that the

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49 *Submission* 1012, p.2 (Stem Cell Sciences).

50 ibid.

51 For example *Submissions* 86, 210, 369, 1036 and 1071.

52 *Submission* 614, p.2 (Professor Good).

53 *Submission* 1843, p.2 (GeneEthics Network).

embryo is excess and given their written authority for its use for purposes other than their own ART treatment.

4.66 This definition is seminal as it defines the scope of the regulation provided in the Bill. An important element of the definition is that of the consent required before an human embryo is regarded as 'excess'. Several submissions expressed concern as to which parties were required to give consent, and as to whether that required consent had to be fully informed.[54]

4.67 During public hearings an issue was raised as to whose consent should be required before an excess ART embryo may be used. In particular, the question was asked whether the consent was required of an anonymous gamete donor before an embryo may be used.[55]

4.68 Paragraph 24(1)(b) of the Bill provides that an excess ART embryo is one that is excess to the needs of a woman and her spouse (if any). In the case of an anonymous gamete donor, the donor will almost certainly not be the spouse of the woman for whom the embryo was created. As such Subparagraph 24(1)(b)(ii) would not apply to the donor and the authorisation and determination of the donor would not be required under Subclause 24(2).

4.69 Therefore the consent of an anonymous gamete donor will not be required for an embryo to meet the definition of an 'excess ART embryo' under the Bill. However, there is a further issue as to whether consent of the anonymous gamete donor is required for that excess ART embryo to be actually used.

4.70 Clause 25 of the Bill provides that an excess ART embryo may be used:

- as authorised by a licence (discussed below under 'Licensing system'); or
- for an exempt use.

4.71 Under Subclause 25(2), an exempt use of the excess ART embryo may be made without requiring the further consent of any other parties. That is, it seems that the consent of an anonymous gamete donor will not be required for an exempt use of a human embryo.

4.72 The Catholic Archdiocese of Melbourne opposed this situation, explaining that:

> Justice would surely require that both the couple for whom the embryo was intended and the donors (if any) should be consulted. The donor(s) (and their spouses if any) might prefer to receive the embryo themselves or have the embryo used in another way.[56]

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54 For instance, *Submissions* 216, p.1 (K Seager); 876, p.11 (CAM); and 1020, p.5 (I Hamilton).

55 *Committee Hansard,* 17.9.02, p.52 (Senator Barnett).

56 *Submission* 876, p.11 (CAM); see also *Submission* 1061, p.1 (Dr Joshua).

4.73 For an exempt use of an embryo to be authorised in accordance with paragraph 24(2)(b), consent must be given 'for the use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned'. In particular, the authorisation required does not need to specify the particular exempt uses for which the consent is given, only that it is given for an exempt use of that embryo. It was argued that greater steps to inform the consent of embryo donors should be provided:

> Given the moral and emotional importance of these decisions, the Bill should explicitly provide that those concerned must be given detailed information about the proposed research before they are asked for consent to the use of their embryos, are given an opportunity to restrict consent to particular research, and are advised of their right to withdraw or vary their consent up to the time that their embryo is used for research.[57]

4.74 Another suggestion was Stem Cell Sciences' proposal that a 'cooling-off' period be imposed to ensure that potential donors have the opportunity to fully consider whether they wish to authorise the exempt use of their embryos.[58]

4.75 The Catholic Archdiocese of Melbourne called for the legislation to explicitly provide that the donors may withdraw their consent up to the time that their embryo is used for research.[59] In addition, Salt Shakers, a Christian ethics group, suggested that an independent counsellor should give any counselling leading to consent for the exempt use of embryos.[60]

4.76 Each of these matters is discussed further in relation to the licensed use of an embryo under the heading 'Licensing System' below.

Offences and exempt uses

4.77 As mentioned above, Clause 25 outlines the exempt uses to which an excess ART embryo may be put, that is, uses for which a licence is not required. Subclause 25(2) lists the various exempt uses of an excess ART embryo as:

- storage, removal from storage and transport of an excess ART embryo (Paragraph 25(2)(a));
- observation of an excess ART embryo (Paragraph 25(2)(b)), which includes photographing or recording an embryo (Subclause 25(4));
- allowing the excess ART embryo to succumb (Paragraph 25(2)(c));
- diagnostic investigations on embryos that are not suitable to be placed in the body of the woman (Paragraph 25(2)(d));

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57 *Submission* 876, p.11 (CAM).

58 *Submission* 1012, p.2 (Stem Cell Sciences).

59 *Submission* 876, p.11 (CAM).

60 *Submission* 1502, p.6 (Salt Shakers – a Christian Ethics Group).

- using the excess ART embryo the purpose of achieving pregnancy in another woman (Paragraph 25(2)(e)); and
- any other use prescribed in the regulations (Paragraph 25(2)(f)).

Diagnostic investigations

4.78 The Committee received a number of submissions commenting on the term 'diagnostic investigations' in Paragraph 25(2)(d). In particular, several submissions noted that the term is undefined in the legislation, and expressed concern that it could allow a wide range of experiments on embryos which otherwise would be prohibited under the legislation.[61]

4.79 Addressing the concerns that this might create a loophole, the NHMRC reiterated that the investigations can only be carried out on embryos that are unsuitable for implantation and may only be carried out for the purposes of diagnostic investigations for the particular woman for whom the embryos were created. It also advised that significant penalties apply in the event of non-compliance (up to 5 years imprisonment) and the regulatory framework requires the collection of significant data and close monitoring of license holders. In response to calls for the exemption to be removed the NHMRC noted that:

> Without an exemption for diagnostic investigations, clinics would be required to obtain a licence from the NHMRC Licensing Committee to carry out such diagnostic tests. The following concerns have been expressed regarding licensing requirements for diagnostic investigations:
>
> - although the embryo is unsuitable for implantation, some of these investigations may damage the embryo. Under the legislation, no licence could be granted for any such investigation to be carried out on embryos created after 5 April 2002. This would effectively prohibit such diagnostic investigations being carried out for women who commenced their treatment after 5 April 2002. These women would be disadvantaged relative to those whose treatment commenced prior to 5 April 2002; and
>
> - the timeframes for applying to a Human Research Ethics Committee and then to the NHMRC Licensing Committee would limit the capacity of ART clinics to provide a timely and appropriate treatment for patients. For example, if the embryo is unlikely to survive freezing, the clinician may only have a narrow window of time (ie 1 or 2 days) when the diagnostic investigation can be carried out on the embryo.[62]

4.80 Although the term 'diagnostic investigations' is undefined in the legislation, the explanatory memorandum expands on its intended meaning:

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61 See *Submissions* 876 (CAM), 981 (ACBC), 1035 (Australian Youth Alliance (Vic)) and 1843 (GeneEthics Network).

62 *Submission* 23, Additional information 15.10.02, p.3 (NHMRC).

> In some cases, as a part of routine clinical practice, it may be beneficial to the woman for whom the embryo was created for diagnostic tests to be undertaken on ART embryos that are unsuitable for implantation to determine the reason why they are not suitable for implantation so as to improve the likelihood of successful pregnancy in the next attempt.[63]

4.81 The NHMRC also advised the Committee as to the intended scope of 'diagnostic investigations'. It advised that where an embryo fails to develop properly and is unsuitable for implantation:

> The exemption allows these embryos to be used by the ART clinic, with the consent of the couple, to try to work out why the embryos are abnormal or not developing properly…The exemption enables work of a purely diagnostic type (that is part of an ART treatment program) to be undertaken in order to try to increase the chance of suitable embryos being developed in a particular couple's subsequent round of treatment. The exemption does not allow such embryos to be used for general research or general quality assurance activities – any such use must be licensed.[64]

IVF clinical practice and training

4.82 The NHMRC also noted that the Bill does not create an exempt use for the purposes of ART training. It advised the Committee that:

> During consultations on the Bill, many ART clinics noted that, with the consent of the couple, they currently use many abnormal or unsuitable embryos for training purposes. For example, to train technicians in micro-surgical sperm injection techniques, to train people to take individual cells from embryos so that the cells can be tested for genetic illness.
>
> Following detailed consideration of the issues, it was considered that including an exemption for training could create a loophole in the legislation because it would be very difficult to distinguish between training, quality assurance activities and research. For example, it could be argued that a person was 'training' in the derivation of stem cells.
>
> The legislation therefore requires that the use of embryos in ART clinics for training purposes must be licensed by the NHMRC Licensing Committee.[65]

4.83 In this way the Bill would regulate activities of IVF clinics. The Committee heard from several witnesses who were concerned that the delivery of IVF clinical services could be impeded. Dr Adrianne Pope, of Monash IVF, gave evidence that:

> The IVF community has undertaken varying degrees of research or investigation on embryos as part of the evolving nature of the infertility treatment for the last 24 years. During that time both Government legislation

63 Explanatory memorandum, p.17.

64 *Submission* 23, p.20 (NHMRC).

65 *Submission* 23, pp.20 and 21 (NHMRC).

> and self-regulation have unfolded and worked well hand in hand The [Bill] will have an impact on material available to IVF researchers and to couples wishing to donate embryos in the future.[66]

4.84 In addition, Dr Pope submitted that:

> It would be a tragedy to all those people who have embraced the need to utilise assisted reproductive technologies as the only way to achieve a family, to see the limitations placed by the Bill, prevent the use of this material for the common good of so many. I would hope that society can accept the benefits associated with the use of abnormal embryos, fated to succumb, in the beneficial techniques aimed at assisting those couples desiring their own children.[67]

4.85 Accordingly, Dr Pope proposed that a distinction should be made between viable and non-viable embryos, with all non-viable embryos being available for 'diagnostic investigations' rather than just those created before 5 April 2002. Dr Pope commented that:

> As the Bill stands abnormal embryos created after the 5th April 2002 would not be available for training or development of techniques as these would result in the destruction of the fresh abnormal embryos. I would ask the [Committee] to make an exception to the Bill and allow abnormal material available at the time of IVF, to be used for techniques and training which would aid couples in future treatments.[68]

4.86 Professor Illingworth estimated that 40 000 non-viable embryos were created annually as part of clinical IVF in Australia.[69] This number referred to an approximation of the number of embryos per year that were unsuitable (by virtue of their appearances) for either freezing or for transfer. The Professor clarified his comments made at the hearing:

> I need to emphasise that these are embryos that are not suitable for freezing, cannot be held in storage and are therefore outside the terms of this act. My response did not in any way intend to suggest that this number is currently being used for research. On the contrary, the value of such embryos for research would be extremely limited.[70]

4.87 ACCESS, a consumer-based infertility network, submitted that:

> Consumers of ART services are extremely concerned about the way in which the [Bill] goes substantially beyond the COAG communique by

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66 *Committee Hansard,* 26.9.02, p.204 (Dr Pope).

67 *Submission* 1001, p.1 (Dr Pope).

68 *Submission* 1001, p.2. (Dr Pope).

69 *Committee Hansard*, 26.9.02, p.205 (Professor Illingworth).

70 Professor Illingworth, Additional information, 8.10.02

> targeting clinical IVF practice, which is already governed by several layers of accountability[71]

4.88 The Queensland Government stated that it did not support any further increase in the regulatory and administrative burden on the IVF clinical sector. It submitted:

> Queensland is concerned that the recent separation of the original Bill and the capacity for separate consideration of the new Bills and their further amendment will negatively impact on the IVF clinical sector.[72]

4.89 In response to these concerns, the NHRMC emphasised that the legislation does not regulate routine IVF clinical practice, although the legislation could impact on some IVF clinics, particularly in relation to the use of excess ART embryos for research, training and quality assurance purposes. The ethical and scientific considerations (including the requirement for informed consent and ethics committee approval) are the same irrespective of how an excess ART embryo is used. Therefore, IVF clinics will be subject to the same regulatory approach as applied to all institutions proposing to use excess ART embryos. The NHMRC advised:

> The legislation has been drafted so that an even regulatory hand is applied to all types of excess ART embryos, all types of research and all persons. The Bill does not prevent the continuation of ART clinical practices, including training of ART clinicians and quality assurance testing to ensure that culture and pre-implantation testing is optimal. By requiring a licence for these practices, the Bill takes a consistent approach to the treatment of embryos that may be damaged or destroyed, whether the use of the embryos is for training an ART clinician or for the derivation of stem cells.
>
> …
>
> The Licensing Committee will consider options to streamline the administration of the legislation, where it is satisfied that the use of the excess ART embryos will not damage or destroy the embryo. For example, ART service providers could apply for one licence to undertake quality assurance work using an approved list of techniques and a defined number of excess ART embryos. It may also be appropriate to consider similar arrangements for certain uses of excess ART embryos that may damage the embryo but are part of routine ART clinical practice, such as the use of embryos for training people in specific techniques of assisted reproductive technology. This would ease the administrative burden on ART clinics but still enable close regulatory oversight by the NHMRC Licensing Committee.[73]

4.90 Clause 26 makes it an offence to knowingly use a human embryo that is not an excess ART embryo where the use is not part of an ART program carried out by an accredited ART centre, and the person knows, or is reckless as to that fact.

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71 *Submission* 1047, p.2 (ACCESS).

72 *Submission* 1500, p.3 (Qld Government).

73 *Submission* 23, Additional information 15.10.02, pp.1, 4 (NHMRC).

4.91 Finally, under Clause 27 it will be an offence to intentionally or recklessly breach the condition of a licence issued under the Bill.

Embryo Research Licensing Committee of the NHMRC

4.92 Clause 28 establishes the NHMRC Licensing Committee. As a Principal Committee of the NHMRC, many provisions of the NHMRC Act will apply in respect of its operations. For example, as a Principal Committee of the NHMRC, the Licensing Committee must comply with the statutory requirement that the NHMRC promulgate ethical guidelines for research developed by AHEC.[74]

4.93 The GeneEthics Network argued that the NHMRC was not the appropriate body to be responsible for licensing activities and that this licensing function should be vested in the Office of the Gene Technology Regulator 'who has statutory responsibilities and authority commensurate with the importance of this licensing work, and has processes and mechanisms to engage with the interested and general publics'.[75]

4.94 Clause 29 sets out the functions of the Licensing Committee, which are essentially to administer the licensing system, monitor compliance with the legislation and where necessary take enforcement action.

4.95 Under Clause 30 the Licensing Committee has the power to do all things necessary or convenient to be done in connection with its functions.

4.96 Under Subclause 31(1) the membership of the Licensing Committee is to comprise:

- a member of AHEC (Paragraph 31(1)(a));
- a person with expertise in research ethics (Paragraph 31(1)(b));
- a person with expertise in a relevant area of research (Paragraph 31(1)(c));
- a person with expertise in assisted reproductive technology (Paragraph 31(1)(d));
- a person with expertise in a relevant area of law (Paragraph 31(1)(e));
- a person with expertise in consumer health issues as they relate to disability and disease (Paragraph 31(1)(f));
- a person with expertise in consumer issues relating to assisted reproductive technology (Paragraph 31(1)(g));
- a person with expertise in the regulation of assisted reproductive technology (Paragraph 31(1)(h)); and

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74 The Committee received several submissions that expressed concern with references the Bill makes to guidelines issued by the NHMRC and other bodies. These concerns are discussed below in relation to clauses 36 and 39 under the heading 'Licensing System'.

75 Submission 1843, p.2 (GeneEthics Network); See also *Committee Hansard*, 24.9.02, p.165 (Dr Tonti-Filippini).

- a person with expertise in embryology (Paragraph 31(1)(i)).

4.97 BresaGen submitted that given the differences and lack of overlap between ART research and embryonic stem cell research it is very important that there be adequate representation of both broad fields. It proposed that the third committee member should be 'a person with expertise in embryonic stem cell research' rather than merely 'a person with expertise in a relevant area of research' under Paragraph 31(1)(c).[76]

4.98 The members of the Licensing Committee must be appointed by the Minister after seeking nominations from the organisations described in regulations. The explanatory memorandum explains that placing the list of organisations in the regulations enables the list to be updated relatively simply as organisations change their name or as new organisations are formed that should be consulted. The Minister must also seek nominations from all States and Territories, consult the States and Territories on proposed appointments and have regard to their views (Subclauses 31(2) and (3)).[77]

4.99 The AHEC member must not be appointed as the Chair of the Licensing Committee, thus ensuring the position cannot also be held by the Chair of AHEC (Subclause 31(4)).

4.100 Subclause 31(5) provides that before appointing the Chair of the Licensing Committee, or the member with expertise in the regulation of assisted reproductive technology, the Minister must have the agreement of a majority of the States and Territories.

4.101 Subclause 31(6) provides that in appointing members to the Licensing Committee the Minister must also have regard to the desirability of ensuring that the Licensing Committee as a whole comprises members from different States and Territories.

4.102 Despite these safeguards, several submissions suggested that the membership of the Licensing Committee might be unrepresentative. For instance, the Catholic Archdiocese of Melbourne submitted that:

> The membership of the Licensing Committee could easily be stacked with those who have a particular interest in the embryo industry. There is no attempt to minimise this conflict of interest. Nor is there any attempt to ensure a broad spectrum of opinion or representation. Even with the inclusion of positions (b), (f), (h) and (i) there is no representative of the churches and no provision for a member with expertise in philosophical ethics, women's issues or other social issues.[78]

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76 *Submission* 1030, p.12 (BresaGen).

77 Explanatory memorandum, p.21.

78 *Submission* 876, p.12 (CAM); See also *Submission* 1843, p.3 (GeneEthics Network).

4.103 The Australian Catholic Bishops Conference added that:

> The Bill provides nothing with respect to 'conflict of interest'. Only in the Explanatory Memorandum is one referred to certain sections of the *National Health and Medical Research Council Act 1992* (Cth) which summarily states (s.38 (b)(vi)) that it is the Council which determines 'the disclosure of members' interests in matters being considered by the Committee'. Given the vast sums of money at stake in embryo research, conflict of interest of researchers, decision-makers and commercial interests with respect to licences must be dealt with comprehensively in the legislation.[79]

4.104 As noted by the Australian Catholic Bishops Conference, under the NHMRC Act, the NHMRC may determine the procedure to be followed by the Licensing Committee (as a Principal Committee) in relation to the disclosure of members' interests in matters being considered by the Licensing Committee.

4.105 The terms of appointment to the Licensing Committee may be on a part-time basis and may last for terms of up to 3 years (Clause 32).

4.106 Clauses 33 and 34 provide that the Licensing Committee must provide details of its operations to the NHMRC for inclusion in the NHMRC Annual Report and may report to Parliament at any time that it considers necessary.

Licensing system

4.107 An application for a license authorising the use of excess ART embryos is required to be made in accordance with Clause 35. The Licensing Committee will be able to specify the requirements for an application, and the regulations may require a fee to be paid.

Determination of application

4.108 Clause 36 describes the matters that must be considered by the Licensing Committee when deciding whether or not to issue a license. Particular matters that the Licensing Committee must have regard to include:

- the number of excess ART embryos likely to be necessary to achieve the goals of the activity or project proposed in the application;
- the likelihood of significant advance in knowledge, or improvement in technologies for treatment, as a result of the use of excess ART embryos proposed in the application, which could not reasonably be achieved by other means;
- any relevant guidelines issued by the NHMRC; and
- the HREC assessment of the application.

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79 *Submission* 981, p.17 (ACBC).

4.109 The explanatory memorandum lists a number of the uses for which a license may be granted, including using excess ART embryos:

- for research, e.g. to derive stem cells or to improve ART clinical practice;
- to train people in ART techniques;
- for Quality Assurance testing to ensure that pre-implantation diagnostic tests give accurate results; and
- to examine the effectiveness of new culture media for growing human embryos.[80]

4.110 A number of submissions commented that the provisions of Clause 36 were vague and indeterminate. For example, the National Civic Council (WA) noted that there is no specification of the kinds of 'knowledge' that may be sought or of the 'technologies for treatment' that may be improved:

> The inclusion of 'training people in ART techniques' and 'quality assurance testing' is significant. It is hard to see how these lead to a 'significant advance in knowledge' or 'improvements in technologies for treatment'.
>
> This suggests that the drafters of the Bill and the explanatory memorandum may be reading down Section 36 (4), which only requires the NHMRC Licensing Committee to 'have regard to' various matters, including 'the likelihood of significant advance in knowledge, or improvement in technologies for treatment'. This wording does not require the Committee to reject license applications for uses that do not have any likelihood of advancing knowledge or improving technologies for treatment.[81]

4.111 The NHMRC advised the Committee that:

> The Australian Health Ethics Committee (AHEC) is currently reviewing the NHMRC *Ethical Guidelines on ART* and a consultation draft of these revised guidelines is likely to be released shortly. It is anticipated that these guidelines will include information about the types of matters that should be considered in order to establish that certain uses of excess ART embryos are likely to result in a significant advance in knowledge, or improvement in technologies for treatment as a result of the use of excess ART embryos.[82]

4.112 As noted above, Paragraph 36(4)(c) specifically states that the Licensing Committee must have regard to any relevant guidelines issued by the NHMRC, which would include the *Ethical Guidelines on Assisted Reproductive Technology*.

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80 Explanatory memorandum, p.18.

81 *Submission* 282, p.9 (NCC-WA). See also *Submissions* 870 (Qld Bioethics Centre); 981, p.19 (ACBC); and 1235 (Don't Cross the Line (NSW)).

82 *Submission* 23, p.21 (NHMRC).

4.113 Several submissions noted that these guidelines are currently under review and commented on the Bill being considered while Parliament cannot predict what the new guidelines will ultimately contain.[83] Dr Kerry Breen, Chair of AHEC, described the process that was being undertaken to prepare the revised guidelines. He advised that the revision was foreshadowed in AHEC's strategic plan in mid-2000, and was initially deferred to await the House of Representatives Standing Committee on Legal and Constitutional Affairs report. Dr Breen informed the Committee that:

> During the time from which parliament commenced debate of the bill, AHEC considered carefully the timing of the release for consultation of the revised guidelines, which are presently entitled *Ethical guidelines on the use of reproductive technology in clinical practice and research*. It is the belief of AHEC that, even if the draft were ready for release for public consultation, it would be inappropriate for AHEC and the NHMRC to release the document before parliament has completed its current task. This belief has been formed out of respect for parliament and because some aspects of the draft guidelines are premised on the decision of COAG.[84]
>
> [Dr Breen added]
>
> We have not set a date for completion of the draft. We had originally hoped to conduct our public consultation and complete this by the end of the year. As we have made the decision to wait for parliament to complete the legislation, it may be later than that.[85]

4.114 Clause 37 requires the Licensing Committee to notify the applicant, the HREC and the relevant State authority of its decision on an application and to provide copies of any licence that is issued.

4.115 Clause 38 provides that a licence may be issued for the period specified in that licence. The GeneEthics Network noted that this provision appears to give the Licensing Committee discretion to issue long term licences and suggested that the term of a licence should be capped with an annual review and renewal for longer periods.[86]

'Proper consent' to authorised use of excess embryo

4.116 Under Clause 39, before an excess ART embryo may be used, each 'responsible person' must have given 'proper consent' to the use authorised under the licence. This is in addition to the donor's determination that the embryo is excess and their written authority for its use for purposes other than their own ART treatment. The definition of 'responsible person' in Clause 23 is:

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83 *Submissions* 282, p.8 (NCC-WA); 981, p.19 (ACBC); and 1015, p.2 (Dr Piercy).

84 *Committee Hansard*, 26.9.02, p.248 (Dr Breen).

85 *Committee Hansard*, 26.9.02, p.251 (Dr Breen).

86 *Submission* 1843, p.3 (GeneEthics Network).

- any woman who provided the egg (and any spouse of that woman at the time it was provided); and
- any man who provided the sperm (and any spouse of that man at that time it was provided); and
- the woman for whom the embryo was created (and any spouse of that woman at that time it was created).

4.117 This would suggest that the licence holder requires the consent of at least two people, and at most six people, before the embryo may be used as authorised under the licence. That is, it seems that the consent of an anonymous gamete donor will be required before an excess ART embryo may be used as authorised under a licence.

4.118 Professor Jansen of Sydney IVF confirmed that any donor would be able to find out what general type of research has been performed on donated embryos. He gave evidence that:

> Every embryo that passes through our laboratory can be traced–its location is accounted for. …
>
> I may not, for example, be able to tell a patient whether the medium was designed to test magnesium concentrations compared with calcium concentrations. I would be able to inform them that the embryos were used in the development of culture medium. Likewise, I would be able to tell them to what extent their cells were developed along ES cell development lines.[87]

4.119 However, the Committee heard evidence that the instance of anonymous donors in Australia is very low. Professor Jansen informed the Committee that Sydney IVF does not deal with anonymous donors at all. He added that:

> In a research context, I do not think that one would ever use embryos that had been conceived as a result of sperm donation. The ethics are just too complex for that and the numbers involved are exceptionally small in any case.[88]

4.120 'Proper consent' is defined in Clause 23 to mean consent obtained in accordance with:

- the *Ethical Guidelines on Assisted Reproductive Technology* (which as noted above are currently under review); or
- other guidelines issued by the NHMRC, if specified by notice in the *Gazette*.

4.121 The *Ethical Guidelines on Assisted Reproductive Technology* provide direction on what sorts of information should be given to ensure informed decision-making. For instance, the guidelines currently require all information which may be of

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87 *Committee Hansard*, 26.9.02, p.194 (Professor Jansen).

88 *Committee Hansard,* 26.9.02, p.194 (Professor Jansen).

significance to the participant to be given in a way that is appropriate to, and sufficient for, informed decision-making. That is, full, accurate and objective information must be given.[89]

4.122 In addition, that information must be explained orally, supported by written material in plain language that is provided to participants with enough time for it to be taken away and considered. This aspect of the guidelines would seem to approach Stem Cell Sciences' proposal for a 'cooling-off' period to be imposed to ensure that potential donors have the opportunity to fully consider whether they wish to authorise the use of their embryos for research.[90]

4.123 Under the guidelines, informed decision-making is required of all participants, including the donors of gametes and embryos.[91] However, as noted above, informed consent was still raised as a concern in several submissions.[92]

4.124 The guidelines also state that '[c]ounselling may be provided within, or independently of, the clinic. It should be incorporated into the routines of the clinic and be available as part of long-term follow-up'.[93] This does not fully address Salt Shakers' proposal that an independent counsellor should be required to give counselling leading to consent for the licensed use of embryos, which they support with this cautionary comment:

> If the IVF staff counselling the couple are supportive of the embryonic stem cell research and aiming to obtain as many embryos for research we need to ask if they would give unbiased and accurate information.[94]

4.125 Aside from the contents of the guidelines referred to in the Bill, several submissions expressed concern that areas of the Bill are given effect by incorporating material for which the Parliament is not responsible. In particular, a number of submissions were concerned that 'proper consent' is defined by reference to the *Ethical Guidelines on Assisted Reproductive Technology* and other NHMRC guidelines rather than being comprehensively defined within the Bill.[95] The Australian Family Association argued that:

> It is the responsibility of government to be more directly involved in the control and direction of this industry.[96]

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89 *Ethical Guidelines on Assisted Reproductive Technology*, p.5, paragraph 3.1.1.

90 *Submission* 1012, p.2 (Stem Cell Sciences).

91 *Ethical Guidelines on Assisted Reproductive Technology*, p.5, paragraph 3.1.3.

92 For instance, see *Submission* 1036, p.5 (FINRRAGE).

93 *Ethical Guidelines on Assisted Reproductive Technology*, p. 8, paragraph 4.1.

94 *Submission* 1502, p.6 (Salt Shakers – A Christian Ethics Group).

95 *Submissions* 282, p.8 (NCC-WA); 981, p.19 (ACBC); 1015, p.2 (Dr Piercy) and 1843 (GeneEthics Network).

96 *Submission* 1029, p.1 (Australian Family Association, Newcomb Branch).

4.126 The Senate Scrutiny of Bills Committee has in the past drawn attention to provisions which give power to a particular person or body to issue guidelines, directions or similar instruments which determine the way authority given under an Act of Parliament is to be exercised. It usually suggests that such instruments be tabled in Parliament and, where appropriate, be disallowable by either House.[97]

4.127 There are a number of reasons for imposing such a standard. Without it, a person or organisation outside the Parliament may change the obligations imposed without the Parliament's knowledge, or without the opportunity for Parliament to scrutinise and (if so minded) disallow the variation. In addition, such a rule also encourages more certainty in the law, and ensures that law-makers bear the onus of ensuring that those obliged to obey a law have adequate access to its terms.

4.128 However, the distinction has long been drawn between delegated matters that are legislative in nature, and those that bear some administrative character. This distinction was drawn by Latham CJ in *Commonwealth of Australia v Grunseit*.[98] In that case, his Honour held that legislation determines the content of the law as a rule of conduct or a declaration as to power, right or duty, whereas executive authority applies the law in particular circumstances.

4.129 Where the power delegated is administrative in nature, the delegation is generally considered acceptable. Where the power delegated is legislative in nature, the Senate Scrutiny of Bills Committee has generally expected that legislation should establish a sufficient regime of scrutiny over the exercise of that power.[99]

4.130 On this occasion, the Senate Scrutiny of Bills Committee considered the Bill and found no cause to comment.[100]

4.131 Under Subclause 39(5), the Licensing Committee may also impose a number of conditions upon a license. These may include conditions relating to reporting and monitoring. The GeneEthics Network suggested that these matters should be mandated, rather than imposed only on the discretion of the Licensing Committee.[101]

4.132 Clauses 40 to 43 provide that the Licensing Committee may vary, suspend or revoke a licence and in so doing must notify the licence holder, the HREC and relevant State bodies. A license holder may surrender a licence.

4.133 Under Clause 41, the Licensing Committee has a discretion to suspend or revoke a licence if it believes, on reasonable grounds, that a condition of the licence

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97 Senate Scrutiny of Bills Committee, Work of the Committee during the 38th Parliament, chapter 6.

98 (1943) 67 CLR 58.

99 Senate Scrutiny of Bills Committee, Work of the Committee during the 38th Parliament, chapter 6.

100 Senate Scrutiny of Bills Committee, Alert Digest No. 7 (21.8.02), p.36.

101 *Submission* 1843, p.4. (GeneEthics Network).

has been breached. During the public hearings the NHMRC were questioned as to why the breach of a licence (which is an offence under Clause 27) or the commission of another offence would not lead to the automatic revocation of that licence. In particular, it was noted that a corporation that has committed an offence may be liable only for a monetary penalty and would not necessarily lose its licence.[102]

4.134 The NHMRC responded:

> 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.[103]

4.135 The explanatory memorandum explained that this Clause enables the Licensing Committee to suspend or revoke a licence that has been issued if they believe, on reasonable grounds, that a condition of the licence has been breached. Importantly, this permits the Licensing Committee to take immediate action in the event of apparent non-compliance without the need to establish a conviction of an offence. The explanatory memorandum further explained the advantages to the Licensing Committee of having the flexible powers:

> The NHMRC Licensing Committee has the power to re-instate the licence should the suspected breach of condition fail to be established or should the licence holder rectify the situation and the Committee is convinced that the work can continue without risk of further breaches. Whether or not the licence is suspended, cancelled or subsequently reinstated would depend on the individual circumstances of the case and the extent, severity and importance of the alleged breach.
>
> It is important that the NHMRC Licensing Committee has a degree of discretion in this respect given that breaches of licence can range from fairly minor infringements (for example, late submission of annual reports to the NHMRC Licensing Committee) through to very serious breaches such as using more embryos than has been authorised by the licence.[104]

Reporting and confidentiality

4.136 Clause 44 of the Bill requires the Licensing Committee to keep a publicly available database that contains information relating to licences it has issued including the name of the licensee, the nature of the uses of the embryos authorised by the licence (e.g. whether the embryos are proposed to be used for the derivation of stem cells, for testing culture medium, for training of technicians etc.), the number of embryos proposed to be used and the conditions of licence.

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102 *Committee Hansard*, 29.8.02, p.17 (Senator Barnett).

103 *Committee Hansard*, 29.8.02, pp.17-18 (Ms Matthews).

104 Explanatory memorandum, pp.25-26.

4.137 While agreeing with the creation of the database, the GeneEthics Network argued that it should contain more information than is proposed. GeneEthics referred to the OGTR process to maximise information available on its website and commented that this process may be a good model for the NHMRC database as it will make the maximum amount of information available in a form that is accessible to all interested people.[105]

4.138 An important constraint on the information that may be disclosed by the Licensing Committee under Clause 44, or by any person, is that confidential commercial information must not be disclosed. The term 'confidential commercial information' is defined in Clause 23 to mean 'information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed'.

4.139 Several submissions noted that the legislation provides no protection for 'whistle-blowers', that is persons who may disclose information in the public interest. For example, the Australian Catholic Bishops Conference considered that the Bill gives undue protection to commercial interests without balancing those against the public interest:

> 'Confidential commercial information', as defined (cl.23), is so broad, and so subjective, as to defy any relevant meaning (e.g. 'Or other value' - to whom?). 'Whistle-blowers' are not protected under the legislation. As the legislation presently stands, they are likely to be the principal source of information to the public. Accordingly, they should be protected. Combined with the effect of cl.45, there is abundant protection for commercial interests but precious little either for embryos or whistle-blowers.[106]

4.140 In response to suggestions that the commercial-in-confidence provisions will inappropriately inhibit public access to information about the licences granted by the Licensing Committee, the NHMRC stated:

> Firstly, the bill makes a lot of information publicly available in relation to the determinations of the licensing committee. Secondly, in relation to what would be deemed commercial-in-confidence information, that sort of information may not be relevant to the determination of the committee. There is always an obligation to maintain the privacy of the people putting in applications. There has to be a balance between making a decision, having a transparent process and protecting confidentiality.[107]

Review provisions

4.141 Applicants and licence holders may apply to the Administrative Appeals Tribunal (AAT) for a review of certain Licensing Committee decisions including a

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105 *Submission* 1843, p.4. (GeneEthics Network).

106 *Submission* 981, p.17 (ACBC).

107 *Committee Hansard,* 26.9.02, p.267 (Dr Morris).

decision not to issue a licence, decisions about licence conditions, and decisions about varying, revoking or suspending a licence (Clauses 46 and 47).

4.142 The inclusion of provision for review by the AAT of the Licensing Committee's decisions was considered by governments as important given the nature of the decision making process proposed for the Licensing Committee and the fact that a licence will be the only means by which a person would be allowed to undertake research or other activities involving excess ART embryos.

4.143 However, the GeneEthics Network argued that:

> Restricting appeal rights over NHMRC Licensing Committee decisions to the applicants and licensees alone removes important democratic and legal checks and balances on the proper administration of this law. Any interested party should have standing to appeal, including the present or former 'owners' of the embryos, interest groups and the public at large.[108]

Part 4 - Monitoring powers

4.144 Under Clause 48, the Chair of the Licensing Committee may appoint Commonwealth or State employees as inspectors to monitor compliance with the Bill. Clauses 49 to 55 provide inspectors with the power to enter premises and having entered premises, specify the range of monitoring powers that they may exercise.

Part 5 - Commonwealth/State arrangements

Operation of State laws

4.145 Clause 56 provides that the Act is not intended to exclude the operation of State and Territory laws except where the State or Territory laws are inconsistent with the Act and cannot operate concurrently. The explanatory memorandum notes that one of the intended effects of this clause is that if a State has existing legislation that, for example, bans the use of excess ART embryos, such a law would not be capable of operating concurrently with the Act and as such it is intended that the Act override the State law to the extent that it is inconsistent. Three States – South Australia, Victoria and Western Australia – have laws which attempt to ban human reproductive cloning and regulate, to differing extents, research on human embryos.[109]

4.146 Some argued that for a federal law to override 'inconsistent' State laws was neither democratic nor warranted by the COAG agreement. It was noted that the existing State laws regulating aspects of human reproductive technology had only been passed after thorough debate in the respective State parliaments, and therefore the Commonwealth Bill should leave existing State laws intact until the State

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108 *Submission* 1843, p.4. (GeneEthics Network).

109 Parliamentary Library Bills Digest No.17 2002-03, p.10 and House of Representatives' report on human cloning, pp.132-145.

parliaments considered whether they supported national uniform legislation and, if so, amended their laws accordingly.[110]

4.147 An amendment was moved in the House of Representatives proposing that the operation of State law prohibiting the use of excess ART embryos should not be affected whether consistent or inconsistent with this Act. In response, the Attorney-General emphasised that the COAG agreement was quite clear that a nationally consistent approach to the regulation of research involving embryos was required. The effect of the amendment would be to create differences across jurisdictions that would be inconsistent with one nationally consistent single licensing regime.

4.148 The Attorney also stressed that as part of the COAG agreement the States would introduce corresponding legislation to establish a comprehensive and effective national scheme. He noted that South Australia, Victoria and Western Australia are currently in the process of amending their existing legislation so that it will mirror the Commonwealth legislation. Therefore the States that currently have legislation to ban research on excess ART embryos will be lifting those bans, consistent with the Commonwealth legislation.[111] The amendment was defeated.

Constitutional issues

4.149 A further issue raised in relation to the COAG agreement on nationally consistent legislation concerned the Commonwealth's constitutional powers to legislate with respect to human cloning and related unacceptable practices.

4.150 Clause 4 describes the constitutional powers that the Commonwealth is relying on to support the legislation. As there is no express power in the constitution relating to human cloning and the use of embryos, the Commonwealth is relying on a range of powers to support the legislation, including the corporations power, the trade and commerce power and the external affairs power.[112] The NHMRC referred to advice from the Australian Government Solicitor that stated:

> Under the Constitution, the Commonwealth Parliament has reasonably extensive powers in this area. However these powers would not support comprehensive legislation to regulate human cloning, assisted reproductive technology or the proposed unacceptable practices…
>
> As a result of the Commonwealth's lack of comprehensive legislative power in relation to this subject, it would, for example, be difficult for the Commonwealth to prohibit or control human cloning and related unacceptable practices carried on within a State by a natural person or persons, alone or in partnership. Other limits might include the prohibition

110 *Submissions* 282, p.11 (NCC-WA), 764 (CNI-WA), 1073, p.6 (Festival of Light).

111 *House of Representatives*, *Hansard*, p.6866, 24.9.02 and p.6888, 25.9.02 (Mr Williams).

112 The Parliamentary Library Bills Digest No.17 2002-03, pp.10-14, provides a detailed outline of the heads of constitutional power that might support the legislation.

> or control of research and development related to human cloning and related unacceptable practices by private research institutes in the States.[113]

4.151 In recognising the limitations of the Commonwealth's constitutional powers, the Commonwealth legislation forms part of a national legislative scheme, which will include corresponding laws in each State and Territory. Once all jurisdictions have enacted corresponding State and Territory laws, the legislation will apply equally to all persons and all activities in Australia. The NSW Government explained the importance of nationally consistent legislation:

> As the Commonwealth does not have a constitutional power directly relating to this matter, it has primarily relied upon the corporations' power, the trade and commerce power and the external affairs power. However this does not provide complete coverage. The advantage of having corresponding State and Territory legislation is that it gives complete coverage of all people and activities relating to the subject matter of the Bills, thereby ensuring that a truly national scheme can be implemented.[114]

4.152 Clauses 57 and 58 provide for the effective operation of the national scheme relating to the regulation of uses of excess embryos. Corresponding State laws will provide that the NHMRC Licensing Committee will undertake the licensing functions exercised under a State law. The intention is that there would not be dual licensing systems in any jurisdiction. Rather, anyone wishing to undertake work using excess ART embryos would need to apply for a licence from the NHMRC Licensing Committee whether or not they are technically organisations that come within the scope of the Commonwealth's constitutional powers or State powers.

Part 6 - Sunset clause, review provision and regulations

Sunset clause

4.153 Clause 60 gives effect to the COAG decision that the regulation restricting the use of excess ART embryos created after 5 April 2002 will cease to have effect on 5 April 2005, unless an earlier date is agreed to by COAG. Removing the restriction in three years time is aimed at ensuring the adequacy of the supply of excess ART embryos for research.

Numbers of embryos required for research

4.154 The question as to the actual number of excess ART embryos required for research was the subject of considerable debate during the inquiry. However, answers to questions put by the Committee were not always consistent, some referring to human embryos and some to embryonic stem cells.

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113 *Submission* 23, Additional information 13.9.02 part 2 (c). Copies of the AGS advice dated 13 February and 30 April 2002 were provided to the Committee through the Committee Chair.

114 *Submission* 891, p.3 (NSW Government).

4.155 The figure of over 71 000 available embryos was regularly referred to in evidence. It should be noted that this figure is the total number of embryos in storage. Many of these embryos are currently in storage because the couples for whom they were created either still want them, have not yet decided that they are no longer required, or if they have decided they are excess, do not yet know what they want done with them. Professor Illingworth has also estimated there are a further 40,000 non-viable human embryos created each year in Australia, though these are not suitable for freezing, cannot be held in storage and are therefore outside the terms of this act.

4.156 The Australian Catholic Bishops' Conference notes the rapid rise in the number of embryos, observing that:

> …the latest statistics from the Australian Institute of Health and Welfare confirm that there has been a more than threefold increase in the number of embryos frozen between 1994 (22,280) and 2000 (71,176). To so manipulate the production of human life is an affront to human dignity and fosters a view of life which is more akin to the embryo as "property", able to be bought and sold as a commodity, than as a member of the human family.[115].

4.157 Nevertheless, Professor Illingworth gave evidence to put these numbers in context, stating that there were:

> 3,695 embryos in storage in our clinic. However, the vast majority of these embryos are in active clinical use. In 2001 we stored 1,708 embryos and thawed 1,210 embryos. In other words, the turnover every year is over 60 per cent of the total number of embryos in storage at any one time. Only six per cent of the embryos stored in our unit have ever been actively disposed of. Another six per cent have been in storage longer than five years.[116]

4.158 Accordingly, the number of embryos that would be an 'excess ART embryo' in conformity with the definition in the Bill would be considerably less than the figure of 71 000. However, the number of embryos estimated to be required for research has varied widely according to different sources and depending upon the use to which they are to be put. It is necessary to differentiate within the estimates the number of embryos required as distinct from the number of stem cell lines derived from embryos.

- 'My own view is that, if we were able to be successful with methodologies such as the induction of tolerance, we would not really need a large number of embryonic stem cells – around 20 to 30 or 50 may well be enough' – Professor Trounson;[117]

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115 *Submission* 981 (ACBC).

116 *Committee Hansard,* 26.9.02, p.190 (Professor Illingworth); see also additional information from Professor Illingworth, 16.10.02.

117 *Committee Hansard,* 24.0.02, p.140 (Professor Trounson).

- 'In the development of culture medium for meaningful results then we are talking about hundreds [of embryos]' – Professor Jansen;[118]
- 'BresaGen believes that only 600-1000 such therapeutic ESC lines will provide adequate immunological tissue matching' – BresaGen;[119]
- 'The view of our members, though, is that, because we are at such an early stage of the research, anyone who wants to hazard a guess at the number is purely crystal-balling – we really do not know' – AusBiotech.[120]

4.159 The lack of a precise number was commented upon in evidence.[121] Dr McCullagh submitted:

> The number of embryos actually used in Australia is likely to be determined by the extent to which the requirement is met after a finite time when a certain number of cell lines are available or, alternatively, exciting new prospects continue to necessitate an indefinite continuation. I believe that it would be extremely naive to expect that the former outcome is the more likely…[122]

4.160 Professor Good argued that proponents of this research were trying to 'sell a story' and suggested that "to hear these numbers differ vastly between different people just tells me that this is an afterthought: 'We hadn't really thought about cell therapy, but we had better put some numbers up because we want to find some numbers that'll fit under the legislation'."[123] Professor Good had his own estimate:

> I believe that to get a bank suitably large enough to guarantee you a reasonable chance of finding a correct tissue typing match, you would need a bank of approximately 10 million, of that order, for each of the major human races: Caucasian, Asian, African and Hispanic.[124]

4.161 The contrary argument proposed that rapid developments in research and the constantly changing science involved made it difficult to provide a definitive number. Professor Hearn remarked that 'I think we are talking here about a moving field, in terms of the knowledge of what stem cells can do, and indeed how one can derive them and how few or many embryos might be needed'.[125]

4.162 The NHMRC noted that arising out of their consultations with IVF clinics:

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118 *Committee Hansard,* 26.9.02, p.211 (Professor Jansen).

119 *Submission* 1030, p.1 (BresaGen).

120 *Committee Hansard,* 19.9.02, p.125 (AusBiotech).

121 For example *Committee Hansard* 17.9.02, p.58 (Professor Silburn).

122 *Submission* 480, p.9 (Dr McCullagh).

123 *Committee Hansard,* 19.9.02, p.99 (Professor Good).

124 *Committee Hansard* 19.9.02, p.90 (Professor Good).

125 *Committee Hansard,* 19.9.02, p.123 (Professor Hearn).

> It appears that, based on current practices and proposed future practices, it is possible that more excess ART embryos will be required for ART related research, quality assurance and training than for the derivation of stem cells. However…the precise numbers that may be required for ART related research or for the derivation of stem cells is not clear at this time and is dependent on future developments in research.[126]

Implications of the 5 April 2002 restriction and its proposed removal

4.163 Several submissions referred to the implications that the 5 April 2002 restrictions would have for potential research. BresaGen argued that the 5 April 2002 'sunset' date is incompatible with the need for safe therapeutic ES cell lines:

> While those embryos developed and frozen before 5 April will be satisfactory for basic research, they will not necessarily meet adequate current Good Manufacturing Practice (cGMP) safety requirements for therapeutic product development. These cGMP requirements are different from the standards required in IVF programs and are more stringent. The legislation should therefore allow derivation of more ES cell lines under cGMP conditions. These conditions can only be fully applied prospectively, and thus to ART embryos that come into existence after 5 April 2002, embryos currently prohibited from use by the new legislation.[127]

4.164 The banning of research involving fresh and frozen excess embryos produced after 5 April 2002 was also pointed to by Monash IVF as severely compromising embryology training programs, laboratory quality assurance process and embryo culture system improvements and techniques.[128]

4.165 Conversely, the Southern Cross Bioethics Institute claimed that 'if embryos created at any time and excess to requirements are available to researchers, it would not be difficult to create an excess of embryos by simple changes to practices in IVF clinics'.[129]

4.166 A response to this comment was provided on both medical and regulatory grounds. Professor Jansen noted that 'it is not medically possible to vary the number of eggs that respond to stimulation upwards at all and it is not possible downwards without compromising the chance of success for the woman'.[130] RTAC guidelines specifically prohibit the practice of deliberately super ovulating patients in an attempt to generate excess embryos for use in stem cell research or stem cell based product development. If any clinic did opt for such an unethical and unacceptable practice it would be readily apparent to RTAC due to the data reporting process for IVF clinics

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126 *Submission* 23, Additional information 13.9.02, p.12 (NHMRC).

127 *Submission* 1030, p.9 (BresaGen).

128 *Submission* 1007, p.1 (Monash IVF).

129 *Submission* 892, p.9 (SCBI). A similar view was put by the Catholic Archdiocese of Melbourne in *Submission* 876, p.13 (Professor Jansen).

130 *Submission* 897, Additional information 1.10.02 (Professor Jansen).

to the National Perinatal Statistics Unit being extended this year to include a requirement for every clinic to report quite specific information about the number of eggs collected and the number of embryos stored in every treatment cycle.[131]

4.167 The Bill provides that it is an offence to create human embryos specifically for other purposes such as for use in research or to derive embryonic stem cells for potential therapeutic use.

4.168 As noted earlier, the Bill also includes requirements that the NHMRC develop and maintain a comprehensive, publicly available database containing information on all licences issued by the NHMRC Licensing Committee. The database will ensure that the public will have access to detailed information about the number of embryos used for research each year and the nature of such research.

Reviews of 'sunset' date

4.169 The need to retain the restriction will be considered as part of two reviews commissioned by COAG to report by 5 April 2003. These reviews, to be undertaken by the working committee of the Australian Health Ethics Committee that is revising the Ethical Guidelines on ART and by the NHMRC, were referred to in the COAG communique (see Appendix 3):

> The regulation restricting the use of embryos created after 5 April 2002 will cease to have effect in three years, unless an earlier time is agreed by the Council. The Council also agreed to establish an Ethics Committee with membership jointly agreed by the Council to report to the Council within 12 months on protocols to preclude the creation of embryos specifically for research purposes, with a view to reviewing the necessity for retaining the restriction on embryos created on or after 5 April 2002. The Council also agreed to request the National Health and Medical Research Council (NHMRC) to report within 12 months on the adequacy of supply and distribution for research of excess ART embryos which would otherwise have been destroyed.

4.170 The Attorney-General has stated that 'these reviews will ensure that strong ethics and research protocols and appropriate safeguards are in place prior to the sunset clause coming into effect'.[132]

Review of Act

4.171 Clause 61 provides for an independent review of the Act to be commissioned by the NHMRC as soon as possible after the second anniversary of Royal Assent. The Clause describes the nature of the review and stipulates that the review report must be submitted to COAG before the third anniversary of Royal Assent.

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131 *Submission* 1047 (ACCESS) and Professor Illingworth, Additional information 27.9.02.

132 *House of Representatives*, *Hansard*, p.6896, 25.9.02 (Mr Williams).

4.172 In the House of Representatives an amendment was moved to Clause 61 seeking to establish a parliamentary joint committee to review the Act. Proponents of the amendment argued that allowing the NHMRC to establish the review lacked independence and removed from the Parliament its role in reviewing the operation of the legislation. The amendment sought to 'establish the authority of the democratic process on making difficult decisions'.[133] Pro-Life Victoria in its submission also supported the amendment.[134]

4.173 In response the Attorney-General argued that the amendment:

- risked losing a nationally consistent approach by limiting the role of the States in helping to choose appropriate persons to undertake the review and by not providing a report back to COAG; and
- it did not preserve the integrity of the original bill before it was split, that is the concurrent review of both Bills by the same persons.

4.174 The Attorney-General also noted that Parliament's role would not be subverted or supplanted through the review process proposed by Clause 61 as it would consider any amendments to the Act arising from the review. Furthermore, the NHMRC would not itself be undertaking the review, rather it must appoint an independent review and may only choose the reviewers with the agreement of all States and Territories. The Attorney-General indicated that the arrangement was in accordance with the COAG agreement for national consistency.[135] The proposed amendment to Clause 61 was not agreed to.

4.175 Following the splitting of the original Bill, the NSW and Queensland Governments raised concerns about the impact that this may have on the original review provisions. Under the new Cloning Bill, the Minister must cause an independent review to be undertaken and the review is to be undertaken by persons chosen by the Minister with the agreement of each State and be provided to COAG by the third anniversary of Royal Assent. The Research Bill provides for the NHMRC to cause an independent review to be undertaken by the same persons who conduct a review of the Cloning Bill. The research review must be undertaken concurrently with the cloning review and must accompany the report of that review to COAG.

4.176 The NSW Government stated that the new provisions 'represent an unnecessary and problematic departure' from the original provisions 'which more accurately reflected the spirit and intention of the COAG agreement'.[136] The Queensland Government argued that the amendments had implications for the implementation of a meaningful review of the Bills.[137]

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133 *House of Representatives*, *Hansard*, p.6905, 25.9.02 (Mr Cadman).

134 *Submission* 1570, Attachment 2, p.5 (Pro-Life Victoria).

135 *House of Representatives*, *Hansard*, p.6907, 25.9.02 (Mr Williams).

136 *Submission* 891, p.6 (NSW Government).

137 *Submission* 1500, p.4 (Qld Government).

4.177 Both Governments supported the NHMRC as the appropriate body to cause the independent reviews to be undertaken. The Queensland Government regarded the original review clause as superior with the NHMRC 'well-placed to ensure the delivery of an evidence-based, rigorous and objective evaluation of the functional operation of the two statutory instruments for both the prohibition and regulation regimes'.[138]

4.178 The Governments voiced concern that under the new provisions it was possible for a person or body other than the NHMRC appointees to undertake the reviews. The Queensland Government argued that:

> For example, the reviews might be undertaken by a parliamentary committee. The Queensland Government regards this as a further risk to the objectivity of the review process because the complex subject matter and objective evaluation of the operation of the licensing committee necessitates a high level of expertise and familiarity with the content area.[139]

4.179 It was noted that because of the relationship between the activities to be reviewed in both Bills, the reviews should be undertaken concurrently. Both Governments pointed to the impact of delays between the Bills coming into operation on concurrent reviews and noted that these would be minimised if the Senate considered and voted on the Cloning and Research Bills together.[140]

4.180 In response to State concerns, the Minister's Second Reading Speech for the Prohibition of Human Cloning Bill, stated that:

> The Prime Minister also expressed the hope that the States and Territories would remain committed to the vision of national consistency. The Prime Minister disagreed with statements of three of the Premiers that splitting the bill would not be consistent with the spirit of the COAG Agreement. The agreement dealt with a series of matters to be incorporated into a nationally consistent legislative scheme. Those matters will still be addressed as agreed, albeit in two separate pieces of legislation.
>
> Nothing has been lost by implementing the agreement reached at COAG through two pieces of legislation rather than one. The two bills give effect to the COAG agreement in exactly the same way as the one consolidated bill would have done. The bills must, however, be preserved without further amendment.[141]

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138 *Submission* 1500, p.4 (Qld Government).

139 *Submission* 1500, p.4 (Qld Government); see also *Submission* 891, p.8 (NSW Government).

140 *Submission* 891, p.9 (NSW Government); *Submission* 1500, p.6 (Qld Government).

141 *Senate*, *Hansard,* 18.9.02, p.4324.

Regulations

4.181 Clause 62 empowers the Governor-General to make regulations prescribing matters required to be prescribed by the Act or necessary for giving effect to the Act. Before the Governor-General makes regulations, the Minister must be satisfied that the States and Territories have been consulted in relation to the proposed regulations and that there was regard to the views of the States and Territories in the preparation of the proposed regulations.

CHAPTER 5

INTERNATIONAL COMPARISONS

5.1 The regulation of stem cell research and cloning has been undertaken in a number of countries. Without being comprehensive, the following provides an overview of some of the regulatory regimes in these countries.

United Kingdom

5.2 Issues of assisted reproduction were first considered by the Committee of Inquiry into Human Fertilisation and Embryology, chaired by Dame Mary Warnock. The Committee reported in 1984.[1]

5.3 The Warnock report formed the basis of the Human Fertilisation and Embryology Act 1990 (HFE Act). The Act established the Human Fertilisation and Embryology Authority (HFEA), which regulates the activities authorised under the Act. Destructive embryo research is permitted but must be carried out under a licence. Three types of licence may be issued under the Licensing Committee of HFEA: a licence to provide treatment services; to store embryos and gametes; or to carry out research on embryos. In order for a research licence to be issued, the HFEA must be satisfied that the use of human embryos is 'necessary and desirable' for one of the following purposes:

- to promote advances in the treatment of infertility;
- to increase knowledge about the causes of congenital disease;
- to increase knowledge about the causes of miscarriage;
- to develop more effective techniques for contraception;
- to develop methods for detecting the presence of gene or chromosome abnormalities in embryos prior to implantation;
- other such purposes as may be specified in regulations.

5.4 Certain activities cannot be authorised. These include research on human embryos over 14 days old; placing an embryo in any animal; and replacing a nucleus of a cell of an embryo with the nucleus taken from a cell of any person, embryo or subsequent development of an embryo. In 1977 the HFEA announced a policy not to issue licenses for any procedures involving embryo splitting or nuclear transfer.[2]

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1 Report of the Committee on Inquiry into Human Fertilisation and Embryology, HMSO, July 1984 (cm.9314).

2 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*, August 2001, pp.191-94 [hereafter *Human Cloning*].

5.5 In November 2000, following the recommendations of a report by the Chief Medical Officer's Expert Advisory Group entitled *Stem Cell Research: Medical Progress with Responsibility*,[3] draft Regulations were presented to Parliament to extend the permitted research purposed under the HFE Act. The regulations were passed and came into effect on 31 January 2001 as the Human Fertilisation and Embryology (Research Purposes) Regulations 2001. The regulations allow the HFEA to licence research involving embryos for the purposes of increasing knowledge about the development of embryos; increasing knowledge about the development of disease; and enabling any such knowledge to be applied in developing treatment for serious disease. The Regulations legalise embryo research to extract stem cells and the deliberate creation of embryos by somatic cell nuclear transfer for research purposes (often referred to as 'therapeutic cloning').[4]

5.6 The ProLife Alliance sought a judicial review of the regulations, claiming that human embryos created by cell nuclear replacement (CNR) were outside the operation of the Act. In November 2001 the High Court ruled in support of the claim. The Government responded by introducing the Human Reproductive Cloning Bill under which it is an offence to use cloning techniques such as cell nuclear replacement for human reproductive cloning. In January 2002, the Government's appeal against the High Court judgement was allowed, in effect bringing embryos created through CNR within the scope of the 1990 Act.

5.7 In February 2002, the House of Lords Select Committee on Stem Cell Research concluded that research on embryonic stem cells to help develop new therapies should be allowed under strictly controlled conditions. The committee did not see any ethical difference between an IVF embryo and an embryo produced by CNR (or other methods) in their use for research purposes up to the 14 day limit. The committee approved further research into the practice of 'therapeutic cloning' under strict regulation by HFEA, while reiterating its total opposition to 'reproductive cloning'.[5]

United States

5.8 In the United States, regulation of human cloning and embryo research has been established at both the State and federal level. Following the cloning of Dolly, the Clinton administration directed that no federal funding for human cloning research be allocated. The President also requested the National Bioethics Advisory Commission (NBAC) examine and report on the ethical and legal implications of human cloning through somatic cell nuclear transfer techniques. The President

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3 Chief Medical Officer's Expert Advisory Group on Therapeutic Cloning, *Stem Cell Research: Medical Progress with Responsibility*, (the Donaldson Report), Department of Health, 2000, http://www.doh.gov.uk/cegc/stemcellreport.htm

4 House of Commons Science and Technology Committee, *Developments in Human Genetics and Embryology*, 4th Report of Session 2001-02, HC791, p.9; also, *Human cloning* pp.196-98.

5 House of Lords Stem Cell Research Committee, *Report,* February 2002, Session 2001-02, HL 83(i), http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm

introduced into Congress the Cloning Prohibition Bill 1997. This did not pass Congress and subsequently, a number of other Bills have been introduced.[6]

5.9 Federal funding for human embryo research was banned under provisions attached to the spending bills that fund the National Institutes of Health (NIH). A report from the NBAC in January 2000 concluded that federal funding should not be provided for making embryos solely for the generation of human embryonic stem cells. Rather, funding should be provided for research using embryonic stem cell using cadaveric fetal tissue and surplus embryos from fertility treatment. It was also recommended that no funding be provided for research involving the derivation or use of human embryonic stem cells from embryos made using somatic cell nuclear transfer.[7] In August 2000, the NIH published guidelines for use of human pluripotent stem cells. The guidelines include that NIH funds may only be used for research on cells derived from frozen embryos excess to fertility treatment; there is no inducements for the donation of the embryo; and there is informed consent for the donors.[8]

5.10 In August 2001, President Bush announced that US Government funding may only be spent on research using existing embryonic stem cell lines, as listed on the National Institutes of Health Human Embryonic Stem Cell Registry, but not on derivation of new lines. The rationale of this decision was that using already destroyed embryos it 'allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line, by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life'.[9] The President also announced the formation of a President's council to monitor stem cell research, to recommend appropriate guidelines and regulations and to consider all of the medical and ethical ramifications of biomedical innovation.

5.11 In March 2002, the NIH issued a clarification of its policy that allows federally-funded researchers to work on new embryonic stem cell lines or create new lines, as long as they can prove that this research is not paid for with Government money. Biotechnology Australia stated 'this effectively allows all US researchers, both those in the public and private sector, to derive and work with new embryonic stem cell lines'.[10]

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6 For a more extensive discussion of the US situation, see *Human cloning,* pp.180-91.

7 NBAC, *Ethical Issues in Human Stem Cell Research*, Rockville, Maryland, January 2000; see also *Human cloning,* pp.184-85.

8 National Institutes of Health, *Guidelines for Research Using Human Pluripotent Stem Cells,* http://www.nih.gov/news/stemcell/stemcellguidelines.htm see also *Human cloning*, pp.186-87.

9 President George W Bush, *Remarks by the President on Stem Cell Research*, 9.8.01, http://www.whitehouse.gov/news/releases/2001/08/print/20010809-2.html

10 *Submission* 1263, p.14 (Biotechnology Australia).

5.12 While the federal government has acted to control the use of federally funded embryo research, there is no federal control of privately funded research. Privately funded research is generally subject to State rather than federal regulation. There is significant variation between States. Currently, nine States prohibit such research, however, in the other States there is effectively no control over private research on embryos.

5.13 In August 2002, California became the first US State to allow researchers to use public funds for research involving the derivation of and use of human embryonic stem cells and human embryonic germ cells from any source, including somatic cell nuclear transfer for the purpose of developing new medical treatments. The Californian legislation bans reproductive cloning.[11]

5.14 In July 2001, the US House of Representatives passed Republican-backed legislation to ban both reproductive and therapeutic cloning. But Senate Democrats are drafting legislation that would allow cloning for medical research, but not for producing live clone births. On 1 May 2002 a Bill 'To prohibit human cloning while preserving important areas of medical research, including stem cell research' was introduced, was read twice and referred to the Senate Committee on the Judiciary.[12]

Canada

5.15 In 1993, the Canadian Royal Commission on New Reproductive Technologies reported after a four year examination of activities related to human reproduction in Canada. The Royal Commission made 293 recommendations. The two overarching recommendations were for federal legislation to prohibit certain practices and the establishment of a national regulatory body to govern permissible assisted human reproduction activities.

5.16 Following the release of the Report, the Canadian Government conducted extensive consultations with interested stakeholders and the public on the main recommendations of the Royal Commission. Health Canada also established the Discussion Group on Embryo Research to provide policy advice on embryo research. The Discussion Group reported in November 1995.

5.17 In July 1995, the Canadian Government announced a voluntary moratorium on nine applications of human reproductive and genetic technologies as the first phase in the development of an overall framework to regulate these technologies. The applications included human embryo cloning, sex selection, and the buying and selling of eggs, sperm and embryos. An advisory committee was established to help monitor compliance by researchers and health professionals.

5.18 In June 1996, Bill C-47, the Human Reproductive and Genetic Technologies Bill was introduced. The Bill proposed a series of prohibitions based on the voluntary

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11 http://info.sen.ca.gov/pub/bill/sen/sb_0251-0300/sb_253_bill_20020830_enrolled.html

12 *Submission* 23, p.23 (NHMRC).

moratorium. The Bill did not complete the legislative process before the calling of the 1997 federal election.

5.19 When Bill C-47 was introduced, Health Canada published *Setting Boundaries, Enhancing Health*, outlining the Government's intention to establish a regulatory framework for assisted human reproduction. Consultations were held with stakeholders and provincial and territorial representatives. Draft legislative proposals were submitted by the Minister for Health to the House of Commons Standing Committee on Health in May 2001. The Committee reviewed the draft and provided recommendations.

5.20 Bill C-56, An Act Respecting Assisted Human Reproduction, was introduced in May 2002. The proposed legislation seeks to protect the health and safety of Canadians using assisted human reproduction (AHR) to build their families by regulating ethically acceptable practices such as *in vitro* fertilisation; to prohibit certain unacceptable activities; to regulate AHR activities and related research; and establish a regulatory body, the Assisted Human Reproduction Agency of Canada.[13]

5.21 The proposed legislation seeks to ban the following activities:

- creating a human clone for any purpose (ie reproductive or therapeutic purposes);
- creating an *in vitro* embryo for any purpose other than creating a human being or improving assisted reproduction procedures;
- creating an embryo from an embryo or fetus for purposes of reproduction;
- maintaining an embryo outside the body of a woman past the 14th day of development;
- identifying the sex of an embryo created for reproductive purposes, except for medical reasons such as sex-linked disorders;
- changing the DNA of human sperm, eggs or embryos so that the change can be passed to subsequent generations (germ-line alteration);
- transplanting non-human reproductive material/embryo into humans;
- creating a human being from reproductive material or an embryo that was previously transplanted into an animal;
- creating human/non-human combinations for reproductive purposes;
- paying a woman a financial incentive to be a surrogate mother;
- paying a donor for their sperm or eggs or providing goods or services in exchange; and
- selling or buying human embryos, or providing goods or services in exchange.

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13 http://www.parl.gc.ca/37/1/parlbus/chambus/house/bills/government/C-56/C-56_1/C-56_cover-E.html; *Submission* 23, p.24 (NHMRC).

5.22 Regulations will also be developed to govern AHR activities such as the collection, alteration, manipulation or treatment of any human reproductive material for the purpose of creating an embryo; the storage, handling and use of reproductive materials and embryos; the type of research allowed; and the donation of embryos no longer needed for reproduction.[14]

5.23 The Assisted Human Reproduction Agency of Canada will issue licences to AHR clinics and researchers conducting AHR-related activities regulated under the legislation to ensure that the activities are conducted in a safe and appropriate manner. It will inspect facilities to ensure compliance and will maintain a donor/offspring registry. The Agency will also provide reliable information on AHR to Canadians.

5.24 The Canadian Parliament has not completed its consideration of the Bill.

Sweden

5.25 In Sweden, there is no legislation specifically directed at stem cell research, however, other legislation applies. Adult stem cells and stem cells from aborted fetuses are regulated through the law on transplantation. Research on fetal tissue may only be performed with approval of the National Board of Health and Welfare and where special circumstances exist. The *In Vitro* Fertilisation Act 1988 and the Act Concerning Measures for Research or Treatment Involving Fertilised Human Ova 1991 govern embryo research. The 1988 Act regulates the practice of assisted reproduction and also permits some research on human embryos. The research must be performed within 14 days of fertilisation and only with the consent of the donors. Any research that seeks to genetically modify the embryo is prohibited. The Act stipulates that once research is completed the embryo must be destroyed and prohibits the implantation of a research embryo in a woman. The 1991 Act regulates reproductive research and research on embryonic development, covers storage of embryos and allows for embryos to be cryopreserved for five years.[15]

5.26 The Swedish Research Council issued guidelines in December 2001 covering stem cell research.[16] The use of embryos in research is permissible if there are no acceptable alternatives to attain equivalent results and if the project is judged to be necessary for the advancement of stem cell research. Embryos must be considered to be of no use for IVF treatment and the donors must give informed consent. The Council did not endorse the creation of embryos solely for research. The Council considered stem cells from embryos created by somatic cell nuclear transfer may be 'ethically justifiable' but cannot be allowed due to present laws in Sweden. The Council recommended a review to enable regulated therapeutic cloning to be

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14 Health Canada, *Proposed Act Respecting Assisted Human Reproduction-An Overview*, May 2002, http://www.hc-sc.gc.ca/english/media/releases/2002/2002_34.htm

15 European Parliament, Directorate General for Research, *The Ethical Implications of Research Involving Human Embryos, Final Study*, July 2000, p.49.

16 http://www.vr.se/fileserver/index.asp?fil=LCK7HDEK3U6H

undertaken. The Council also recommended the banning of reproductive cloning. The Swedish Government is currently preparing legislation on research ethics.[17]

Germany

5.27 The Embryo Prohibition Act 1992 prohibits all forms of 'consumptive research' on human embryos; that is, research not explicitly designed to preserve the embryo and facilitate implantation in a woman contravenes the Act. Those contravening the Act face up to five years imprisonment. The Act also creates a number of criminal offences for engaging in practices involving IVF technology. For example it is an offence to attempt to fertilise an egg cell for any purpose other than bringing about pregnancy in a woman from whom the oocyte originated or attempt to fertilise more oocytes than may be reimplanted within one treatment cycle. Research on the human embryo is only permitted where the objective of the research is to benefit the embryo. Cloning is prohibited.[18]

5.28 The use of fetal germ cells following abortions does not fall within the terms of the Embryo Protection Act. Fetal cells and tissues may be used for experimental and therapeutic purposes regulated through the Guidelines for the Utilisation of Fetal Cells and Fetal Tissues produced by the German Federal Medical Council.

5.29 In May 2001 the DFG (Germany's research funding agency) issued a statement supporting research on imported embryonic stem cells produced from surplus embryos. The DFG noted that imported ES cells were not subject to the Embryo Protection Act and that there was no justification to bar research on ES cells legally produced in a foreign country as a matter of principle. The DFG refused to endorse the production of embryos exclusively for research. It also stated that therapeutic cloning was neither scientifically or ethically justifiable.[19] Two ethics commissions then considered the issue, with each coming to differing conclusions. In January 2002 the German Parliament voted to allow human embryo stem cells to be imported for medical research. A motion to allow eventual production of embryonic stem cells in Germany was rejected.[20]

European Union

5.30 In early 2001, following the UK Government's decision to support therapeutic cloning, the EU established the Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine. The Committee was to report to the European Parliament on the ethical, social, legal and economic developments in modern medicine. The report was extensively amended before its final adoption and

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17 Information provided by the Embassy of Sweden, 1.10.02.

18 European Parliament, Directorate General for Research, *The Ethical Implications of Research Involving Human Embryos, Final Study*, July 2000, p.47.

19 DFG, *New DFG Recommendations concerning research with human stem cells*, May 2001, http://www.dfg.de/english/press/releases/Archive/presse_2001_16_eng.html

20 BBC News, *Germany authorises stem cell imports*, 03.1.02, http://www.bbc.co.uk

called for a complete ban on all forms of cloning, a prohibition on funding for stem cell research on surplus embryos and proposed that the report's guidelines take priority over national procedures.[21] In November 2001, the European Parliament rejected the report.

5.31 In July 2002, the EU agreed to a compromise to postpone all EU funding, except in certain specified cases, for research on human embryos and embryonic stem cells until the end of 2003. No EU funds may be used for research activities aimed at human reproductive cloning, modification of the genetic heritage of human beings, or the creation of embryos solely for research or stem cell procurement. At the core of the compromise was a commitment to establish by 31 December 2003, detailed implementation provisions for bioethical scrutiny of research activities within life science involving the use of human embryos and human embryonic stem cells.[22]

5.32 The EU's decision does not effect national governments which are free to spend their domestic research budgets as they see fit.

Other countries

5.33 The NHMRC also provided information on other countries and indicated that many countries currently do not have legislation relating to ART and research involving ART embryos. In these countries, such work may be undertaken.

5.34 In addition to Germany, no human embryo research is currently permitted in France, Switzerland, Norway, Ireland, Austria, Poland and Brazil. The Swiss national ethics committee is currently considering allowing use of existing embryonic stem cell lines. The French government has proposed allowing derivation and use of embryonic stem cells.

5.35 Both the derivation and use of stem cells from excess IVF embryos is permitted in Japan, Spain, Italy, Finland, Sweden, Israel and Singapore.[23]

Senator Sue Knowles
Chairman

October 2002

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21 The Scientist, *Never European twain shall meet*, 26.11.01, http://www.biomedcentral.com

22 Danish EU Presidency, *Press release,* 31.7.02, http://www.eu2002.dk/news/news_read.asp?iInformationID=21356

23 *Submission* 23, p.24 (NHMRC).

QUALIFYING COMMENTS

PROVISIONS OF THE RESEARCH INVOLVING EMBRYOS AND PROHIBITION OF HUMAN CLONING BILL 2002

EXECUTIVE SUMMARY

- There are a number of fundamental flaws in the Bill raised during the Committee's Inquiry amounting to a failure to justify the need for the legislation with respect to destructive embryo research, and a failure to make the case for the ethically-questionable destruction of human embryos. The flaws we have identified in our Qualifying Comments include:
  - Evidence about extensive but still largely unexamined commercial considerations of the Bill's supporters and the misrepresentation of the relevant science to Senators has raised questions about the possible dubious motivations of those supporting the Bill.
  - There are a range of concerns about the consequences of passage of the Bill and the drafting of its provisions, including:
    - the breadth of the destructive human embryo research that would be allowed;
    - concerns with the utilitarian approach adopted in the Bill and the precedent-setting nature of the Bill; and
    - concerns relating to various provisions of the Bill and their regulatory adequacy.
  - It is questionable whether the Bill is broader than the COAG agreement, upon which it is supposed to be based.
- Supporters of the Bill have argued that the legislation is critical as it offers the hope of a cure to sufferers of a range of disabilities by allowing embryonic stem cell research to continue. That argument is flawed because:
  - Embryonic stem cell research will continue in Australia whether or not this Bill passes the Parliament. The purpose of the Bill has been fundamentally misrepresented – it does not regulate the use of stem cells, rather, it permits the destruction of so-called 'excess' IVF embryos.
  - Research on embryonic stem cells is at a very basic stage, and there is no evidence that embryonic stem cell research offers any hope of a cure to sufferers of various diseases. Many witnesses agreed that existing stem cell lines are adequate for present research purposes.
  - Even if embryonic stem cells did hold promise of treatments for human patients, the number of human embryos to which this Bill grants possible access would be completely insufficient for the creation of therapies for human patients.
  - Present science suggests that embryonic stem cell research offers inferior outcomes to alternative areas of research, which do not pose the same ethical dilemmas, and do not require the destruction of human embryos.

PROVISIONS OF THE RESEARCH INVOLVING EMBRYOS AND PROHIBITION OF HUMAN CLONING BILL 2002

INTRODUCTION

A considerable range of scientific, legal and ethical issues have been raised during this inquiry into the provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002. With some notable exceptions, the Chair's Report generally covers the evidence provided. However an important omission is the lack of serious critical analysis of the evidence, submissions and arguments. All evidence is given equal weight or value in the Chair's Report. Consequently, there are key issues that the Chair's Report fails to highlight despite the fact that the evidence raises issues of considerable concern.

Accordingly, this Report contains analysis of and comments on the evidence presented to the Committee.

The Research Involving Embryos and Prohibition of Human Cloning Bill 2002 was split in the House of Representatives into two separate Bills, the Prohibition of Human Cloning Bill 2002 and the Research Involving Embryos Bill 2002. The reference of the original Bill to the Senate Committee, however, occurred prior to the splitting of the Bill, and so the Committee has inquired into the original Bill in its entirety.

Throughout the Inquiry a number of witnesses before the Committee raised serious concerns about the Bill including:

- the motivation for its introduction;
- the extensive but still largely unexamined commercial considerations;
- the misrepresentation of the relevant science to Senators;
- concerns with the utilitarian approach adopted in the Bill;
- the breadth of the destructive human embryo research that would be allowed;
- the precedent-setting nature of the Bill; and
- concerns relating to various provisions of the Bill and their regulatory adequacy.

The Bill was drafted to implement a nationally consistent approach agreed to by the Council of Australian Governments (COAG) on 5th April 2002. A communiqué setting out the agreed outcomes of the discussions that day stated that the Council had agreed:

- That research be allowed only on existing ART [assisted reproductive technology] embryos, that would otherwise have been destroyed, under a strict regulatory regime including requirements for the consent of donors and that the embryos were in existence at 5 April 2002. It was agreed donors would be able to specify restrictions, if they wish, on the research uses of such embryos.
- The regulatory regime would be reviewed within three years.
- Research would need to have approval from an ethics committee and be in accordance with NHMRC and Australian Health Ethics Committee guidelines.

On that basis, the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 was drafted.

This Inquiry has revealed that there are a number of fundamental flaws in the arguments of the proponents of the Bill. These flaws will be considered in detail in this Report. They raise concerns:

- That there has been a failure to justify the need for the legislation with respect to destructive embryo research, and in particular, a failure to show that the existing regulation and permissible research is inadequate, which amounts to a failure to make the case for the ethically-questionable destruction of human embryos. There is almost unanimous support for the much less contentious part of the Bill which bans human cloning;
- About possible dubious motivations of those supporting the Bill;
- About the consequences of passage of the Bill and the drafting of its provisions;
- About whether the Bill is broader than the COAG agreement.

CHAPTER 1

FLAWS IN ARGUMENTS SUPPORTING BILL

Failure to justify need to destroy human embryos

Our primary concern with the Bill is that the need to permit destruction of so-called 'excess' IVF embryos has not been demonstrated. The issue of destruction of embryos created during IVF processes is a highly controversial one and would require persuasive arguments in its favour. The evidence before the Committee relating to the need for this Bill has been conflicting and contradictory, with many scientists arguing against allowing access to these embryos.

The purpose of the Bill has been fundamentally misrepresented. A large amount of scientific evidence was presented to the Committee supporting the continuation of embryonic stem cell research. In evidence the National Health and Medical Research Council (NHMRC) clearly stated that the Bill:

> …**does not regulate the use of stem cells**. What the Bill does do is provide for the first time a strong national framework for the regulation of research on excess ART embryos that would otherwise have been destroyed.[1] [formatting added].

Those who support this legislation argue that it is critical as it offers the hope of a cure to sufferers of a range of disabilities by allowing embryonic stem cell research to continue. Those arguments are flawed for three main reasons:

a) Embryonic stem cell research is not facilitated by this Bill. Whether or not this Bill passes the Parliament, embryonic stem cell research will continue in Australia. A significant number of witnesses agreed that existing stem cell lines are adequate for present research purposes.[2]

b) There is no evidence whatsoever that embryonic stem cell research offers any hope of a cure to sufferers of various diseases. Research at this stage is very basic.[3] Even if embryonic stem cells did hold the

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1 Prof. Pettigrew, *Committee Hansard*, 29/8/02, p.2.

2 For example: Dr Juttner, BresaGen Ltd, *Committee Hansard*, 17/9/02, pp.32, 38; Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.51, 58-59; Prof. Rowe, *Committee Hansard*, 19/9/02, p.104; Prof. Good, *Committee Hansard*, 19/9/02, p.91; Prof. Bartlett, *Committee Hansard*, 19/9/02, p.95.

3 Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.52; Prof. Rowe, *Committee Hansard*, 19/9/02, p.95; Prof. Hearn, ANU, *Committee Hansard*, 19/9/02, p.95; Prof. Shine, *Committee Hansard*, 19/9/02, p.118.

possibility of some future treatment, it would be up to 30 years before those therapies become available.[4]

c) If embryonic stem cells did, at some stage in the future, hold promise of treatments for human patients, the 70,000 embryos to which this Bill grants possible access would be completely insufficient for the creation of these therapies. Estimates based on existing data on immune rejection suggest that 10 million embryonic stem cell lines would be required to give a 53% possible match of stem cells that would not be rejected, for Caucasians alone.[5] Therefore, the potential treatments that this research will lead to will require the creation and destruction of large numbers of embryos to produce these stem cells, leading to further ethical issues.

The issue of whether arguments in support of the Bill justify its passage take into account the adequacy of existing research. The Committee has received considerable evidence on this issue, particularly from those scientists who question the motivations of the Bill's supporters based on their view that present science does not justify making excess IVF embryos available, or that present science suggests that embryonic stem cell research offers inferior outcomes to alternative research.

Adult stem cells and alternative research

A number of scientists have suggested that adult stem cell research is either adequate at this time, or preferable to embryonic stem cell research. Certainly adult stem cell research is not ethically problematic, unlike embryonic stem cell research, and all other things being equal, would be preferable on that basis.

Arguments to the Committee in favour of alternatives to embryonic stem cell research include:

- Adult stem cell research is presently more advanced.[6]
- Adult stem cells are preferable to embryonic stem cells as therapeutic models based on the use of stem cells from an adult source eliminate any

4 Prof. Tuch: 3,4,5 plus years, *Committee Hansard*, 17/9/02, p.47; Prof. Rowe: 20 to 30 years, *Committee Hansard*, 19/9/02, p.95; Prof. Bartlett, *Committee Hansard*, 19/9/02, p.99; Dr Coulepis: 9, 10, 15 years to get a therapy plus 8-14 years to get therapy on the market, *Committee Hansard*, 19/9/02, p.122.

5 Prof. Good, *Committee Hansard,* 19/9/02, p.98.

6 Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.56; Prof. Rowe, *Committee Hansard*, 19/9/02, p.95; Prof. Good, *Committee Hansard*, 19/9/02, pp.90-1; Prof. Hearn, *Committee Hansard*, 19/9/02, pp.114, 122, 123.

risk of graft rejection by the recipient's immune system.[7] Immunological rejection problems arise if foreign tissue is used in transplantation and derived from embryonic cells.[8] It was even said that animal embryonic stem cell rejection suggests that it is not worth progressing to research with human embryonic stem cells.[9]

- Adult stem cells overcome problems with tumurogenesis when using embryonic stem cells.[10]

- Adult stem cells are preferable to embryonic stem cells because the plasticity of embryonic stem cells is a disadvantage not an advantage.[11] Differentiation and proliferation arguments in support of use of embryonic stem cells are misleading.[12]

- Umbilical cord blood stem cells and somatic or adult stem cells are good alternatives.[13]

- Placing dopamine neurgic cells in the brain can help the motor symptoms of Parkinson's disease.[14]

- Autologous glial cells obtained from the patient's olfactory mucosa is the state of the art prospect for treating paraplegia/quadriplegia.[15]

- It is possible to obtain stem cells which could give rise to the insulin-producing beta cells of the pancreas from a source other than embryonic stem cells – that is, it is possible to use cells created in vitro from pancreatic stem cells.[16]

One alternative which deserves special mention is the use of germ stem cells (those used in the infamous 'rat experiment' used by Prof. Trounson in support of his

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7 Prof. Good, *Committee Hansard*, 19/9/02, p.90; Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.54; Prof. Bartlett, *Committee Hansard*, 19/9/02, p.94.

8 Prof. Good, *Committee Hansard*, 19/9/02, p.89.

9 Prof. Good, *Committee Hansard*, 19/9/02, pp.91, 97; Prof. Bartlett, *Committee Hansard*, 19/9/02, p.95.

10 Prof. Good, *Committee Hansard*, 19/9/02, p.91; Prof. Bartlett, *Committee Hansard*, 19/9/02, p.94.

11 *Committee Hansard*, 19/9/02, p.91.

12 Submission 480; *Committee Hansard*, 19/9/02, p.91.

13 Dr Fleming/Dr Pike, Southern Cross Bioethics Institute, Submission 892.

14 Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.53.

15 Dr McCullagh, Submission 480.

16 Dr McCullagh, Submission 480.

arguments). Germ stem cells are obtained from foetal tissue of aborted foetuses. According to Prof. Trounson:

> Embryonic stem cells from embryos are functionally indistinguishable from embryonic germ cells and will do everything that embryonic germ cells can do in terms of differentiation and tissue colonisation.[17]

Importantly however, the use of germ stem cells does not involve the destruction of human embryos and is therefore not relevant to the Bill.

The question remains that if germ cells and embryonic stem cells are "functionally indistinguishable", as argued by Professor Trounson in defence of his use of the "rat video", why isn't Professor Trounson using germ cells in his research instead of embryonic stem cells?

Motivations of supporters of Bill

A number of witnesses argued that it was too early to say whether any source of stem cells would deliver greater benefits than any other.[18] The consensus of scientific witnesses before the Committee was that there are adequate embryonic stem cell lines available to ensure that research in Australia will continue,[19] without the destruction of additional human embryos, and that will occur whether or not this Bill is passed.

The distinction has been drawn between the number of embryonic stem cells required for therapeutic and research purposes. While there is agreement that embryonic stem cells are still a long way off being used in the production of therapies,[20] and that there are adequate stem cell lines to continue research and establish proof of principle,[21] it is unclear why access is now being sought to excess IVF embryos.

There being no indication of any valid reason why access to these 70,000 or so embryos is required now, the evidence suggests that there are some underlying commercial interests behind the push for access to these embryos. A number of scientists speculated that commercial interests must have motivated the Bill, because

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17 Prof. Trounson, *Committee Hansard*, 24/9/02, p.136.

18 Prof. Hearn, ANU, *Committee Hansard,* 19/9/02, p.114; Prof. Tuch, *Committee Hansard*, 17/9/02, p.35; Ms Royles, CAMRA, *Committee Hansard*, 17/9/02, pp.70, and Mr Turner at p.75; Prof. Bartlett, *Committee Hansard,* 19/9/02, p.95; Ms Hartland, Biotechnology Australia, *Committee Hansard*, 26/9/02, p.228.

19 Footnote 2.

20 Prof. Rowe, *Committee Hansard,* 19/9/02, p.95; Prof. Hearn, *Committee Hansard,* 19/9/02, p.114; Dr Coulepis, *Committee Hansard,* 19/9/02, p.121; Prof. Serjeantson, Australian Academy of Science, *Committee Hansard,* 19/9/02, p.120; Prof. Shine, *Committee Hansard,* 19/9/02, p.118; Prof. Tuch, *Committee Hansard*, 17/9/02, p.40; Prof. Bartlett, *Committee Hansard,* 19/9/02, p.94; Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.53.

21 Prof. Rowe, *Committee Hansard,* 19/9/02, p.104.

there was no scientific basis justifying the need for those embryos.[22] Some scientists raised questions as to the type of research commercial interests sought to perform on embryos.[23]

We can only speculate as to the motivations behind those seeking access to the embryos, however, if there existed a rational and reasonable explanation of the need for them, we are sure it would have arisen in evidence to the Committee. None has arisen.

The only arguments that have been advanced in support of a need for access to IVF embryos have been that new embryonic stem cell lines are needed:[24]

- To create "safer" stem cell lines without using mouse feeder cells that have been used for derivation of existing stem cell lines,[25] except one[26];
- To achieve adequate tissue matching to avoid immune rejection in clinical therapy;[27]
- To produce improved cell lines if there are future improvements to the methodology for initiating and growing cell lines;[28]
- To overcome restrictions to use stem cells derived from commercial funding.[29]

None of those arguments compels immediate access to embryos that will be destroyed for research purposes. Research on embryonic stem cells is at such an early stage that much more research on animal models is required for any of these reasons to justify the destruction of embryos.[30]

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22 Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.52, Prof. Rowe, *Committee Hansard,* 19/9/02, p.95. See below "Commercial interest in embryos".

23 H51, H91, H96, H98 (Good and Rowe), H99 (Bartlett). See also below "Commercial interest in embryos".

24 Prof. Pera, *Committee Hansard,* 24/9/02, p.135.

25 Prof. Pera, *Committee Hansard,* 24/9/02, p.135; Mr Ilyine, Stem Cell Sciences Ltd, *Committee Hansard*, 17/9/02, p.40; Dr Juttner, BresaGen, 17/9/02, p.38; Dr Simmons, *Committee Hansard*, 19/9/02, p.111 (also to improve stem cell lines if derivation conditions were not optimal). According to Dr Juttner, BresaGen, 100 to 200 stem cell lines would be required for this purpose: *Committee Hansard*, 17/9/02, p.50.

26 Prof Trounson, *Committee Hansard,* 24/10/02, p.153.

27 Prof. Pera, *Committee Hansard,* 24/9/02, p.135.

28 Prof. Pera, *Committee Hansard,* 24/9/02, p.135.

29 Prof. Pera, *Committee Hansard,* 24/9/02, p.135.

30 Dr Silburn, *Committee Hansard*, 17/9/02, p.52; Prof. Good, *Committee Hansard*, 19/9/02, p.102.

Clinical therapy is 20 to 30 years away,[31] if there will ever be any clinical therapy using embryonic stem cells, and that is far from certain.[32] Many scientists have given evidence that existing stem cell lines are adequate for research that will be conducted in the near future given the present restricted state of knowledge.[33] The Committee has also received evidence that excess embryos to which this Bill will permit access will be completely inadequate for the purposes of achieving adequate tissue matching.[34]

The arguments presented to the Committee to destroy excess IVF embryos based on a need to create additional stem cell lines are, therefore, not convincing.

The issue of the number of embryos required for the purposes of "research" was contentious among scientists, and clearly depends upon their interpretation of the definition of "research" in the Bill. Opinions on the number required varied from "tens"[35] to 600-1,000[36] to "up to ten million" embryonic stem cell lines[37] to those not prepared to hazard a guess.[38] Those who based their figures on the number required for basic research (the type of research already being conducted) were at the lower end of the scale, while the higher figure was premised on the possible eventuality of a therapy, and on the number required to develop a therapy which would have a reasonable (greater than 50 per cent) chance of obtaining a match to avoid immune rejection.[39]

There was a further ethical consideration resulting from that analysis of the number of human embryos required. Namely, that if 10 million embryonic stem cell lines were to be required in the future to produce a therapy, then that would involve the creation of human embryos by cloning:[40]

> **Senator HUTCHINS –** How would you get the 10 million stem cell lines?
>
> **Prof. Good –** Under the current legislation before parliament, as I understand it, you would not. I believe there are some 70,000 'surplus'

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31 Footnote 4.

32 Prof. Good, *Committee Hansard*, 19/9/02, p.96.

33 See Footnote 2, especially Dr Juttner, BresaGen, 17/9/02, p.39; Prof. Good, *Committee Hansard*, 19/9/02; p.96; Prof. Tuch, *Committee Hansard*, 17/9/02, p.39.

34 Prof. Good, *Committee Hansard*, 19/9/02, p.98.

35 Prof. Trounson: "20 to 30 or 50 may well be enough", *Committee Hansard*, 24/9/02, p.140.

36 In order to create therapeutic cell lines to provide therapies for a wide range of humanity: Dr Juttner, *Committee Hansard*, 17/9/02, p.39.

37 Prof. Good, *Committee Hansard*, 19/9/02, p.98; Dr Simmons: that estimation "seems perfectly reasonable", *Committee Hansard*, 19/9/02, p.106.

38 Dr Morris and Ms Matthews, NHMRC, 29/8/02, pp.7, 8; Prof. Tuch, *Committee Hansard*, 17/9/02, p.37; Prof. Shine, *Committee Hansard*, 19/9/02, p.116; Dr Coulepis, *Committee Hansard*, 19/9/02, p.125.

39 Prof. Good, *Committee Hansard,* 19/9/02, p.98; Dr Juttner, *Committee Hansard,* 17/9/02, p.39.

40 *Committee Hansard*, 19/9/02, p.98.

> embryos. There are nowhere near 10 million. You would not be able to get 10 million. I do understand that this has already been banned by the parliament, but the alternative that people say is, 'Let's do therapeutic cloning', where you take the nucleus from one of your cells, put it into an enucleated egg of a woman, make a little clone of you and use those cells to make tissue which would be identical to you.
>
> **…**
>
> **Senator HUTCHINS –** But to get 10 million, you would have to think of something like that, wouldn't you?
>
> **Prof. Good –** You would have to make the embryos.

Cloning is the only apparent way to produce the number of embryos that would be required while producing tissue which is compatible with the patient.[41] In order to create embryos, obviously human eggs are required, and while prohibited by the Bill, there will undoubtedly be pressure to remove that prohibition if large numbers of human embryos should be required for a therapy. That raises all manner of ethical concerns about the so-called farming of eggs from women, concerns which have resulted in the prohibition contained in this Bill in the first place. While imposing a prohibition, the Bill potentially creates demand for the removal of that prohibition.

If the destruction of human embryos for research is permitted, the issues that arise will become ever more complicated, and will continue to raise ethical concerns. The obvious ethical concerns that will arise in the foreseeable future are very perturbing. To proceed down this moral and ethical slippery slope is unwarranted when there are so many viable alternatives to the destruction of embryos for research.

Commercial interest in embryos

The question of exactly what the human embryos and embryonic stem cells will be used for has been raised by a number of scientists, as there has been no present demonstrable need for the stem cells for research purposes. There have been a number of suggestions from scientists and industry as to the uses to which they might be put:

> ... these cells will be highly useful for screening drugs for both toxicology and effectiveness.[42]
>
> … this is about commerce , not about science. Let us not kid ourselves.[43]

The breadth of subjective definitions of research permissible using human embryos and embryonic stem cells under the Bill illustrates that the Bill's provisions are open to interpretation and potential abuse if commercial interests are involved. There has

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41 Prof. White, *Committee Hansard*, 19/9/02, p.124.

42 Prof. Trounson, *Committee Hansard*, 24/9/02, p.141.

43 Dr McCullagh, *Committee Hansard*, 24/9/02, p.157.

been considerable evidence about the potential research uses of embryos that might be permissible pursuant to the Bill. The following quotes are examples of that evidence:

> In fairness to companies like BresaGen, they are aware that therapy is 10 to 20 years away. Stem Cell International's CEO has said publicly that therapy, in their eyes, is 10 to 20 years away. *So they have to generate some form of income along the way. To use stem cells for screening and diagnostic purposes is a perfectly understandable use of such cells.*[44] [Italics added]

> My understanding was that the object of the Act was to allow frozen excess embryos in ART labs around the country to be used to derive embryonic stem cells specifically; but that is not specified in this legislation. In fact, any use of human embryos which the NHMRC Licensing Committee feels is worthwhile is approved, under this legislation.[45]

> …as much as I can know, there is no future in cell therapies. There are already ES cell lines which will not be affected by the Act, which could be used for research. … So why do they want the embryos? The only reason I can think of is that drug companies may wish to use them for screening. … there are plenty of embryonic cell line companies that are looking to make lots of money out of getting hold of these embryos.[46]

> For example, you can take embryonic stem cells and make them differentiate into certain tissues, like blood vessels. They would be very good to test certain drugs that you might want to stop this process in, say in tumours, because the approach to many tumour treatments is blocking the growth of blood vessels which support them. That is the sort of thing that you want them for, to be able to approach that sort of treatment in the test tube.[47]

> On reading the research involving embryos Bill, it is fairly clear that the consent provisions do allow, once the embryos are released from parental care, for those embryos to be used for all manner of purposes.[48]

> For me, research is a scientific endeavour aimed at answering questions and moving ahead and improving the way one does things, and my interest is therapeutic, so I am interested in new therapies. For me, research involves everything from where we are now to having products that are being used to treat patients, in the case of cellular transplants. It also includes the possibility of using embryonic stem cell lines for things like drug testing, which I think is actually a proper activity if it saves patients from being exposed to testing of new drugs, but I am not talking about, and absolutely

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44 Prof. Bartlett, 19/9/02, p.99

45 Dr Best, *Committee Hansard*, 24/9/02, p.158.

46 Prof. Good, *Committee Hansard*, 19/9/02, p.98.

47 Prof. Rowe, *Committee Hansard*, 19/9/02, p.98.

48 Dr Pike, *Committee Hansard*, 17/9/02, p.55.

> reject, the concept of using embryos as such for that testing. It is embryonic stem cell lines or the products of them, and actually it is more likely that cell lines that have differentiated into liver cells, kidney cells or heart cells would be wanted for things like drug testing.[49]
>
> My definition of research would include the development of therapies which could be of benefit to humans and the modifications thereof until we have reached the point where we accept them or reject them.[50]
>
> The other thing that sometimes therapeutics is used for is to say, 'Let's establish these lines and test drugs on them.' The argument has been put forward that if you have a muscle cell lines, say, or a liver line you can put chemicals in it and basically see what happens to the liver or muscle before you use it on humans. It is very plausible. Wouldn't it be ideal to get somebody with the disease you are looking at and to establish the line from them and then see what happens to the drug? Number one, you get an idea of whether the drug is going to be toxic to the cell, whether it is a normal cell or a diseased cell, and you might see that it might improve its function.[51]
>
> I do not see anything within the bill which would directly restrict the broader use of human embryos to direct application in pharmaceuticals testing or in toxicological testing.[52]

Professor Hearn on the other hand, did not accept pharmacological testing as an appropriate use of embryos, saying that we need "to restrict the use of embryos to stem cell derivation and not to pharmacological testing-say of teratologic agents"[53] and that "the criteria to allow research need to take that on board".[54] Professor Hearn interpreted "research" in a far more restricted way than many other witnesses:

> My definition of the more basic research and the sort of research I have been engaged in is understanding the fundamental processes—in this context—of how cells behave and the potentials of cells, and our astounding new understanding of how cell nuclei can be programmed and reprogrammed and how cells can be pluripotent. I would not personally put testing of pharmaceuticals on cells or embryos in the realm of basic research.[55]

There is a distinct possibility – as it is not prevented by the legislation – that human embryos could be destroyed for the purposes of pharmacological testing. There have

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49 Dr Juttner, *Committee Hansard*, 17/9/02, p.40.

50 Prof. Tuch, *Committee Hansard*, 17/9/02, p.40.

51 Dr Silburn, *Committee Hansard,* 17/9/02, p.56.

52 Dr Pike, *Committee Hansard,* 17/9/02, p.57.

53 Prof. Hearn, *Committee Hansard*, 19/9/02, p.115. Dr Best agreed with this limitation: *Committee Hansard*, 24/9/02, p.158.

54 Prof. Hearn, *Committee Hansard*, 19/9/02, p.119.

55 Prof. Hearn, *Committee Hansard*, 19/9/02, p.123.

been indications that there is commercial interest in obtaining embryos for such purposes.

The research permissible under the legislation is left at the discretion of the NHMRC. We consider it important that if this Bill is to become law it should include more restricted prescription of permissible research, in line with COAG's apparent intention and agreement.

Conclusion

Given the ethical sensitivity associated with the destruction of excess human embryos created in IVF procedures, we consider it important that there be some degree of consensus on the scientific consequences of agreeing to or rejecting this Bill. Given the considerable variation of opinion, it is up to those who support the Bill to justify its existence. This has patently not been achieved. Indeed, more reasons have been advanced supporting rejection of the Bill than have been advanced in support of it. This is not adequate for such a contentious issue.

We believe that for Parliament to mandate the expansion of ethically contentious research, involving the destruction of human life, there must be compelling reasons. We do not find any of the reasons presented to the Committee compelling.

For example, the Australian Academy of Science sought the flexibility contained in this legislation because the scientific knowledge underpinning it is flawed.[56] While the knowledge underpinning the legislation is so flawed there should be no decision to permit the destruction of embryos in order to improve that knowledge, especially when that course of action is unnecessary to improve the knowledge.

56 Prof. Serjeantson, *Committee Hansard*, 19/9/02, p.120.

CHAPTER 2

ETHICAL AND MORAL CONSIDERATIONS

Definition of "embryo" – moral considerations

The destruction of a human embryo is a destruction of human life, in our moral judgement.

> Either it is permissible to destroy human embryos in the name of science or it is not. … We are concerned that the harm may affect us and future generations if we come to regard the early stages of human life as raw material for use in exploitation. We contend that the human embryo is just that – human. This is supported by embryology and agreed on by scientists on both sides of the debate. That is why people want to use them. The question is not "Are they human?' but 'How are we going to treat them. ... The moral status of an embryo is not a fact but a value.[57]

The issue then, is that the Bill contains a value judgement about how we are going to treat embryos. To our minds, that value judgement should not involve commercial considerations above all else. In view of the underwhelming evidence in support of the destruction of embryos and the divergence of views among scientists as to the need for embryos to be destroyed in the name of research, we cannot reach the conclusion that embryos should be destroyed in these circumstances.

The assumption underpinning this Bill is that parents have absolute proprietorial rights over their progeny – including embryos. In fact, this is not the case because there are broader social values which override parental interests, whether they be derived from religious views or from commonly held social views. It is inconsistent with accepted policies and ethical arguments to give parents proprietary rights over embryos.[58]

Allowing to succumb v destroying an embryo

This Bill represents a move away from established principles by rejecting the ethical distinction between letting life succumb and killing or destroying a human life.

It may be true that:

> … no embryos would be saved by defeating the legislation.[59]

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57 Dr Best, *Committee Hansard*, 24/9/02, p.155.

58 See also, Dr Pike, *Committee Hansard,* 17/9/02, p.55.

59 Dr Elefanty, *Committee Hansard*, 24/9/02, p.138.

However, if it is believed that a human embryo is human life, then there is a distinct difference between letting an embryo "succumb" and destroying it for research. The end outcome should not be confused with how that outcome is achieved.

> … we have tried to clarify what we see as a distinction which in one respect we hoped would never have to be made, and that is the distinction between intentional killing and allowing to die. It is a difficult one, but one recognised in ethics in several different arenas. What concerns me most about this particular application of the 'they're going to die anyway, so let's use them' approach is that that line of reasoning has been used in other arenas in the past and some of those have been quite disturbing. As often happens in ethics and philosophy, what is a consistent argument in one arena gets transferred into another arena. So it is quite possible that if this distinction is not recognised here, whereas it is at other places and times—for example, end of life, which is one of the best examples we have of that particular distinction—if we lose it here we may lose it elsewhere.[60]

Some witnesses stated that the Bill was dealing with embryos that would otherwise be destroyed.

> What the Bill does do is provide for the first time a strong national framework for the regulation of research on excess ART embryos **that would otherwise have been destroyed**.[61]

> … the proposed legislation will permit the use of surplus embryos from in vitro fertilisation procedures **that would otherwise be destroyed**…[62]

In fact, the embryos, would not "otherwise be destroyed", they would, rather, be allowed to succumb. To our minds, active destruction is ethically quite a different proposal.

> ... there is no proof of principle for destructive embryonic stem cell research. … This is no basis for legislation which sets the precedent for the deliberate destruction of human life.[63]

As noted by Dr Pike, this issue has serious implications for how we treat human beings in the future where people are 'going to die anyway'. We are concerned at this change in our present approach to forbidding experimenting on and putting an end to a human life, irrespective of the subject's consent.

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60 Dr Pike, *Committee Hansard*, 17/9/02, p.55.

61 Prof. Pettigrew, *Committee Hansard*, 29/8/02, p.2.

62 Dr Elefanty, *Committee Hansard*, 24/9/02, p.137.

63 Dr Neville, *Committee Hansard*, 26/9/02, p.217.

CHAPTER 3

SPECIFIC CONCERNS WITH BILL AND REGULATORY REGIME

Omissions from Bill

Number of embryos

The number of embryos required for research is not a requisite consideration of the NHMRC's Licensing Committee in this legislation. That is a serious inadequacy. The NHMRC stated:

> One of the criteria that the Licensing Committee must examine is the number of embryos necessary to achieve the goals of the project … That is one of the criteria that COAG set.[64]

That criterion is not, however, enshrined in legislation, and we believe that it is appropriate that it be an object of the Act. The concept that it is desirable to minimise the number of embryos has been removed from the Bill, and even though the licensing process is to take account of the number of embryos proposed to be used, there is no objective to limit the number.

Clearly there is dispute over the number of embryos that will be required to be destroyed for research purposes, if any are in fact required.[65] We believe that it should be an object of this legislation to minimise the number of embryos destroyed, so that embryos are not unnecessarily destroyed.

We suggest amendment of the Bill to include such a limitation, as this should be a critical consideration for the NHMRC Licensing Committee.

There have been suggestions that the approach in the UK of establishing a "stem cell bank" so that there are no intellectual property rights over stem cell lines would better achieve a purpose of minimising the number of embryos used than the approach in this Bill.

> In the UK they have taken a decision … to establish a national stem cell bank which will be managed independently of academic research institutes and commercial companies. … in trying to minimise the number of embryos destroyed for that purpose [producing stem cell lines], the UK government saw that it would make sense to hold all of the stem cell lines in a central

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64 Ms Matthews, NHMRC, *Committee Hansard*, 29/8/02, p.8.

65 See above "Number of embryos".

> point where there would be free and unencumbered access to those stem cell lines to qualified researchers.[66]

In Europe, the prohibition of patents on unmodified human stem cell lines, also reduces the destruction of embryos:

> So there could be no encumbrance of research being conducted on the human stem cell lines, no patents were granted for their isolation or their development. But for discoveries made when using those cells which are beneficial for one matter or another … those discoveries would indeed become patentable.[67]

There is merit in these international approaches, and this Bill takes a very different approach which we do not believe will restrict the number of embryos destroyed. Alternative approaches should be investigated.

There is a distinct possibility, as it is not prevented by the legislation, that embryos could be destroyed for the purposes of pharmacological testing. There have been indications that there is commercial interest in obtaining embryos for such purposes.

The research permissible under the legislation is left at the discretion of the NHMRC. We consider it important that if this Bill is to become law it should include more restricted prescription of permissible research.

Revocation of license not automatic

One other concern that was raised during Committee hearings was that there is no automatic revocation of license by NHMRC if a person commits an offence:[68]. The NHMRC should not have, nor is it likely to desire any discretion in such circumstances, and the license should be automatically revoked.

Definition of "proper consent"

The Bill requires consent of the 'owners' of the embryo. The adequacy of the requirements have been brought into question. AHEC has stated that it has concerns that the definition of "proper consent" is open to interpretation, and does not reflect the strict regulatory regime that COAG approved.[69]

The submission from ACF GeneEthics Network expressed the concern that:

> It is important that advance informed agreement (with evidence of full notification and maybe even counselling) be required before an embryo is

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66 Mr Ilyine, *Committee Hansard*, 17/9/02, p.36.

67 Mr Ilyine, *Committee Hansard*, 17/9/02, p.45.

68 NHMRC, *Committee Hansard*, 29/8/02, p.17.

69 *Committee Hansard*, 26/9/02, p.251.

> used for any purpose other than pregnancy, rather than mere consent sufficing as that is too passive.[70]

It is important that proper procedures for the obtaining of consent from the 'owners' of the embryo is obtained before any embryo is destroyed. This needs to be prescribed in the legislation.

Assessment of research

It was suggested to the Committee that in order to address concerns that research may be carried out without sufficient evidence-based justification, there should be mechanisms in the legislation that require assessment and review of the research conducted under licenses and re-assessment of the potential of future research based on developments and contemporary community standards.[71]

We agree that there should be regular assessment of the outcomes of research conducted under the Bill, and that this should be included in the Licensing Committee's reports to the Parliament.

Concerns with regulatory regime

The importance of proper mechanisms for scrutiny and adequate transparency of decisions of NHMRC licensing committee were issues raised with the Committee.[72] It has been suggested that there are some possible deficiencies in public scrutiny and accountability under the Bill.

The NHMRC gave evidence to the Committee that:

> 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. … 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.[73]

There is the prospect here (in Clause 45 of the Bill) as Senators frequently encounter when seeking information, that claims of commercial-in-confidence restrict access to information. As stated in a submission:

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70 Submission 1843, ACF GeneEthics Network.

71 Submission 1843, ACF GeneEthics Network.

72 Prof. Hearn, *Committee Hansard*, 19/9/02, p.115; Prof. White, *Committee Hansard*, 19/9/02, p.118.

73 Prof. Pettigrew and Dr Morris, NHMRC, *Committee Hansard*, 29/8/02, p.28.

> The amount of "confidential commercial information" withheld from publication should always be minimised. The public's right to know has at least equal status with commercial interests.[74]

We believe that this is particularly so in the present circumstances where there is considerable public interest in the ethical issues involved. The reporting requirements of the NHMRC should be strengthened, and the NHMRC Licensing Committee should be required to table in the Senate a six-monthly report on the operation of the Bill and details of licenses provided pursuant to this Bill.

The question has been raised whether the Parliament has the power to directly require a report from the Licensing Committee.[75] That certainly should be a reporting requirement of the Committee and we intend to pass a motion in the Senate to this effect.

Additionally, the openness of NHMRC has been brought into doubt, raising questions about the appropriateness of NHMRC control of the regulatory (licensing) regime:

> The NHMRC is impenetrable and effectively answerable to no-one outside. GTRAP and AHEC are examples of NHMRC with whom we have attempted to engage over many years, with very little success. We propose that this licensing function be vested in the Office of Gene Technology Regulator who has statutory responsibilities and authority commensurate with the importance of this licensing work, and has processes and mechanisms to engage with the interested and general publics.[76]

We believe that alternatives to the regulatory arrangements in the present Bill need to be considered.

Appeal rights

We consider that it is appropriate that as well as applicants for licences and licence holders, any other interested party should have standing to appeal decisions of the NHMRC Licensing Committee including present or former "owners" of the embryos, interest groups and the public at large.[77]

In this Bill there are so many ethical concerns that it is proper that decisions made in the licensing process be subject to appeal.

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74 Submission 1843, ACF GeneEthics Network.

75 Submission 1843, ACF GeneEthics Network.

76 Submission 1843, ACF GeneEthics Network.

77 See Submission 1843, ACF GeneEthics Network.

Grants of funding

Given the division within the scientific community on many issues, the potential for bias and conflict of interest in decision-making, in particular where funding is concerned, it is recommended that in the future, there be greater accountability to the Parliament of committees appointed to distribute research funding, and greater oversight by the Parliament of significant funding grants.

Sunset clause and review

Sunset clause

Clause 60 of the Bill provides for repeal paragraphs 36(3)(b) and 39(1)(c) and subsection 39(3) on 5 April 2005 or, if COAG declares, an earlier date. Those provisions that are to be repealed prevent the use of embryos created after 5 April 2002. Therefore after 5 April 2005 (or earlier if so declared) there will be no restriction on the date of creation of the embryo to be used for research.

Concerns have been expressed, which we share, that this sunset clause could result in the de facto production of human embryos (through IVF procedures) deliberately for the purposes of research.

Review

Clause 61 of the Bill provides for a review of the legislation within three years of its commencement. We consider review of the legislation developed by COAG[78] and coordinated by the NHMRC, which has significant regulatory responsibilities in this area, to be inappropriate in these circumstances.

The ACF GeneEthics Network stated in its submission that:

> An inhouse committee of the NHMRC is not open to public scrutiny, communication, or participation and cannot be therefore assured of acting in the public interest.[79]
>
> Without full public participation the object of the Act "to address concerns, including ethical concerns …" cannot be realised. The Bill, as drafted fails to enable full public participation.[80]

Rather, we consider review by a joint house parliamentary committee, comprising representative numbers of members of each party to be more appropriate.

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78 Ms Matthews, NHMRC, *Committee Hansard*, 29/8/02, pp. 14-15.

79 GeneEthics Network, Submission 1843.

80 Ibid.

There are serious ethical issues that this review needs to take into account, and not only are members of parliament appropriate representatives of community concerns, but furthermore, it is appropriate that legislators have a role in the review of contentious legislation such as this.[81]

Constitutional issues

Advice from the Australian Government Solicitor raises serious doubts about the constitutionality of the legislation.[82] Clearly, the legislation would be open to challenge if individuals were prosecuted for an offence under this legislation, as there is no apparent Commonwealth head of power in the Constitution. Consequently, the States will need to enact empowering legislation in order to give full effect to this legislation.[83] If there is national agreement on the content of legislation by each of the States and Territories, why are they not left with responsibility when they have complete constitutional power?

It is of concern that this Parliament is being asked to knowingly pass legislation that is not constitutional and offences that are unenforceable unless or until the States and Territories confirm transfer of their constitutional power to the Commonwealth. There is no clear rationale for this action.

81 Prof. White, *Committee Hansard*, 19/9/02, p.118.

82 Ms Matthews, NHMRC, *Committee Hansard*, 29/8/02, p.11.

83 Ms Matthews, NHMRC, *Committee Hansard*, 29/8/02, pp. 11-13, 17.

CHAPTER 4

COMMENTS ON CHAIR'S REPORT AND CONDUCT OF INQUIRY

Australian concepts

The Chair's Report refers to a Morgan poll indicating that 72 per cent of Australians surveyed have indicated their approval of research using excess IVF embryos for the development of therapies, assuming the informed consent of donors.[84]

We do not believe that this poll reliably represents the views of Australians on this Bill because:

- The poll refers to "the development of therapies", not mentioning that the development of a therapy involves up to 30 years of research using human embryos, and even then a positive therapeutic outcome is still an unlikely consequence.
- This poll does not relate to the Bill, as the Bill is not about "developing therapies", the Bill is about using excess human embryos for destructive research, and even permits pharmacological testing.
- It is probable that those responding to this question were not properly informed about the likelihood of successful therapies being developed using alternate methods and were influenced by media reports overstating the possibility of cures resulting from embryonic stem cells for Parkinson's and Motor Neurones diseases, spinal cord and brain injuries, juvenile diabetes and the like. It is not likely that respondents were well informed about the true nature of this Bill.
- The poll contradicts other evidence that shows 56% of Australians responded 'definitely yes', 'probably yes', had 'mixed feelings' or were 'undecided' when asked if an embryo is a human being at the moment of conception.[85] These figures clearly show that the majority of people at the very least had mixed feelings or were undecided about whether an embryo is a human being at conception. In that case, we need to give very careful consideration to the ethical issues surrounding the destruction of human embryos.

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84 Chair's Report, para [3.104].

85 Melbourne Institute of Applied Economic and Social Research, "When human life begins: Public perceptions", *Australian Social Monitor*, Vol. 5, No. 1, February 2002, pp.15-16.

There is evidence that there is a mixture of views internationally on this issue, and that mixture is likely to be evident in a properly informed Australian public.

The Chair's Report, in Chapter 5, considers the variety of international approaches to the destruction of embryos for research purposes. Clearly, the ethical issue is not as clear-cut as some witnesses would have us believe, with a range of approaches being adopted by governments across the modern world. This represents the ethical element of decision-making where the destruction of embryos is concerned, and the different ways parliaments have exercised their judgement in that situation indicates the diversity of views and conclusions on the available evidence.

Approach to ethical issues

The Chair's Report, in Chapter 3, describes "third way" approach to ethics. We draw attention to this because we are unaware of any substance to or support for that ethical position. In fact, we believe that this approach is a creation of the Chair.

Important questions arise if this approach to ethics is to be used to justify the ethical position represented in the Bill. For example, no evidence is provided that there are any ethicists who support this approach. It also seems that there is no theological or ethical basis for this "third way" concept.

It is a dangerous situation ethically when you need to create a new approach to ethics to justify ethically contentious legislation.

Equally bewildering is the conclusion to Chapter 3 where the possibility that the research would continue unregulated is a greater evil than passage of a Bill, even given ethical concerns. This argument fails to take account of the fact that the Bill does not regulate stem cell research, and the embryos would only be available for destruction if States permit such action.

Incorporation of guidelines into Bill

Several areas of the Bill are given effect by the incorporation of material for which the Parliament is not responsible. This is cause for concern considering the breadth of legislative delegation by the Bill.

As noted in the Chair's Report, in the past, the Senate Scrutiny of Bills Committee has drawn attention to provisions of Bills which give power to a particular person or body to issue guidelines, directions or similar instruments which determine the way authority given under an Act of Parliament is to be exercised. It usually suggests that

such instruments be tabled in Parliament and, where appropriate, be disallowable by either House.[86]

The Chair's Report states that "On this occasion, the Senate Scrutiny of Bills Committee considered the Bill and found no cause to comment".[87] The unusual omission to comment on this issue when there is such a considerable degree of delegation of legislative power dictates that the Parliament seek to amend the Bill to establish a sufficient regime of scrutiny over the exercise of that power.

The Australian Health Ethics Committee of the NHMRC has expressed some dissatisfaction with the drafting of the Bill:[88]

> **Senator JACINTA COLLINS-** Let me characterise for you my understanding of the way those concerns have been described. AHEC raised the concern that, without further describing the parameters of significant gain in knowledge or other similarly grey areas of the draft bill- for instance, those terms open to interpretation such as 'proper consent'-the proposed regulatory system will not deliver the strict regulatory regime required by the COAG decision.
>
> **…**
>
> **Dr Breen-** It is in our notes from 16 May.

It is recommended that the Bill be amended to include scrutiny of the legislative power extended by the Bill.

AHEC review of ART guidelines

One instance where guidelines are incorporated into the Bill is of particular concern. As noted by the Chair, Paragraph 36(4)(c) of the Bill requires that the Licensing Committee have regard to any relevant guidelines issued by the NHMRC. Pursuant to that paragraph, the Licensing Committee would need to have regard to the Ethical Guidelines on Assisted Reproductive Technology.

However, those guidelines are under review and the revised draft is not available for Senators to take into account in their deliberations on the Bill.

The NHMRC advised the Committee that:

> The Australian Health Ethics Committee (AHEC) is currently reviewing the NHMRC *Ethical Guidelines on ART* and a consultation draft of these

86 Chair's Report, para [4.126] referring to the Senate Scrutiny of Bills Committee, Work of the Committee during the 38th Parliament, chapter 6.

87 Chair's Report, para [4.130]

88 *Committee Hansard*, 26/9/02, p.251.

> revised guidelines is likely to be released shortly. It is anticipated that these guidelines will include information about the types of matters that should be considered in order to establish that certain uses of excess ART embryos are likely to result in a significant advance in knowledge, or improvement in technologies for treatment as a result of the use of excess ART embryos.[89]

This is an important aspect of the regulatory regime, and contrary to AHEC's comments, work should have continued on those guidelines even when this Bill was introduced. The guidelines involved important ethical considerations, and should have been ready for the parliament's consideration of this Bill. AHEC stated that:

> AHEC considered carefully the timing of the release for consultation of the revised guidelines, which are presently entitled Ethical guidelines on the use of reproductive technology in clinical practice and research. It is the belief of AHEC that, even if the draft were ready for release for public consultation, it would be inappropriate for AHEC and the NHMRC to release the document before parliament has completed its current task ... We had originally hoped to conduct our public consultation and complete this by the end of the year. As we have made the decision to wait for parliament to complete the legislation, it may be later than that.[90]

Furthermore, in the review of those guidelines, information on how institutional ethics committees reached their decisions, what they saw as extraordinary circumstances, what types of research were regarded as perhaps extraordinary will not be available. Dr Breen of the Australian Health Ethics Committee of the NHMRC conceded this during public hearings:

> They are valid criticisms, and we do not have access to that information.[91]

It is not appropriate that AHEC does not have access to this very relevant information in its review process. This lends further support to arguments for parliamentary review.

It is not proper that Parliament delegate such a critical part of the licensing regime without the ability for proper parliamentary scrutiny of the substance of the Bill during our Inquiry.

Recommendation: that the revised guidelines should be referred to the Parliament – tabled in parliament and be disallowable by either House.

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89 NHMRC, Submission 23, p. 21.

90 Dr Breen, *Committee Hansard*, 26/9/02, p. 251.

91 *Committee Hansard*, 26/9/02, p.249.

Conduct of Inquiry

There are a few comments that remain to be made about the conduct of the Inquiry. There has been undue haste in the process, the period in which submissions could be made was very short, yet over 1800 submissions were received. In spite of the clear community interest in the process, public hearings were only held in Canberra, on sitting days (not typical for a Senate Inquiry). Time was regularly an issue for witnesses and Senators alike. It was an issue of considerable interest among Senators, and there were seemingly unnecessary time restrictions imposed.

The question needs to be asked why the passage of this legislation is so pressing an issue for some States and the Commonwealth Government. Embryonic stem cell research is occurring and will continue to occur, irrespective of the passage of the legislation.

It is disappointing to say the least, and does not help the perception that there are vested commercial and political interests at play.

CONCLUSIONS

In our consideration of this Bill we conclude:

- That human embryos surplus to ART purposes should not be exploited in destructive research. No persuasive argument has been put forward that justifies the destruction of human life.
- That research on pre-existing human embryonic stem cells lines can continue, as this research is not dependent upon the passage of the Bill.
- That research should use available resources without destroying human life. There are clearly very viable research alternatives open to scientists that will not result in the destruction of embryos.
- That there are a number of amendments to the Bill which we foreshadow, to address the inadequacies in the Bill that have been considered in these qualifying comments. Those inadequacies are particularised in Chapters 3 and 4.

SIGNATORIES

Full Members

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Senator Guy Barnett (Liberal Party, Tasmania)

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Senator Bill Heffernan (Liberal Party, N.S.W.)

_____

Senator Stephen Hutchins (A.L.P., N.S.W.)

Participating Members

_____

Senator Mark Bishop (A.L.P., W.A.)

_____

Senator Ron Boswell (National Party, Queensland)

_____

Senator Jacinta Collins (A.L.P., Victoria)

_____

Senator Brian Harradine (Independent, Tasmania)

_____

Senator John Hogg (A.L.P., Queensland)

Supplementary Report in Favour of the Legislation

1. Introduction

1.1 The provisions of the *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* concern, directly and indirectly, issues of considerable public interest.[1]

1.2 The decision of the Council of Australian Government (COAG) of 5 April 2002 and subsequent legislation, are important stages in a long running debate in Australia and overseas concerning biotechnology, cloning and the regenerative potential of stem cell research.

1.3 In the course of this inquiry the committee received submissions and heard evidence from people and organisations with divergent and sometimes irreconcilable views. We recognise and respect the wide range of sincerely held views.

1.4 We do not believe any one particular group, be they politicians, scientists or church leaders, has any special privileged access to wisdom in such matters thus welcome robust and informed debate as an essential feature of a pluralist democracy.

Having considered the evidence and views carefully, we recommend that the Bills be passed.

2. Consideration of the Legislation

The Chair's Report

2.1 It is customary in a Senate Legislation Committee for the Chair's report to provide recommendations on the legislation before it. However, as the Coalition and Opposition granted Senators a conscience vote, the Committee decided that the purpose of the Chair's report was to balance the major issues and arguments relating to the provisions of the *Research Involving Embryos and Prohibition of Human Cloning Bill 2002,* without providing recommendations or conclusions (1.5).

2.2 We support this decision but simply state that no inference can or should be drawn from this concerning the capacity of the Parliament to arrive at a coherent majority position.

History of Debate

2.3 As the Chair's report points out, the issues concerning cloning and research involving embryos has been extensively debated over the past two decades,

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[1] All references to sections and clauses in the Chair's report are to the original Bill. However, as this was split in the House of Representatives subsequent to the referral to the Senate Committee, all references in this supplementary report will be to the two Bills that the Senate will actually debate.

particularly since 1998 (1.11 – 1.32). Moreover, the issues have been exhaustively debated in other jurisdictions notably in the United Kingdom, the USA (federally and in various states, including California) and Canada.

Research Involving Embryos and Prohibition of Human Cloning Bill 2002

2.4 On 29 August, 2002, the *Research Involving Embryos and Prohibition of Human Cloning Bill 2002*, was split in the House of Representatives. The *Prohibition of Human Cloning Bill 2002* was passed by the House on 29 August and the *Research Involving Human Embryos Bill 2002* was passed on 25 September 2002.

2.5 Though not noted in the Chair's report, the review provisions in the original bill were changed when it was split.

2.6 In the original Bill, the National Health and Medical Research Council (NHMRC) is required to cause an independent review of the Act (s61). This is retained in the *Research Involving Human Embryos Bill 2002* (s61) however in the *Prohibition of Human Cloning Bill 2002*, it is the Minister who causes an independent review (s25).

2.7 s.61(2) of the *Research Involving Human Embryos Bill 2002* requires the review be undertaken by the same people and concurrently with the Minister's review of the *Prohibition of Human Cloning Act*.

2.8 The net effect is to ensure the Minister rather than the NHMRC selects the people who will conduct the review. However, there is a requirement in both the original and subsequent split bills that the persons selected must be approved by each State. Therefore, we do not consider this change to be of material significance or inconsistent with the intent of the COAG communiqué, thus see no compelling reason to amend the Bills to bring these provision strictly into line with the original Bill.

2.9 In our view, the *Prohibition of Human Cloning Bill 2002* is very widely supported throughout the community and for very good reasons. We believe human reproductive cloning is unethical and unacceptable and recommend the Bill be passed in its current form.

2.10 By contrast, the *Research Involving Human Embryos Bill 2002* is more contentious and most of our supplementary comments go to issues directly or indirectly related to this Bill.

COAG and the Legislation

2.11 The legislation enacts the COAG communiqué of 5 April 2002, and

- provides for a national framework for the regulation of research on excess assisted reproductive technology (ART) embryos that would otherwise be destroyed;

- prohibits the creation, importation, export or implantation of a human embryo clone and provides for legally enforceable sanctions against these and other prohibited practices;

- establishes a national licencing committee of the NHMRC that will assess applications for licences to conduct;

    - research,

    - training in ART techniques

    - quality assurance in ART

    - examine effectiveness of new culture media in ART.[2]

- provides a centralised, publicly available database of information about all licences, the number of research projects involving excess ART embryos, the nature of those projects and the numbers of excess embryos being used.

2.12 The legislation seeks to treat all uses of excess ART embryos even-handedly. All non-exempt activities will require scrutiny and approval at the local human research ethics committee (HREC) level and at the national level of the NHMRC licencing committee.[3]

2.13 We also make the point that the legislation is relatively conservative. For instance, the *Prohibition of Human Cloning Bill 2002* bans;

- Somatic Cell Nuclear Transfer (s.13) - which is permissible in the UK, Israel and non-National Institutes of Health funded research in the USA.

- Cytoplasmic transfer (s.15), a new ART treatment, which may be of benefit for older women and is permissible, for example, in the USA, Italy, Israel and Taiwan.

- Germ line gene therapy (s.18) - which may have considerable benefits overcoming heritable diseases such as Spina Bifida.

2.14 In addition, the *Research Involving Human Embryos Bill 2002* applies a new level of regulation on some practices in IVF clinics that have been carried out, with no apparent systematic abuse, for up to 25 years in some cases.

Consequences if Research Involving Human Embryos Bill Fails

2.15 We believe it is important to understand what will occur if the *Research Involving Human Embryos Bill 2002* is not passed.

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2 EM, Research Involving Embryos and Prohibition of Human Cloning Bill 2002, p. 18

3 Dr Clive Morris, NHMRC, *Committee Hansard*, 29.8.02, p. 7

a) It will have no impact on the rate of production and disposal of ART embryos;

b) Embryonic stem cell research will continue on existing lines (which we are advised are not acceptable for future clinical research – and are limited for research purposes - as they were created using mouse feeder cells);[4]

c) As most jurisdictions do not ban or regulate destruction of embryos to derive embryonic stem cells then retention of status quo will mean such activities are permissible in all jurisdictions apart from VIC, SA and WA;

d) The States and Territories can determine their own approach and given the public comments of several State premiers, this may result in more liberal regimes than this Commonwealth legislation permits;

e) Substantial differences between VIC, SA and WA relative to the other States and Territories may lead to inconsistent approaches, criteria and "possible loopholes and safe havens";[5]

f) There will be no central agency to provide oversight, informed monitoring or review;

g) There will be no central data collection agency; and

h) Research may be hampered as researchers will only be able to access existing stem cell lines, or lines from overseas from, most likely, commercial sources who may require some rights over IP developed from the research.[6]

2.16 In addition, defeat of the legislation may send a strong negative message about Australian science policy, both domestically and internationally. Uncertainty and inconsistency may lead to a loss of scientists – in an area where Australia is recognised as a world leader – to more liberal or consistent regulatory regimes including the UK, Singapore and the USA.[7]

2.17 Such an outcome is inconsistent with recent policy initiatives or election statements including the *Wills report*, the Coalition's *Backing Australia's Ability*, the Labor Party's *Knowledge Nation* and the Democrats' Higher Education, Innovation and Science policy statements. Having said that, it can be argued that the impact on the science community – in terms of 'brain drain' and loss of control over commercialisation of research done in Australia - is not sufficient, in and of itself, to support the Bill.

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4 Bresagen, Submission No. 1030.

5 Queensland Government, Submission No. 1500.

6 Professor de Kretser, Submission No. 1041, Professor Trounson, *Committee Hansard*, 24.9.02, p. 153

7 Bresagen, Submission No. 1030, p. Privately funded ES research is largely deregulated in the USA.

3. Scientific and Ethical Issues

3.1 Chapters 2 and 3 of the Chair's report provide a summary of the scientific and ethical issues and views put to the committee in this inquiry. Moreover, as the Chair's report points out, the scientific and ethical issues have been well canvassed in various reports and inquiries (2.2).

3.2 Unsurprisingly, much of the inquiry focused on the scientific and ethical dimensions of embryonic stem cell research, and the relative merits of embryonic and adult stem cells.

3.3 Strictly speaking, many of the concerns raised in the Committee's inquiry are outside the direct concerns of the provisions of the Bills but nevertheless form a helpful backdrop to understanding the issues at hand.

Ethical question

3.4 The central ethical question posed by the legislation is whether people believe destructive research on excess ART embryos that have been donated with consent, and which would otherwise be allowed to succumb, is acceptable or not. Or to pose that question in more general, philosophical terms: Is an embryo the moral equivalent of an adult or a child?

3.5 We believe that for any one person, the answer to that question ultimately relies on their personal commitments. As Dr Best, representing Dr Jensen, the Anglican Archbishop of Sydney, pointed out;

> The moral status of an embryo is not a fact but a value. We will each decide that which is valuable to us on the basis of our world-views. But we live in a multicultural democracy and world-views abound.[8]

3.6 While we respect the wide range of sincerely held views, there is clearly no prospect of consensus or the acceptability of an absolute position in a pluralistic society.

3.7 Chapter 3 of the Chair's report provides a framework for considering the question and we do not intend to recapitulate that work here.

3.8 We do, however, wish to offer some comments about the ethical debate both in terms of the inquiry and more broadly.

a) To a significant extent, the Committee can only deal with the submissions and oral evidence it receives. It cannot be assumed therefore, that the views expressed in an inquiry exhaust the issues or are broadly representative of community opinion.

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8 *Committee Hansard*, 24.9.02, p. 155

b) It is fair to say that the vast majority of the evidence opposed to destructive research on embryos on ethical grounds came from individuals or organisations with explicit religious or church commitments.[9]

c) The committee neither sought nor received evidence from other professional philosophers who may have provided other perspectives on the ethical questions.

d) We do not believe it is helpful or fair to reductively characterise the debate as a battle between, say, 'radical Utilitarians' or 'dogmatic Christians' (or, indeed, science and religion). The evidence, particularly from those opposed to destructive research on embryos, ranged from the highly nuanced through to very direct, simple dogmas.

3.9 There are elements of the ethical debate, which are not novel.

3.10 The ethics of donating organs or tissue is well considered. The question of whether an embryo or foetus has the equivalent moral status as an adult has been widely addressed in debates on abortion. Moreover, the issue of whether there is an important distinction between actively facilitating death or allowing someone to die by withdrawing medical life-support systems is widely canvassed in voluntary euthanasia debates.

3.11 However, as Dr Best pointed out, analogies to other ethical debates are limited;

> When you create an embryo in an ART process, you are planning for that to become a life and it is very carefully made and implanted; whereas most pregnancies, in an abortion context, have occurred by accident – they were not planned pregnancies. Also in the case of an abortion you have the competing needs of a mother. In New South Wales, abortion is allowed because of the mother's rights to avoid any particular hardship that any pregnancy would cause – whereas in the case of a frozen embryo, the mother is not pregnant and there is no risk to her health.[10]

3.12 The substantive difference between destructive research on embryos and, say, the abortion debate is highlighted by Dr Van Gend, a General Practitioner representing Do No Harm, who stated:

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[9] Eg Australian Catholic Bishops Conference, submission 981, Anglican Diocese of Sydney, Social Issues Executive, Submission No. 672, Queensland Bioethics Centre is an agency of the Catholic Archdiocese of Brisbane. Mr Campbell, *Committee Hansard*, 26.09.02, p. 217 (We make it clear this is a transparent relationship and no attempt was made by QBC to represent itself as independent). Catholic Health Australia, Submission No. 897, Catholic Women's League Australia Submission No. 882, Catholic Archdiocese of Melbourne, submission No. 876, Right to Life Australia, Submission No. 1003. In addition, Southern Cross Bioethics Institute's parent is Southern Cross Care which was established by the Knights of the Southern Cross: *Committee Hansard* 17.09.02, p61. Dr Nicholas Tonti-Filippini is a consultant ethicist to the Catholic Church.

[10] *Committee Hansard*, 24.09.02, p. 168

> at the heart of the matter before us is whether we do harm to the human embryo by commodifying it as a raw material for science, whether we cross the line where for the first time a subgroup of the human family becomes defined as material that can be used destructively for the benefit of others.[11]

3.13 However, to what extent people will choose to weight the various ethical dimensions to this debate is a personal choice. Potential donors of embryos, for instance, face a rather different set of ethical issues than a non-donor, and these do include considerations of autonomy and choice.

3.14 As a community, we do not currently accept an absolutist determination on the moral status of an embryo or hold 'uniform protection of all human life'. This does not mean, however, that the embryo is of no account.

3.15 We are concerned, therefore, that in considering the ethical debate, the options should not be collapsed to a choice between a (morally sophisticated) rejection of destructive research on embryos and a (laissez-fair) utilitarianism that supports it.

3.16 We do not accept Archbishop Wilson's claim that "the radically utilitarian public policy which supports this legislation creates a significantly dangerous, if not chilling, precedent."[12] There is nothing inevitable about what choices people might make in the future.

3.17 We do not believe people have to be committed to a crude utilitarianism or moral relativism to hold a position that supports regulated and prudent research on genuinely excess ART embryos that have been donated with full and informed consent.

Stem Cell Science

3.18 The committee received considerable evidence and commentary on stem cell science and this is extensively considered in the Chair's report (primarily chapter 2).

3.19 In our view, the key points that emerged from that evidence are as follows.

- Stem cell science is in its infancy. Human embryonic stem cells were first isolated and characterised in 1998 and adult stem cell research followed shortly after (although some therapeutic uses of adult stem cells associated with bone marrow have been successfully used for approximately 40 years).

- Stem cell science is a fast moving field with new insights and research results appearing in the scientific literature with great rapidity.

- Possible therapies that may arise from stem cell science include:

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[11] *Committee Hansard*, 24.09.02, p. 175

[12] *Committee Hansard*, 24.09.02, p. 214

  - Replacing or transplanting damaged or diseased cells with tissue developed from stem cells; and

  - Development of drugs or other therapies to control and direct cell differentiation.

- While some results in adult stem cell research and therapies and mouse embryonic stem cell research appear well confirmed, many results, including, for instance, Professor Verfaillie's recently published work identifying and culturing a rare adult stem cell, have not been confirmed or replicated in other laboratories.[13]

- The characteristics of stem cells and basic biological questions such as understanding the factors that contribute to cell differentiation, specialisation and regeneration are not at all well understood. This constitutes a fundamental and significant ongoing research challenge for stem cell science.

3.20 Consequently, we believe it is premature and unreasonable to expect definitive answers on many of the questions that arise from stem cell science. We see unpredictability and uncertainty as intrinsic characteristics of science particularly at the forefront of a new and complex field. Whether scientists will fully or partially address the myriad challenges and questions in the short, medium or long term is simply not known.

Embryonic Stem Cells

- Embryonic stem cells are derived from embryos, which necessarily results in the contentious destruction of the embryo.

- Embryonic stem cells by definition, can give rise to all tissue types (pluripotent). Specialised cell types from human ES cells, including heart muscle, insulin producing cells and nerve cells have been successfully derived.[14]

- ES cells can be placed in a culture medium and replicate and remain undifferentiated indefinitely.

- There have been no therapies, treatments or cures developed from human embryonic stem cells to date.

- There are considerable problems to overcome if embryonic stem cells will have therapeutic application for tissue transplantation because of immunological rejection and insufficient knowledge to control differentiation (in animal

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[13] Yiang Y et al, *Pluripotency Of Mesenchchymal Stem Cells Derived From Adult Marrow*, *Nature* 418, pp. 41-49, 4 July 2002. Given the weight attached to this paper in arguments privileging adult stem cell research over embryonic stem cell research we emphasize that this comment does not infer that Verfaillie's results are flawed. It would be surprising if the result had been replicated so soon after publication.

[14] Associate Professor Pera, Submission No. 873, p. 2

experiments, embryonic stem cells have demonstrated a tendency to produce benign tumors called teratomas).[15]

3.21 These problems were acknowledged by all proponents of stem cell research and the committee was advised of a variety of research projects seeking to overcome them.[16]

- Bresagen described its current work exploring methodologies to 'reprogramme' adult stem cells from a patient by fusing them with an embryonic stem cell to avoid immunological differences. This work has had qualified success with mouse models but to date, is neither successfully established nor practical.[17]

- Professor Trounson advised the committee (and provided relevant academic articles) of work being conducted by Associate Professor Boyd to 'tolerise' tissue.[18]

3.22 It is not possible to predict whether such work will be successful in overcoming immunological rejection of ES cells in some or all transplantation therapies. That is an empirical question that cannot be decided at this stage. As a consequence, proponents of ES research advised that transplantation therapies may be 5, 10 or 15 years away if at all.[19]

3.23 Professor Bartlett informed the committee that:

> In fairness to companies like Bresagen, they are aware that therapy is 10 – 20 years away. Stem Cell International's CEO has said publicly that therapy, in their eyes, is 10-20 years away.[20]

3.24 He also outlined the 'clearly defined' difficulties that need to be overcome to achieve ES therapies. He concluded:

> In no way am I suggesting that we should not have a shot at seeing if embryonic stem cells really can fulfil a potential that these other cells cannot

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15 Refer Professor Good, Submission 614, also his contributions in *Committee Hansard*, 19.9.02, pp. 89-91.

16 However, Dr Simmons also stated "but to be fair, in kidney transplants patients are given immunosuppressive drugs and they may be on those for many years, as a means of combating rejection in that setting, and that is viewed as a perfectly acceptable therapy". *Committee Hansard*, 19.9.02, p. 97

17 Bresagen, Submission No. 1030, p. 4. Dr Tonti-Filippini also referred to such techniques suggesting that such an approach may yield an embryo if placed on a bed of tetraploid embryos. Although he qualified this by noting that it is not known whether this capacity (totipotency) is intrinsic to stem cells or to the capacity of the bed of embryos. *Committee Hansard*, 24.9.02, pp. 169-170. It is widely held that stem cells are not totipotent, in any event, the use of this technique to create an embryo would be banned in the legislation.

18 *Committee Hansard*, additional material.

19 See, for example, Professor Tuch, *Committee Hansard*, 17.9.02, p. 47

20 *Committee Hansard*, 19.9.02, p. 99

> … as a scientist I know that discoveries do not often come in a linear manner; they come from left or right field. So I would never cut off a potential cure base or a potential discovery because of the thought that you know the answer.[21]

3.25 We conclude that ES cell research may lead to successful therapeutic applications in the future. It is not certain what form therapies might take (drugs or transplants), nor is it certain which diseases may be amendable to ES therapies. In view of the potential of embryonic stem cell research, we believe it is premature to unnecessarily constrain or prohibit research.

Adult Stem Cells

- Adult stem cells pose no additional ethical issues beyond those associated with convention clinical practice.

- Adult stem cells are difficult to isolate and are not easy to grow or remain undifferentiated in culture. Dr Simmons, an adult stem cell scientist, advised;

  > adult stem cells are limited in numbers and we cannot grow all the adult stem cell populations we would like. These are two important limitations of adult stem cells which, in fairness, the committee needs to take on board if it is to engage in a rational debate on the relative merits of embryonic and adult stem cells.[22]

- Treatments using adult stem cells have been successful or promising with quite a range of diseases including cancer, damaged heart tissue and anaemias.[23] However, it was also argued that adult stem cells have not demonstrated the capacity to meet all needs for cell therapy.[24]

3.26 There was broad based and well-founded support for adult stem cell research. No evidence or oral evidence advocated cessation of adult stem cell research.

3.27 We conclude this is an important area of stem cell science well deserving of public support including funding.

3.28 It should be noted that the legislation has no impact on adult stem cell research.[25] Therefore, it could be argued that, strictly speaking, much of the evidence concerning the utility and potential of adult stem cells was irrelevant to the inquiry. We do not hold that view as the evidence and discussion on adult stem cell research

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[21] Professor Bartlett, *Committee Hansard*, 19.9.02, p. 95

[22] Dr Simmons, *Committee Hansard*, 19.9.02, p. 92

[23] For an extensive bibliography of treatments using patients own stem cells refer Dr Tonti-Filippini, Submission No. 86, pp.10-17. See also Do No Harm, Submission No. 1042

[24] Dr Chris Juttner, Bresagen, *Committee Hansard*, 17.9.02, p. 32

[25] That is not strictly true as there are implications for resource allocation and competition for funds whether the legislation was passed, amended or defeated.

provided a useful perspective to consider embryonic stem cell research specifically and stem cell science more broadly.

Synergies Of Adult And Embryonic Stem Cell Research

3.29 As the Chair's report notes a number of submissions argued or implied that recent developments in adult stem cell research and therapies made embryonic stem cell research redundant (2.98).

3.30 This was firmly rejected by a number of scientists specialising in embryonic and adult stem cell work.[26]

3.31 Dr Simmons argued that many of the experiments purporting to demonstrate 'plasticity' of adult stem cells had not been replicated and "some reported phenomena have been shown to be artefacts due to contamination of transplanted cells."[27]

3.32 Considerable interest was shown throughout the inquiry in the recently published work of Professor Verfaillie and her team. They isolated rare cells from bone marrow, muscle and brain called Multi-potential Adult Progenitor Cells (MAPCs). These cells are slow growing, and to date, their isolation has only been achieved by Professor Verfaillie's team.[28]

3.33 Dr Elefanty advised the committee that MAPCs:

> are able to differentiate into a range to tissue types in vitro and upon transplantation in vivo, although this is not yet an efficient process. MAPCs are different from embryonic stem cells in their appearance, the genes they express and their growth requirements.

3.34 He further added:

> To highlight the difference between adult and embryonic stem cells, I refer to an analysis of the genes expressed by embryonic stem cells and adult stem cells and neural stem cells performed by Melton's group in the USA. These results were published on-line in *Science* on 12 September of this year:
>
> > Our results show that SC's (stem cells) are distinct in that each SC can clearly be identified by highly enriched genes that are not present (or not enriched) in other SCs
>
> It is apparent that adult stem sources of stem cells have great potential to provide cellular therapies and, indeed, no scientist or physician working on embryonic stem cells are advocating that research into these sources for transplantation be abandoned. However, it is just as clear that there are restrictions on the availability and

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[26] Professor Simmons, Dr Elefanty.

[27] Submission No. 1292, p. 2 and also refer table 1.

[28] Drs Elefanty and Stanley, Submission No. 477, p. 2

> applicability of cells from any individual organ and that embryonic stem cells and adult stem cells are not identical.
> Therefore, it is prudent to isolate and investigate the capabilities of both embryonic and adult stem cells, since it may transpire that cells from different sources have specific applications for which they are best suited – horses for courses.[29]

3.35 Dr Simmons stated:

> Adult stem cell researchers and the embryonic stem cell researchers will benefit from understanding the two systems. In the end we both benefit. I think integration between the two is really important. There is a synergy there and it is a driving force for discovery, which neither field of stem cell research alone would likely produce.[30]

3.36 Professor Williamson, Director, Murdoch Children's Research Institute and Professor of Medical Genetics, University of Melbourne (and an adult stem cell researcher), stated:

> What I believe to be absolutely certain is that there are real benefits in allowing adult and embryonic stem cell research to proceed side by side in the same laboratories, so the experiments cross-refer and so that lessons can be learnt by comparing the two systems.[31]

3.37 Professor Trounson advised the Committee that a key feature of the National Stem Cell Centre will be the integration of researchers in adult stem cells, embryonic stem cells, transplantation biology and tissue engineering.[32]

3.38 Professor Verfaillie has adopted a similar approach. In a recent interview on the ABC she stated

> And so I think my message has always been, even though we're excited about the adult cells, that its too early to say that they will replace embryonic stem cells to the point that our institution, the Stem Cell Institute, we actually recruited and investigated who has extensive experience in human embryonic stem cell work, so we're now in a position to do … parallel research and comparing and contrasting the two cell types.[33]

3.39 We conclude that it is a false dichotomy to consider the issue in terms of embryonic stem cells versus adult stem cells. We believe a very strong case has been made to encourage research on both with a view to understanding their relative merits

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29 *Committee Hansard*, 24.9.02, p. 138

30 *Committee Hansard*, 19.9.02, p. 106

31 Submission No. 1002

32 *Committee Hansard*, 24.9.02, p. 142

33 Transcript of interview, Professor Catherine Verfaillie, The World Today, 22 August 2002, http://www.abc.net.au/worldtoday/s656192.htm

and disadvantages. Moreover, there is a very good case to be made for encouraging productive cross-fertilisation of ideas and methodologies. While not relevant to the Bill as such, we note that this synergy between adult and embryonic stem cell research is a central feature of the National Stem Cell Centre.

Embryonic Stem Cell Research – Broader Than Therapies

3.40 The strongest criticisms of proponents of human embryonic stem cell research (as science) was directed at the claims of the potential for the development of therapies to treat or cure diseases including Alzheimer's Parkinsons, Motor Neurone Disease and Type 1 diabetes.

3.41 For instance, Emeritus Professor Martin asserted

> All the proponents of human embryonic stem cell research rely ultimately on the one argument – that cures for chronic disease are sure to follow.[34]

3.42 In our view, a significant consequence of the focus on potential therapeutic applications was that there was a lack of appreciation that ES research is, in fact, multi-faceted.

3.43 A balanced view needs to be mindful that human embryonic stem cell research is a broad term that encapsulates a range of research projects.

3.44 In the course of the inquiry a number of these were identified including;

- Discovering the factors that influence and regulate cell differentiation and tissue formation[35];
- Developing methodologies to control differentiation
- Understanding how diseases occur and how particular genes lose their regulators and are associated with cancer or are involved in formation of cells of genetic diseases;[36]
- Screening drugs for toxicology and effectiveness on stem cell lines that have differentiated into liver, kidney, heart and other cell types[37] (not to be confused with possible toxicology studies on embryos); and
- Possible therapies including tissue transplant and pharmaceuticals.[38]

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[34] Submission No. 162, p. 4

[35] Professor Trounson, *Committee Hansard*, 24.9.02, p. 135

[36] Professor Tuch, *Committee Hansard*, 17.09.02, pp. 40-1, professor Trounson, *Committee Hansard*, 24.9.02, p.135

[37] Dr Juttner, *Committee Hansard*, 17.9.02, p. 40, see also comments of Professor Trounson, *Committee Hansard*, 24.9.02, p. 141, submission Elefanty and Stanley

[38] Professor Trounson, *Committee Hansard*, 24.9.02.

3.45 While science does not neatly divide into basic and applied research, there is clearly a spectrum of discovery and application elements to these broad strands of human ES research.

Are more stem cell lines required?

3.46 If, as we have concluded, there is a strong case for ongoing human embryonic stem cell research, there is a question as to whether existing stem cell lines are adequate.

3.47 Throughout the inquiry there was extensive discussion on how many embryos would be required. Oddly, there was little discussion on the more fundamental question of *why* more embryos might be required.

3.48 It was suggested to the Committee that as there was little prospect of clinical trials using human ES cells in the short to medium term there was no need for additional stem cell lines (thus access to more embryos) because there were adequate existing stem cell lines available for research.

3.49 Professor Silburn, whilst highly critical of the claims concerning possible therapeutic applications of embryonic stem cells, did not object to ongoing research but questions why more embryos are required.[39]

> I think the research should go ahead – absolutely – and it will go ahead whether or not the bill fails … Parkinson's Australia is very happy for research to continue, and I will be pleased to report to everybody that if the bill fails that research will continue.[40]

3.50 Professor Good stated:

> There are already ES lines that will not be affected by the act, which could be used for research. They are already there, they will not be blocked by the act. So why do they want more embryos? The only reason I can think of is that drug companies may wish to use them for screening.[41]

3.51 There seems to be some difference of opinion on this among scientists. Bresagen, for instance, submitted that there is no current need to derive new human embryonic stem cell lines for research, in part, because, new ESC lines will not be eligible for world wide National Institutes of Health research funding.[42]

3.52 In response to a question from Senator Barnett, Mr Ilyine advised the committee:

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39 *Committee Hansard*, 17.9.02, p. 52

40 *Committee Hansard*, 17.9.02, p. 53

41 *Committee Hansard*, 19.9.02, p. 98

42 Submission No. 1030, p. 3

> You suggested that there are a number of people who provided evidence that said that there were no further cell lines needed more or less forever. I think experience in time has shown that that is not really the correct position, which is that there are in fact additional cell lines needed for all sorts of reasons. We already have made some progress from mouse feeder cell systems to human feeder systems, but I would argue that perhaps that is not far enough either, and that actually the cells in time, to be fully GMP compliant, would have to be able to grown in a fully defined medium where all the components of the medium were known and understood to be safe in their own right.[43]

3.53 In evidence and discussion a range of reasons why new embryonic stem cells were required for research were offered.

- Existing stem cell lines have been created with mouse feeder cells "which produce as yet unidentified substances necessary for stem cell research.[44]

- New stem cell lines will need to be created because feeder layers give signals to the cells to allow them to change from inner cell mass lines to cell lines but it is likely that those cell lines will behave differently so that research conducted with mouse-derived feed cells will need to be repeated with human-derived feeder cells.

- Restricting access to existing SC lines is a problem for obtaining proof of principle because "you do not want to be doing experiments on cell lines that have been passaged for hundreds and hundreds of passages. If one were restricted to a very few lines, whether they be mouse or human, the likelihood of being able to obtain that proof of principle may be difficult. You would want to be dealing with cells that were in the best possible state."[45]

- As ES research is in its infancy, it is likely that future methodological improvements in initiating and growing stem cell lines will lead to second generation lines with improved properties.[46]

- Where there are commercial barriers to existing stem cell lines, researchers will want to create their own lines[47]

3.54 In addition, a number of reasons why additional stem cell lines were required for therapeutic reasons were identified, including:

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43 *Committee Hansard*, 17.9.02, p. 40

44 Associate Professor Pera, *Committee Hansard*, 24.9.02, p. 135

45 Professor Bartlett, *Committee Hansard*, 19.9.02, p. 100

46 Associate Professor Pera, *Committee Hansard*, 24.9.02, p. 135, Dr Stanley, ibid, p. 139

47 Mr Ilyine, *Committee Hansard*, 17.9.02, p. 40, Associate Professor Pera, *Committee Hansard*, 24.9.02, p. 135, Professor Trounson, ibid, p. 140

- Human ES lines using mouse feeder cells are considered by the FDA to be contaminated by animal pathogens (xenotransplant) and thus not permitted for clinical trials;[48]

- If and when there is a prospect of safe human trials, stem cell lines compliant with the FDA's current Good Manufacturing Practice (cGMP) guidelines will be required; and [49]

- Clinical therapies using embryonic stem cell lines will have to address immunological rejection and this may require larger panels of stem cell lines.[50]

3.55 Moreover, relying on mouse ES lines is problematic when trying to investigate some diseases. Professor Bartlett informed the committee that:

> animal models are in fact deficient in terms of reflecting the actual disease process. This is because we do not actually know what causes Alzheimer's disease or what causes motor neurone disease. So you have animal models that result in a similar complaint, but they may not reflect the underlying cause of that disease.[51]

3.56 We conclude that a strong case has been made to support the need for new stem cell lines and that existing stem cell lines are not adequate for research and, in the longer term, therapeutic purposes.

How Many Embryos required?

3.57 Recognising that there is an established need for new stem cell lines, the next question - and one that prompted considerable debate during the course of the inquiry - is how many embryos will be required.

3.58 It is likely that the biggest call in the short term will come from IVF Clinics. Professor Jansen advised that hundreds of embryos will be required to develop meaningful results in development of culture medium.[52]

3.59 In respect of embryonic stem cell research, there was a very wide range of numbers offered including 20 – 50 (Trounson), 600 – 1000 (Bresagen), through to millions (Good).

3.60 There was considerable comment on the disparity of these figures. Professor Silburn stated, for instance, that:

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48 Professor Trounson, *Committee Hansard*, 24.9.02, p.140

49 Dr Juttner, *Committee Hansard*, 17.9.02, p. 38, Professor Tuch, *Committee Hansard*, 17.9.02, p. 39

50 Associate Professor Pera, *Committee Hansard*, 24.9.02, p.135

51 *Committee Hansard*, 19.9.02, pp. 100-101

52 *Committee Hansard*, 26.9.02, p. 211

> clearly if the point of the bill is how many we need and nobody can agree on how many we need, we are lacking some science here.[53]

3.61 Professor Trounson explained that part of the difficulty in estimating the number of stem cell lines needed in the future was that:

> it would depend on the outcome of the research. If the research were shown to be successful in the induction of (immunological) tolerance to embryonic stem cells and their derivatives, we may need a panel of embryonic stem cells, in which case maybe 50 is sufficient. I am not really certain, but it would be a number of them. They would have to give you advice in the future when the research was done.[54]

3.62 Dr Juttner believed that 600 – 1000 such therapeutic lines will provide adequate immunological matching.[55]

3.63 Professor Good disputed these figures and outlined some of the complexities of donor matching: I believe that to get a (stem cell line) bank suitably large enough to guarantee you a reasonable chance of finding a correct tissue typing match, you would need a bank of approximately 10 million.[56]

3.64 Professor Silburn is correct, there is some science missing. What is missing, as discussed above, is certitude as to how or whether immunological rejection of embryonic stem cells can be overcome. That is the fundamental basis of the disparity in the figures.

3.65 Although it may seem odd, the arguments are entirely consistent. Professor Good is arguing that millions of stem cell lines are likely to be required to maximise a good match to minimise or eliminate immunological rejection *if no other techniques are discovered to avoid this*.

3.66 Bresagen and Trounson are arguing that they might be able to overcome that by a variety of approaches *and if that is successful* then they believe considerably less lines will be required.

3.67 While we understand the preference and desire for certitude we see uncertainty as an intrinsic feature of new and complex areas of research. We do not regard the disparity as a defect, but simply underscores the fact that this is emergent research. It does, however, reinforce the argument for good, nationally consistent regulation.

3.68 We find it quite unremarkable that there were divergent and at times strongly held differences between scientists concerning the therapeutic potential of embryonic

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53 *Committee Hansard*, 17.9.02, p. 52

54 *Committee Hansard*, 24.9.02, p. 141

55 Bresagen, Submission 1030, No. 1

56 Professor Good, *Committee Hansard*, 19.9.02, p. 90

stem cells. Disputes over the facts and the meaning of the facts is common, typical even, in science, particularly in fields as complex and new as stem cell research.[57]

3.69 It should be noted that COAG requested the NHMRC report within 12 months on the adequacy of supply of excess ART embryos which otherwise would have been destroyed because of the lack of detailed knowledge on the numbers of embryos available for research.[58]

Are there really 70,000 'excess' embryos?

3.70 It was widely claimed in inquiry submissions and by witnesses that there are about 70,000 excess ART embryos. This is not correct.

3.71 The Committee was advised that there are 71,176 ART embryos in *storage* because the couples for whom they are created either still want them; have not decided that they are no longer required; or if excess, have not determined what they want to do with them.[59]

3.72 It is not known how many of these are excess in any given year or how many would be available for research.

3.73 The NHMRC provided data from the South Australian Council on reproductive Technology which shows that, as of 31 December 2001;

- 5718 embryos in storage
- 1239 were stored for couples who at the time still intended to use the embryos
- in 2001, 423 embryos were destroyed (374 at the couples request)
- 110 embryos donated for use by other couples
- 137 embryos donated for research.[60]

3.74 Professor Peter Illingworth, also provided advice to the Committee that

- 450 letters were sent out to couples with embryos in storage for more than 2 years
- 100 couples responded;

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[57] There is a vast literature in History, philosophy and sociology of science that outlines the nature of scientific disputes. The work of Kuhn, Latour, Cangelheim and Feyerabend, for example, are well established 'classics' in these fields.

[58] Council of Australian Governments – Communiqué http://www.pm.gov.au/news/media_releases/2002/media_release1588.htm. See also Dr Clive Morris, NHMRC, *Committee Hansard*, 29 8.02, p. 7 and p. 29

[59] NHMRC Submission No. 23, additional information, 13.9.02, p. 11

[60] ibid, p. 12

- 50 couples had moved; and
- 250 couples did not respond.

3.75 Only 15 couples (3% of couples written to) decided that their embryos were excess to their requirements. Of these;

- 7 couples requested that their embryos be allowed to succumb; and
- 8 couples indicated an interest in donating their embryos. All attended counselling but only three couples went on to donate their embryos.[61]

3.76 The SA data combined with Professor Illingworth's experience suggest:

- There are manifestly not 71,000 excess ART embryos;
- The number of embryos available for research and stored prior to 5 April 2002 is likely to be very small;
- It can not be assumed that many couples will seek to donate embryos excess to their requirements.

Creation of excess embryos

3.77 The prospect of creating excess embryos for research was also raised in the context of restrictions on accessing embryos created after 5 April 2002 after three years or earlier if determined by COAG.

3.78 In their submission to the inquiry, the Southern Cross Bioethics Institute asserted;

> If embryos created at any time and excess to the requirements are available to researchers, it would not be difficult to create an excess of embryos by simple changes to practice of IVF clinics. This would in effect constitute the *de facto* production of human embryos deliberately for the purpose of research.[62]

3.79 In a question on notice by Senator Stott Despoja, witnesses were asked

> Do you agree with the assertion that creation of excess embryos could be done with 'simple changes to practices'? It seems to me that there are two elements to this – the regulatory and the medical.

3.80 In response Professor Illingworth advised the committee that:

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61 Professor Illingworth, Westmead Fertility Clinic, Communication to the Secretary, 10.02

62 Rev. Dr John Fleming and Dr Gregory Pike, Southern Cross Bioethics Institute, Submission No. 892, p. 9

This assertion is unfounded. I would like to make the following points in response.

Medical

1. As outlined in my presentation, due to the variable and highly unpredictable factors involved in the achieving the result of healthy embryos for implantation, current clinical practice is to stimulate the ovaries with the aim of collecting 10 or so healthy eggs in the hope that sufficient will fertilise normally then develop satisfactorily in order to give a chance of a successful pregnancy.

2. The number of eggs is primarily dictated by the number of eggs already growing in the ovary at the time of starting treatment with fertility drugs. The number of eggs already growing in the ovary at the time of treatment cannot be altered by any means currently known to medical science.

3. Thus most patients undergoing IVF already receive a maximal dose of fertility drug and giving a higher dosage will not increase the number of available eggs.

4. There are however a small number of younger patients where a sub-maximal dose is used. This is because the maximum dosage would stimulate a very high number of eggs to grow in these women. This outcome would put those patients at risk of a serious medical condition (called ovarian hyperstimulation syndrome) which leads to accumulation of fluid in the abdomen and sometimes chest with very serious health consequences for the patient.

5. The deliberate and dangerous use of these maximal doses in a minority of younger patients is thus the only way that creation of excess embryos could be initiated

Regulatory

Such a practice would be contrary to explicit RTAC guidelines. As of this year, the data reporting process for IVF clinics to the National Perinatal Statistics Unit has been extended to include a requirement for every clinic to report quite specific information about the number of eggs collected and the number of embryos being collected per treatment cycle for every clinic in Australia. Through this process, these data for each clinic will be compared with natural means. If any clinic did opt for the unethical and unacceptable practice

> suggested above, this will be readily apparent to RTAC from this data set and RTAC would be able to act accordingly.[63]

3.81 In a subsequent communication to the Committee, Southern Cross Bioethics cited evidence given by Dr Jansen to the Senate Select Committee on the *Human Embryo Experimentation Bill 1985* where he stated:

> It is a fallacy to distinguish between surplus embryos and specifically created embryos in terms of embryo research … any intelligent administrator of an IVF program can, by minor changes, in his ordinary clinical way of going about things, change the number of embryos that are fertilised .. it would be but a trifle administratively to make those embryos surplus rather than special.[64]

3.82 Following on, Southern Cross Bioethics stated:

> "Presumably, all that would need to change would be more eggs would be collected and fertilised. Coupled with a trend towards less embryos being transferred, it is likely that even more surplus embryos would be created surplus to requirements and therefore able to be used in research.[65]

3.83 This, they stated, was the basis for their statement that it would not be difficult to create an excess of embryos, in their submission (cited above).[66]

3.84 The 1985 quote of Professor Robert Jansen was referred to a number of times during this inquiry, notably by Senator Harradine.

3.85 It is important to note that in his submission to this inquiry, Professor Jansen explicitly refuted his position of 1985.[67] He pointing out he had changed his position of 17 years prior because of advances in scientific knowledge of the ovulation process.[68] In evidence entirely consistent with Professor Illingworth's and Dr Pope's, he stated that "the number of eggs and embryos available to the woman also is fixed by physiological processes out of the physician's control".[69]

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63 Professor Peter Illingworth, response to Question on Notice. Evidence consistent with Professor Illingworth's comments was also provided by Sandra Dill of Access and Professor Doug Saunders, Chair of RTAC. See also ACCESS fact sheet #32 – Ovarian Hyperstimulation Syndrome by Professor Geoffrey Driscoll.

64 Hansard Report 1986, Vol. 1, p. 391-2, cited in Southern Cross Bioethics Institute, Submission 892, additional information, 2.10.02

65 Southern Cross Bioethics, *Letter to Secretary, Senate Community Affairs Committee*, October 2, 2002

66 ibid

67 Professor Robert Jansen, Submission 897, see also *Committee Hansard*, 26.9.02, pp 207-208

68 ibid

69 ibid

3.86 While we take Southern Cross Bioethics' point that a trend to less embryos being transferred may increase the number of excess embryos it does not follow that there are medical grounds to reduce the number of ova taken for IVF treatments.

3.87 Professor Jansen advised the committee that "it is not medically possible to vary the numbers of eggs that respond to stimulation upwards at all and it is not possible downwards without compromising the chance of success for the woman."[70] The clear message being there are good medical reasons for the current numbers of ova utilised for IVF treatment.

3.88 We conclude that there are no grounds to substantiate Southern Cross Bioethics' assertion that "it would not be difficult to create an excess of embryos by simple changes to practice of IVF clinics… (for) … the *de facto* production of human embryos deliberately for the purpose of research". Moreover, the Bill makes it an offence to deliberately create embryos for research.

3.89 Senator Harradine and a number of witnesses made much of Professor Jansen's 1985 comments to highlight concerns about deliberate production of excess embryos.[71] We would like to place on record our belief that Professor Jansen's refutation of his earlier position is highly credible and entirely consistent with the medical and scientific evidence provided by Professor Illingworth and Dr Pope. Consequently, we contend that any further citation of his 1985 statements that deliberately seeks to advance a position contrary to his current view must be considered mischievous.

4. Impact on IVF Practices

4.1 The committee heard evidence that the legislation would have a significant impact on current IVF practices.[72]

4.2 A major concern is the requirement that training, quality assurance and testing of culture mediums would need to be a licenced activity. These activities are already routine in IVF clinics and "are crucial for maintaining the highest quality care and improving success rates and so impact on couples currently on treatment.[73]

4.3 It was argued that the requirement that these activities be licenced meant the Bill went further than the COAG agreement (also see below).[74] The Committee was

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[70] Professor Robert Jansen, *additional information e-mailed to the Secretary*, 1 October 2002. Professor Jansen also points out that in 1985 embryos were not frozen, so embryos became surplus immediately. Dr Pope gave similar evidence.

[71] *Committee Hansard*, 29 8.02, p. 29

[72] Dr Adrienne Pope, Submission No. 1001, Monash IVF, Submission No. 1007, Access Australia Infertility Network, Submission No. 47, Professor Peter Illingworth, Westmead Fertility Clinic, *Committee Hansard*, 26.9.02, pp

[73] Access Australia Infertility Network, Submission No. 47, p. 4. Under Victorian, South Australian legislation there are some restrictions on such practices.

[74] Access Australia Infertility Network, Submission No. 47, p. 2

advised that these activities should be made exempt from requiring a licence and amendments (the 'Gambaro amendments') passed to treat training, quality assurance and testing of culture mediums as exempt items in s.25(2) of the Research Involving Embryos Bill 2002.[75]

4.4 However, the NHMRC advised the committee that

> including an exemption for training could create a loophole in the legislation because it would be very difficult to distinguish between training, quality assurance activities and research.[76]

4.5 The committee was also advised that the extension of the licencing requirements to practices that have long been conducted in all jurisdictions was to ensure consistent legal and ethical treatment of different uses of embryos.[77]

4.6 IVF clinics will be entitled to apply for a licence to conduct such activities on excess ART embryos created before 5 April 2002. However, it was argued that the ban on fresh or frozen embryos created after that date would "severely compromise" embryology training programs, laboratory quality assurance processes and embryo culture system improvements.[78]

4.7 An additional matter was raised by Professor Robert Jansen, Sydney IVF, who advised the committee that s.15 of the Prohibition of Human Cloning Bill would ban Cytoplasmic transfer, a new ART technique that may be of significance in treating older women.[79]

4.8 In our view, the new licencing requirements will have an impact on IVF Clinics. At least one consequence will be increased costs for treatments as there will be compliance costs although it is not yet known how much they will be.

4.9 While sympathetic to the IVF Clinics concerns, we conclude that the benefits of including training and other practices in the framework of the licencing arrangements is justified.

4.10 We note the Bill provides for a review (s.61) and it will be useful to gauge what actual impacts the Bill has had on IVF practice.

5. Concerns Over Nature of Evidence

5.1 In many submissions and in oral evidence given to the committee, concerns were raised about the nature and quality of evidence given to the media, Members of

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75 The Member for Petrie, Ms Teresa Gambaro proposed these amendments prior to the debate in the House of Representatives on the legislation. The amendments were withdrawn prior to debate.

76 NHMRC, Submission No. 23, p. 21

77 Dr Clive Morris, *Committee Hansard*, 29 8.02, p. 25

78 Monash IVF, Submission No. 1007, p. 1

79 Sydney IVF, Submission No. 897.

Parliament and this Committee during the course of the inquiry. These concerns include allegations of misinformation, misrepresentation of science, deliberate omission of relevant information, creation of false or unrealistic expectations and exploitation of people with disabilities.[80]

5.2 Mr Sullivan, Chief Executive, Catholic Health Australia asserted, for example:

> Put simply, there is a ruse being perpetrated by members of the scientific and business community. I would go so far as to suggest that a deliberate campaign of misinformation is being conducted. They have built up false expectations that miracle cures are just around the corner, if only experimentation on embryos can be permitted … As a consequence, we have COAG making an illogical and rushed decision."[81]

5.3 While many of the criticisms were directed at Professor Trounson with claims he misled politicians by omitting information (see below), we believe some balance is required.

5.4 Recently, Dr David Prentice of Do No Harm (America) travelled to Australia to lobby against permitting embryonic stem cell research. He presented himself as an independent scientist with expertise in adult stem cell research.

5.5 However, neither in the promotional material provided by Do No Harm or Dr Prentice was his work as an "ad hoc science advisor" to Senator Brownback and Congressman Weldon (the Republican sponsors of an anti-cloning Bill) advised. While this makes no claim on the veracity of Dr Prentice's scientific arguments, affiliations of this nature are of more than passing interest in the context of a parliamentary debate, particularly as transparency of interests and misleading information have been key topics of discussion.

5.6 Senator McLucas asked Dr van Gend whether Do No Harm funded Dr Prentice's travel and accommodation. He advised the committee that the visit was initially underwritten for about five thousand dollars by the National Civic Council and this money was largely repaid through Professor Prentice's public meetings in Australia.[82]

Exploitation and False Hopes

5.7 In his submission, Dr McCullagh was highly critical of proponents of ES cell research accusing them of:

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[80] See, for example, Professor Colin Masters, Submission 87, Dr Tonti-Filippini, Submission No. 86, Do No Harm, Submission No. 1042, Australian Catholic Bishops Conference, Submission No. 981. Dr van Gend, *Committee Hansard*, 24.9.02, p. 177, Dr McCullagh, Submission No. 480 and *Committee Hansard* 24.9.02, p. 156,

[81] *Committee Hansard*, 26.9.02, p. 219

[82] Dr van Gend, e-mail to secretariat, 1 October, 2002.

> exploitation of highly vulnerable people living with disabilities … to legitimize ES cell production … individuals with major chronic disabling conditions are a resource to be manipulated in television studios.[83]

5.8 This was rejected by Ms Knott, Director, Australasian Spinal Research Trust, who responded to Dr McCullagh's comment, saying:

> I think it is very sad that you would try to take an opinion like that without actually living through the condition, but I for one was responsible for founding the Australasian Spinal Research Trust, so no one could say I am being manipulated into doing that.[84]

5.9 Mr Robert Turner, Honorary Chief Executive Officer, Australasian Spinal Research Trust stated:

> One of the things … (people with such diseases) … fight against is being talked down to like that as though they have not got the ability to discriminate between what is exploitation and what is not.[85]

5.10 Ms Knott added:

> The reality is that we do follow very closely and we have done for a number of years, what research has gone on around the world, and I think we do have a good sense of what is credible and what is not.[86]

5.11 A number of submittees suggested politicians had been notably susceptible to emotive arguments and over-blown claims of cures. Dr van Gend asserted that:

> It is vital to realise that the debate has largely been driven among the politicians and the public by the emotional images of suffering patients with afflictions … we have let loose an army of mothers on all of you politicians, battering down your doors and saying, 'How dare you get in the way of embryo research when it is going to cure my child of cystic fibrosis?', or of its spinal injury.[87]

5.12 The Chair rejected this assertion, saying:

> I have to say, Doctor, that that is simply not true as I sit here today. There are people who hold hope. They do not hold hope that it is tomorrow or next week or next year. I think it is quite wrong for anyone to come before this committee

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83 Submission No. 480, p. 8 (not numbered in original)

84 *Committee Hansard*, 17.9.02, p. 85

85 *Committee Hansard*, 17.9.02, p. 85

86 *Committee Hansard*, 17.9.02, p. 74

87 *Committee Hansard*, 24.9.02, p. 182

> and tell me that that is what has been put to me... because quite frankly that is not so.[88]

5.13 We can confirm that our experience reflects that of the Chair.

The Trounson Debate

5.14 Strong criticism was directed at Professor Trounson for the way he represented experiments on a rat, by Dr Kerr of Johns Hopkins University, at Parliament House in August 2002.

5.15 As the Chair's report notes the key criticisms went to him misleading politicians and the media by stating the experiment used human embryonic stem cells when it was subsequently established that they were human germ stem cells and his use of unpublished material (2.20-2.23).

5.16 In evidence to the Committee, Professor Trounson explained his terminology:

> I did not mislead members of parliament because the terms 'embryonic stem cells' and 'embryonic germ cells' are often used interchangeably.

5.17 He provided a number of examples, including:

> Firstly, embryonic stem cells are defined as 'cultured cells obtained by isolation of inner cell mass cells from blastocysts – these are the IVF embryos – 'or by isolation or primordial germ cells from the foetus' in the Andrews committee report on human cloning.[89]

5.18 As the Andrews Report (The House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning*, August 2001) has been a key reference for parliamentary and public debate on this issue, the failure of the Chair's report to draw attention to the definition it adopts for embryonic stem cells is a significant oversight.[90]

5.19 Professor Trounson also stated:

> Secondly, the primary review of the subject *Stem Cells: Scientific Progress and Future Research Directions* by the United States Institutes if Health, available on their website, describes the Kerr Research as follows:
>
> > Researchers at Johns Hopkins University recently reported preliminary evidence that cells derived from embryonic stem cells can restore movement in an animal model of amyotrophic lateral sclerosis, ALS.[91]

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88 *Committee Hansard*, 24.9.02, pp. 182-3

89 *Committee Hansard*, 24.9.02, p. 136

90 The definition cited by Professor Trounson is in the Glossary of Terms, p. 270

91 *Committee Hansard*, 24.9.02, p. 136

5.20 Professor *Trounson* went on to address the issue of using unpublished material by stating:

> It is not permissible to distribute manuscripts submitted to *Nature* journals until after publication. This is an undertaking that authors agree to when submitting their papers to these journals. I concluded, therefore, that the manuscript must have been published. … My error was in assuming, as would thousands of scientists familiar with the publication rules of *Nature* journals, that the article had been published.[92]

5.21 On this explanation, Dr van Gend, of Do No Harm, stated:

> It is a fair comment, I think, to say that he thought it had been sent by Dr Kerr meaning that it must have been published – the fact that it was sent in this way gave him an impression.[93]

5.22 Professor Trounson's explanation is on the public record.

5.23 This incident provoked strong attacks impugning the motives of Professor Trounson.

5.24 Professor Silburn stated, for instance:

> it was said that this was a naïve attempt and all that. Professor Trounson is very well regarded, and I do not see how it could be naivety that did that.[94]

5.25 Dr van Gend, claimed:

> there is a much more widespread and pervasive distortion of the science (than the rat), which has primarily been carried out by Dr Trounson because he is the main spokesman."[95]

5.26 However, Dr Tonti-Filippini stated that

> it seems to me that this debate has been greatly harmed on both sides by a lack of reference to materials.[96]

5.27 Claims about misrepresentations of aspects of stem cell science in the media functioned as an unexamined, generalised 'given' in the inquiry, as very few copies or citations of media stories were provided.

5.28 In our view, the evidence provided to the committee by scientists supporting embryonic stem cell, notably Dr Juttner, Associate Professor Martin Pera, Dr

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92 *Committee Hansard*, 24.9.02, 136

93 *Committee Hansard*, 24.9.02, 182

94 *Committee Hansard*, 17.9.02, p. 52

95 *Committee Hansard*, 24.9.02, p. 176

96 *Committee Hansard*, 24.9.02, p. 155

Simmons, Professor Williamson, Dr Stanley and Dr Elefanty were measured, supported and realistic. On the basis of the evidence they provided to the Committee, we do not feel that they, or Professor Trounson, can be accused of building "up false expectations that miracle cures are just around the corner, if only experimentation on embryos can be permitted."[97]

5.29 Nor did representatives from groups with disease or disability over-estimate ES research.

5.30 James Shepherd, a 13 year old who has lived with Juvenile Diabetes since he was 5 years old, told the committee:

> There are approximately 100,000 juvenile diabetics in Australia, and there are more being diagnosed each year. I think all of us deserve a chance for a cure… the cure could lie in adult stem cells or embryonic stem cells or it could lie in one of the many other types of research, but I think that every possibility for a cure should be fully explored before it is banned completely.[98]

5.31 Ms Knott, Director, Australasian Spinal Research Trust, said:

> It is imperative that we protect important areas of medical research that we offer hope to hundreds of thousands of Australians. I do not expect a cure tomorrow or even next year, and I do not intend to overstate the promise of research, but how can you overstate hope?[99]

Public involvement in bioethical issues

5.32 Evidence given to the inquiry shows that there is a need for better mechanisms to educate and involve the public in the bioethical debates. We need to ensure that the public has access to information, that they are educated about the issues in language they understand, and that they feel able to make their voices heard on the issues.

5.33 For some years now, under both Clinton and Bush, the United States has had a Presidential Commission on Bioethics. It is a model we could well adopt here.[100]

5.34 The US Commission provides a forum for a national discussion and exploration of bioethical issues. It is charged with exploring the ethical and policy questions related to developments in biomedical science and technology and assessing public concerns about these developments.

5.35 The Commission is guided by the need to articulate and present a variety of views rather than reaching a single consensus opinion.

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97 Mr Sullivan, Catholic Health Australia, *Committee Hansard*, 26.9.02, p. 219

98 *Committee Hansard*, 17.9.02, p. 71

99 *Committee Hansard*, 17.9.02, p. 73

100 As suggested by the Leader of the Labor Party, Simon Crean, in his second reading speech on this legislation in the House of Representatives.

5.36 Such a process, properly constituted, could help facilitate a greater understanding of bioethical issues and a better public debate here in Australia.

6. Specific Issues Related To The Bill

Scope of the Bill

6.1 A concern raised by a number of submittees to the Committee was the Bills went further than the intent of the COAG agreement.

6.2 Dr Best, representing Dr Jensen, the Anglican Archbishop of Sydney stated

> My understanding was that the object of the act was to allow frozen excess embryos in ART labs around the country to be used to derive embryonic stem cells specifically; but that is not specified in this legislation. In fact, any use of human embryos which the NHMRC Licencing Committee feels is worth while is approved, under this legislation. … If the legislation is to be passed, I would be much happier if there were tightening of the legislation so that the human embryos currently frozen in ART labs can only be used for the extraction of human embryonic stem cells.[101]

6.3 The *Research Involving Embryos Bill 2002* requires all proposed research activities using excess ART embryos are assessed and licenced by the licencing committee and that licences must satisfy;

- consent provisions (36(3)(a) also 39(1)(a))
- embryos must be created before 25 April 2002 if the research will damage or destroy the embryo (36(3)(b); and
- the proposal has been assessed and approved by the local Human Research Ethics Committee (36(3)(c)).

6.4 The bill permits some activities to be exempt from requiring a licence (25(2)) including the storage, removal (from storage), transport and observation of excess ART embryos.

6.5 According to the Explanatory Memorandum activities that would need to be licenced include;

- For research (for example, to derive stem cells or to improve ART clinical practice)
- To train people in ART practice

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[101] *Committee Hansard*, 24.9.02, p. 158

- For quality assurance testing to ensure that pre-implantation diagnostic tests give accurate results; and

- To examine the effectiveness of new culture medium.[102]

6.6 Dr Clive Morris, NHMRC, informed the committee that research could also include understanding embryonic development and fertilisation, studies in genetic make-up and expression and drug testing including toxicology providing any such proposal met the licencing requirements and would be subject to whatever the conditions the licence requires.[103]

6.7 The net affect is to ensure all uses of excess ART embryos are prohibited unless they are licenced or exempt.

6.8 In the introduction to the COAG communiqué, it is stated that:

> the Council agreed that research be allowed only on existing excess ART embryos, that would have otherwise been destroyed, under a strict regulatory regime … donors will be able to specify restrictions, if they wish, on the research uses of such embryos.[104]

6.9 In the appendix to the communiqué (that provides more detail on the contents of the framework), the relevant points are:

> A nationally-consistent approach to research involving human embryos
>
> 5. Research involving human embryos should be regulated through nationally consistent legislation.
> 6. The following principles should underpin nationally-consistent legislation:
>
> > 6.1 legislation should ensure appropriate ethical oversight of research involving embryos based on nationally-consistent standards;
> >
> > 6.2 the nationally-consistent standards should be clear, detailed and describe the ethical issues to be taken into account, research which may be permitted and the conditions upon which it may be permitted
>
> …
>
> A nationally-consistent approach to the development and/or use of embryos for the derivation of stem cells
> 8. Research with existing stem cell lines will be permitted to continue in Australia subject to the observance of conditions set by the NHMRC/AHEC.

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[102] Explanatory Memorandum, *Research Involving Embryos and Prohibition of Human Cloning Bill 2002*, p. 18

[103] *Committee Hansard*, 26.9.02, p. 256

[104] http://www.pm.gov.au/news/media_releases/2002/media_release1588.htm p. 1

> 9. Research and possible therapeutic applications which involve the destruction of existing excess ART embryos (or which may otherwise not leave the embryo in an implantable condition) will be permitted in accordance with the regulatory regime …[105]

6.10 There is nothing in this that supports the contention that COAG intended that stem cell research exhausts all possible research activities. While other research activities such as testing culture mediums are not specified, we believe the broader coverage is not inconsistent with the general consideration of research in the Bill.

AHEC Guidelines

6.11 There was considerable discussion concerning the guidelines.

6.12 One concern was that AHEC are reviewing the current guidelines, and will continue that review after the bill is passed. Thus, Parliament will not have the opportunity to examine the guidelines at the time the Bill is debated.

6.13 One potential approach is to make the guidelines a disallowable instrument. This would ensure parliamentary scrutiny of the guidelines, but may not be consistent with previous treatment of other ethical guidelines issued by AHEC.

6.14 In any consideration of this issue, it needs to be noted that the current AHEC guidelines go beyond activities covered by this Bill and include information about storage of embryos, counselling and other ART clinical practices.

6.15 A specific concern with the guidelines, relates to the provisions relating to the giving of consent to research involving excess ART embryos.

6.16 The Research Involving Embryos Bill requires that proper consent is required from all "responsible persons" before an excess ART embryo can be used in research.

6.17 The Bill defines "proper consent" and identifies who is a "responsible person" with respect to an embryo.

6.18 "Proper consent" is consent that has been obtained in accordance with the Ethical Guidelines on Assisted Reproductive Technology issued by the NHMRC or other guidelines issued by the NHMRC.

6.19 "Responsible person" means:

> (a) each person who provided the egg or sperm from which the embryo was created; and
>
> (b) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and

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[105] http://www.pm.gov.au/news/media_releases/2002/media_release1588.htm p. 7

(c) any person who was the spouse of a person mentioned in paragraph (a) at the time the egg or sperm mentioned in that paragraph was provided; and

(d) any person who was the spouse of the woman mentioned in paragraph (b) at the time the embryo was created.

6.20 The current guidelines, which are currently under review, provide among other things that consent must be in writing and should be given following the provision of information and adequate opportunities for personal preparation.

6.21 While the review of the guidelines which relate to consent in assisted reproductive technology procedures is appropriate, there is no evidence that the existing guidelines have been ineffective or have resulted in consent being inappropriately given.

Constitutional issues – Commonwealth, State and Territory arrangements

6.22 The heads of power in the legislation provide wide Commonwealth coverage of corporations, commerce and trade that cover organisations that engage in interstate trade or are corporations. However, Ms Andrea Matthews advised the committee that the Commonwealth's power may not cover individuals. This opens the prospect of an individual challenging the constitutionality of the legislation if the NHMRC initiated a prosecution against an individual.[106]

6.23 This was acknowledged at COAG and the States and Territories agreed to introduce complementary legislation to ensure full coverage, including individuals within six months after royal assent of the Commonwealth Bills (when the regulatory scheme would commence).[107] Ms Matthews advised that the States and Territories could do this by introducing legislation that mirrored the Commonwealth legislation or applied the legislation in their own legislation.[108]

6.24 We conclude that while complementary State and Territory legislation is required to ensure complete constitutional coverage, there are no compelling grounds to believe that any State or Territory would act in bad faith and not honour the intent of the COAG agreement. Accordingly, we do not believe the requirement for complementary State and Territory legislation constitutes a reason to delay or defeat the Bills.

National Legislation

6.25 The Bill allows for the Commonwealth, to the extent of its constitutional powers, to over-ride existing legislation in Victoria, South Australia and Western Australia.

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[106] *Committee Hansard*, 29.8.02, p. 11

[107] COAG

[108] *Committee Hansard*, 29.8.02, p. 11

6.26 As the Chair's report notes (4.129), some submissions argue that allowing the Commonwealth to over-ride State laws is not consistent with COAG nor democratic.[109]

6.27 This argument is seriously flawed. It ignores the fact that the States and Territories are parties to the COAG communiqué and thus the States-rights rhetoric is misconceived.

6.28 We believe one of the real strengths of the COAG is that it unequivocally intends a nationally consistent legislative and regulatory regime.[110] Indeed, as Ms Matthews of Matthews Pegg, consultants to the NM&MRC pointed out "one of the major drivers for a nationally consistent regulatory system was the absence of regulation previously."[111]

6.29 The Member for Sturt, Mr Pyne, introduced an amendment in the House of Representatives proposing that State laws not be affected if consistent or inconsistent with the Bills (the amendment was defeated).

6.30 We believe permitting significant differences between jurisdictions - which would occur if the Bill is defeated or an amendment analogous to Mr Pyne's was successful – is unacceptable.

6.31 We note the recent Canadian legislation is national, not province based, moreover we believe the significant inconsistencies in US regulation, notably between public and privately funded embryonic stem cell research, has nothing to commend it.

'Therapeutic' Cloning

6.32 The Prohibition of Human Cloning Bill bans human reproductive cloning and 'therapeutic' cloning (s9, 13, 14 and 17). However, a point raised on a number of occasions by Senator Harradine and in evidence to the committee was that 'therapeutic' cloning is misleading as it

> collapses both a) therapeutic and non-therapeutic research on embryos and
>
> b) the distinction between destructive and non-destructive experimentation on embryos.[112]

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[109] See, for example, National Civic Council – WA Division, Submission 282, p. 11, Festival of Light, Submission No. 1076, p. 6

[110] The Attorney General, Mr Williams, advised the House of Representatives that South Australia, Victoria and Western Australia are currently amending their legislation to complement the Commonwealth's legislation. (*House Hansard*, 24.9.02, p. 6866)

[111] *Committee Hansard*, 29.8.02, p. 2

[112] Dr Kerry Breen, Chair, Australian Health Ethics Committee, *Tabled Document*, Australian Senate, 7 February, 2001, p 21477

6.33 We believe the case against the term 'therapeutic cloning' is well made and accept the distinctions between therapeutic and non-therapeutic and destructive and non-destructive are important.

6.34 In one sense, this is not an issue as both reproductive and so-called 'therapeutic' cloning are banned in the legislation, however, it is clear, that more accurate nomenclature would be of considerable benefit in public debates on such issues.

Prohibition on Human Cloning – additional comment

6.35 It would seem that the provisions of this Bill are not entirely understood. In evidence to the committee, Ms Riordan, Executive Director, Respect Life Office, Archdiocese of Melbourne, Australian Catholic Bishops Conference, stated:

> I would like to quote two women legal academics in the United States … Cynthia Cohen … wrote
>
> > Producing eggs engenders increased risks for women. Hyperstimulation can lead to liver damage, kidney failure, or stroke … Although women might be willing to undergo such risks for the sake of having a child, it seems clear that either payment from eggs or coercion would have to be used to persuade women to produce eggs for stem cell research … Thus, before considering embryonic stem cell research, procedures need to be developed to protect women's health and freedom from overbearing financial or other pressure.
>
> Rebecca Dresser … noted in the same journal:
>
> > Creating human embryonic stem cell lines from somatic cell donors would require a large supply of oocytes. Experience in infertility treatment indicates that obtaining such oocytes will not be easy.
>
> These basic issues have never been addressed either at all or satisfactorily by advocates of stem cell research. To my knowledge, they have not been addressed directly in evidence before this committee. These fundamental issues are not addressed in the legislation under consideration.[113]

6.36 Not so. The *Prohibition of Human Cloning Bill* makes it an offence to

a) create an embryo for research (s.14);

b) engage in trade of human eggs, sperm or embryos, including giving (and accepting) financial inducements, including handling fees (s.23);

c) create embryonic stem cell lines from somatic cell donors (s.9 and 13).

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[113] *Committee Hansard*, 26.9.02, pp. 214-5. See also comments of Mrs Ulhmann, National Bioethics Convenor, Catholic Women's League Australia Inc, *Committee Hansard*, 26.9.02, p. 218

6.37 In addition, these issues were widely canvassed in evidence to the committee.[114]

7. Additional Matters not directly related to the Legislation

Intellectual Property

7.1 As the Chair's report notes, an issue that was raised frequently during the course of the inquiry was concerns over intellectual property rights over embryos, stem cell lines and the products of stem cell lines (4.48 – 4.53).

7.2 The issue of patents and intellectual property is not covered by the Bill and the licencing committee will not include the commercial interests of an applicant in their determinations on licence applications.[115]

7.3 Some concerns went to problems for *bona fide* researchers accessing unencumbered stem cell lines. Stem Cell Sciences, for instance, advocated that Australia adopt a recommendation of the European Union's Ethics Group to prohibit patenting of unmodified human stem cell lines.[116] This would mean the unique biological material that underpinned research would be accessible for all researchers and patents could only be taken out on research that generated novelties.[117]

7.4 There were also many comments by some submittees and some Senators seeking to cast aspersions on the motivations and interests of researchers.

7.5 Dr Neville, Research Fellow, Australian Catholic Bishops Conference, advised the committee that

> The use of patents and other intellectual property rights has at least two negative consequences. Firstly, it promotes a view of medicine and the provision of therapy solely as a commercial business. This has implications for those without adequate financial resources to gain access to developments and innovations. Thus, there are very significant questions of justice and equity, not to mention discrimination. Secondly, contrary to standard medical practice and codes of research, patenting and IP rights actually inhibit the distribution of research benefits.[118]

7.6 However, Dr Juttner, Executive Director of Bresagen, noted that patenting was necessary to ensure an inventor had a period of time "to gain some recompense for the hundreds of millions of dollars they invest in development".[119] He added that

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[114] Bresagen, for instance, specifically rejects Somatic Cell Nuclear Transfer for precisely the sort of reasons raised by Ms Riordan.

[115] *Committee Hansard*, 29 8.02, p.28

[116] Stem Cell Sciences Ltd, Submission No. 1012, p. 2

[117] Mr Ilyine, *Committee Hansard*, 17.9.02, p. 45

[118] *Committee Hansard*, 26.9.02, pp. 215 - 6

[119] *Committee Hansard*, 17.9.02, p. 37

Bresagen's "preferred position is to make cells available for a small training fee of $5,000 and then to have a right of first refusal to negotiate on new IP, but with no guarantee or ownership built into that".[120]

7.7 We are sympathetic to many of the concerns raised concerning patents and intellectual property rights. Senator Stott Despoja, in particular, has a long standing interest in such matters and has introduced private members bills seeking to prevent patenting of naturally occurring genetic material and gene sequences and other related genetic issues.[121]

7.8 We do not favour, however, bringing patent and intellectual property amendments forward during debate on these Bills. Ad hoc changes to complex areas of law can create more problems than they solve, despite good intentions. Rather, we would prefer to see a considered approach that is well grounded in the challenges genetic sciences pose to lawmakers seeking to balance the interest of inventors and the community.

7.9 We are well aware of the Australian Law Reform Commission (ALRC) and AHEC's ongoing and comprehensive review of issues relating to the protection of genetic information. We are also aware that stem cell science is outside the terms of reference of that review. The final report is due to be tabled in March 2003.

7.10 We believe it is appropriate that the ALRC and AHEC are given another reference to consider issues of patenting, intellectual property and stem cell science and that this reference should feed directly into the review of this legislation (s.61).

Stem Cell Bank

7.11 The committee was advised by Mr Ilyine that on 9 September, the UK Medical Research Council announced the establishment of a National Stem Cell Bank to:

> hold all of the stem cell lines in a central point where there would be free and unencumbered access to those stem cell lines to qualified researchers.[122]

7.12 It was suggested that such a facility might minimise the number of embryos that would be required to create new stem cell lines.[123] Mr Ilyine advised the committee that UK initiative was to ensure researchers could access stem cell lines but the committee was not provided with specific evidence whether this was to overcome an actual problem. Nevertheless, we believe this idea has merit and believe that the independent review of the act should examine the UK model of a Stem Cell Bank to ascertain whether an analogous facility would be desirable in Australia.

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120 ibid

121 Genetic Privacy and Non-discrimination Bill 1998, Patents Amendment Bill 1996. Also refer to discussion between Dr Neville and Senator Stott Despoja, *Committee Hansard*, 26.9.02, p. 217

122 *Committee Hansard*, 17.9.02, p. 36

123 *Committee Hansard*, 17.9.02, p. 45

Recommendation: That an additional term of reference be applied for the review of the act as outlined in s61 (REIB)/s.25 (PHCB) to investigate the operations and applicability of the UK Stem Cell Bank.

7.13 The Chair's report discusses this and another bank idea (tissue bank) proposed during the course of the inquiry (4.52-3). It should be pointed out that a tissue bank for immunological matching is quite a different concept and should not be conflated with the stem cell bank discussed above. It is premature to consider a tissue bank for this purpose. Any need will be entirely dependent on what success is achieved (or otherwise) in overcoming the significant immunological challenges for ES therapies.

Resource Allocation

7.14 As the Chair's report points out a number of submissions questioned the allocation of resources to embryonic stem cell research on ethical grounds, suggesting that the money would be better spent on disability support or other healthcare programs such as for drug addiction and Aboriginal health (3.112).

7.15 In terms of priorities in research funding, Professor Good argued:

> When there is a limited amount of money for research in this country – I deal with this issue every day and am trying to increase the amount of funding for research – why would we waste it on putting something into human embryonic stem cell research that, in my estimation, will never make it into a therapy.[124]

7.16 A resource allocation argument was (fallaciously) taken further in some submissions to infer a prohibition argument along the lines of; resources are scarce, embryonic stem cell research is 'a huge waste of limited resources', these resources should be committed to 'ethically uncontentious but scientifically more promising avenue' of adult stem cell research; thus prohibit 'embryo destruction for stem cells'.[125]

7.17 While not relevant to the Bill, the funding of the National Stem Cell Centre drew some adverse comments during the course of the inquiry. There seems to be a misconception that the $46.5 million (over four years) for the National Stem Cell Centre is only for embryonic stem cell research.[126] This is not correct. While the funding mix will presumably not be known until all documentation is finalised, the money provided and the Centre becomes operational, Professor Trounson advised the committee that the Centre will have four broad areas of research;

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[124] *Committee Hansard*, 19.9.02, p. 97 It is important to note that Professor Good is not arguing that resources are scarce therefore ban embryonic stem cell research. See exchange between Professor Good and Professor Bartlett clarifying Professor Good's position. *ibid*

[125] Catholic Archdiocese of Melbourne, Submission No. 876, p. 7

[126] Catholic Archdiocese of Melbourne, Submission No. 876, p. 7, Dr Silburn, *Committee Hansard*, 17.9.02, p. 52 and numerous references from Senators Harradine and Boswell in the course of the public hearings.

- Embryonic stem cell;
- Adult stem cell;
- Transplantation, and
- Tissue engineering.[127]

7.18 The Committee was advised by Bio-technology Australia that the Centre will split funding 50:50 between adult and embryonic stem cell research. This does not match the description of the four main areas, but the central point remains that the public investment is by no means exclusively for ES research.

7.19 Professor Pettigrew, CEO, NHMRC, advised the committee that currently the NHMRC fund approximately $10 million for stem cell research; none of which is for human embryonic stem cell research.[128] However, there are other sources of funding available, both public and private, and, as the Chair's report notes, the committee received no analysis of the distribution of funds between adult and embryonic stem cell research (3.117).

Acknowledgement

7.20 On a final note, we would like to acknowledge the work of the Chair of the Committee in managing the hearings of what was at times contentious material in an even-handed and fair manner. Her report provides a good overview of the issues and she has been very generous in accommodating concerns of Senators opposed to some of the provisions of the Bill.

7.21 We would also like to acknowledge the efforts of the Community Affairs Committee staff.

Senator Natasha Stott Despoja

Deputy Chair

Senator Jan McLucas

Senator Ruth Webber

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[127] *Committee Hansard*, 24.9.02, p. 142

[128] *Committee Hansard*, 29.8.02, p. 10

ADDITIONAL COMMENTS

1. Clause 56 of the Research Involving Embryos and Human Cloning Bill overrides the more strict provisions regulating and/or banning human embryo stem cell research in Victoria, South Australia and Western Australia. These state laws which preserve human life, should not be overridden by this federal legislation. Notwithstanding the questions surrounding the constitutionality of the bill, each state parliament and their various members should stand accountable, and not hide behind the Australian Government.

2. Clause 25 (2) (d) (ii) allows assisted reproductive technology centres to undertake diagnostic investigations which are deliberately destructive on human embryos[1]. The Chair's report refers to the explanatory memorandum and evidence provided by the NHMRC but in neither case are deliberately destructive diagnostic investigations prohibited or recommended to be prohibited. The nature and extent of these investigations is unclear and should be clarified to ensure the purpose is legitimate and not deliberately destructive.

3. Apparently research is undertaken on some of the many thousands of non-viable human embryos emanating from assisted reproductive technology centres (estimated at 40,000 per year by one witness[2]). This was a revelation. It is not clear whether this was understood by the Council of Australian Governments when they made their decision on 5th April 2002.

4. The consent provisions in the Bill should be tightened. The terms and conditions of the consent arrangements should more accurately reflect those recommended in the House of Representatives Standing Committee on Legal and Constitutional Affairs Human Cloning Report, August 2001 (the Andrews Report) – refer particularly to pages 232 to 234 – and these should be prescribed in the Bill.

5. The commercialisation of the research and specifically the ability to trade in human embryo stem cell lines was raised as a concern by many witnesses and these concerns are not adequately addressed in the Bill.

Senator Guy Barnett Senator Bill Heffernan Senator Ron Boswell

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1. *Refer submissions 876 (CAM), 981 ACBC and 1035 Australian Youth Alliance (Vic)*
2. *Professor Peter Illingworth, Committee Hansard 26 September 2002, page 205.*

SUPPLEMENTARY COMMENTS

Senator Brian Harradine

Research Involving Human Embryos and Prohibition of Human Cloning Bill 2002: Entrenching the Commercialisation and Commodification of Human Life

This legislation will set the unheard-of precedent for the statutory creation of a biological underclass—namely, those unworthy of life but worthy of sacrifice on the commercial slab of experimentation.[1]

Introduction

1.1 The *Research Involving Human Embryos and Prohibition of Human Cloning Bill 2002* (the Bill) would, for the first time, permit destructive experiments on human embryos. The Bill would set a precedent for vivisection of living human beings at the earliest stage of their development. Should the legislation pass, the embryonic human being will have been reduced to the status of a laboratory rat. As a matter of principle, if enacted, the precedent will have been set by which a certain class of human life is held, according to Commonwealth legislation, to be expendable for profit. Other classes of human life could then be added to this list of endangered life.

1.2 Despite the demonstrable humanity of the embryo and the raft of international treaties and declarations which prohibit destructive non-therapeutic research on human subjects, the Bill would open the door to a wide range of destructive and other research on human embryos and stem cells derived from them.

1.3 The Senate Community Affairs Legislation Committee was entrusted with the task of examining the *Research Involving Human Embryos and Prohibition of Human Cloning Bill 2002* and to report to the Senate by 24 October 2002. The Bill was subsequently split into the *Research Involving Embryos Bill 2002* and the *Prohibition of Human Cloning Bill 2002*.

1.4 The process of examining the Bill was rushed to the point that:

- Only three weeks were allocated for public submissions to the Committee;
- Hearings of the Committee were held, unusually, on Senate sitting days;

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1 Submission 981.

- No hearings took place outside Canberra; and,
- Less than one day was allowed after finalisation of the Chair's Report for dissenting reports to be prepared.

1.5 Despite the process being rushed, public interest in the Committee's consideration of the Bill has been high. Of the 1851 submissions received, 1803 opposed destructive research on human embryos.

Broad scope of the legislation

1.6 The Bill under consideration is commonly understood to relate only to research on embryos to produce embryonic stem cells. What is not generally understood is that the Bill would facilitate a wide variety of destructive research on human embryos of which stem cell research would be but a minor part. In effect, the derivation of stem cells on the basis of exaggerated claims of impending cures has been the Trojan Horse used to establish the principle of destructive embryo research.

1.7 The range of embryo research permitted by the Bill includes using human embryos to examine the effectiveness of new culture media used in assisted reproductive technology (ART) practice, to assist in understanding embryonic development and fertilisation, training clinicians in microsurgical ART techniques, transport, observation and storage of embryos, micromanipulation, lasering, cutting and dissecting, studies in genetic makeup and expression, quality assurance testing to ensure that pre-implantation diagnostic tests give accurate results, drug testing including toxicology studies on human embryos as well as the destructive extraction of embryonic stem cells.[2]

1.8 Apart from stem cell research, nothing in this long list of areas of human embryo research was mentioned in the COAG Communique dated 5 April 2002.

1.9 This research would entrench the commercialisation and commodification of human life.

1.10 As one witness told the Committee:

> Where vast sums of money are at stake, it would be impossible to regulate such research so effectively as to prevent more and more destructive research, requiring more and more embryos, be they bar-coded, fresh, frozen or what have you.[3]

1.11 The Committee was also told in a submission:

> Human life is never disposable, at any stage of its development. It should never be seen as a commodity, as a type of property able to be exploited for

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2 *Committee Hansard*, 26.9.02, p.255-256 (Dr Morris)

3 *Committee Hansard*, 26.09.02, p.215 (Dr Neville)

> profit. Nor is the value of any human life, or its claim to protection, reducible to or dependent on age or its utility to others.[4]

Human status of the embryo

1.12 Weighty evidence was put to the Committee as to the human status of the embryo.

1.13 Dr Nicholas Tonti-Filippini provided the Committee with an ontological definition of the human embryo:

> From the moment that the first cell is formed, a human embryo is an individual organism oriented to development to human adulthood, normally requiring only nutrition and a favourable environment for that development to occur, and whose inherited nature is formed by the human genome which carries the inherent radical capacity for rationality that is distinctive of human beings.

1.14 Dr Tonti-Filippini detailed six propositions and a conclusion to develop the argument:

> 1. All members of the human family, (including those who may not be rational especially the developmentally disabled and the mentally ill, children, and the elderly), have inherent dignity and equal and inalienable rights. (ICCPR)
>
> 2. The capacity for rationality morally distinguishes human beings from animals.
>
> 3. Being of the kind of being which has the capacity for rationality is a basis for an individual to be recognised as having inherent dignity and hence the bearer of equal and inalienable rights.
>
> 4. The human genome contains information that determines that a living individual who possesses and is formed according to the human genome is of the kind of being which has the capacity for rationality.
>
> 5. Those living individuals who possess and are formed according to the human genome have inherent dignity and are the bearers of rights.
>
> 6. Embryonic human beings are living individuals who possess and are formed according to the human genome;
>
> Therefore, embryonic human beings have inherent dignity and equal and inalienable rights.[5]

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4 Submission 981

5 Evidence given on notice to the Committee by Dr Nicholas Tonti-Filippini, 26 September 2002.

1.15 In his submission, Dr Tonti-Filippini also pointed to the implications for other people of a denial of the humanity of the human embryo:

> A fundamental concern I have is that by classifying very immature human beings as not yet human because of their capacities for specifically human activities have not yet come to fruition, capacities such as rationality and thought, we make the status of all human beings dependant upon their capacities rather than simply on membership of the human family.[6]

1.16 Dr Robert Orr from the University of Vermont and Dr Christopher Hook from the Mayo Graduate School of Medicine point to the beginning of life not being determined by where the embryo is positioned:

> The essential nature of humanhood is inherent to the individual, it is not something that is imputed based on location. These arguments based on geography are feeble attempts to avoid the basic fact understood and accepted by scientists for many generations that human life begins with the union of two human gametes.[7]

1.17 They also refute the argument that as the embryo will die anyway it should therefore be used for research:

> [this] only accepts and supports the erroneous and tragic approach of the infertility industry which perceives children as products and embryos as commodities … A society that chooses to capitalise on this tragedy acts as opportunists, not as stewards.[8]

1.18 The Queensland Bioethics Centre clarifies in its submission the difference between killing and allowing to die:

> … in the case of the frozen embryo the decision is made to cease the extraordinary life-support and allow nature to take its course. This [option is] to discontinue the life-support and allow the embryo to return to as natural a state as possible – a warm, moist environment. Development will be restored for a short time, but then nature takes its course. The embryo, because of its immaturity and inability to sustain itself, dies. The person who thaws the embryo in this case is not involved in an act of intentionally killing the embryo anymore than a doctor who does not initiate futile or overly burdensome life sustaining treatment on a dying neonate or who discontinues overly burdensome treatment on a dying patient.
>
> On the other hand when someone takes the embryo and extracts its stem cells, we do not have a case of "nature taking its course". The embryo is carefully and slowly thawed to maintain its viability short-term in order that its stem cells can be harvested. It does not die because it cannot sustain itself in this environment. The embryo dies because someone has ripped it apart.

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6 Submission 86

7 Submission 156

8 Submission 156

> The person who so deliberately destroys the embryo might be doing so for all kind of noble motives, but he/she can't escape the fact that he/she is intentionally killing the embryo.
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> In the former case it is not necessary that the person is willing the death of the embryo. In the latter case it is necessarily so.[9]

Human Rights Implications

1.19 Dr Katrina Hallen points out that there is a body of human rights law specifically relating to human experimentation which states that voluntary consent by the subject of the research is absolutely essential:

> The human rights perspective is that the rights of the subject must prevail over the interests of science. Scientific experiments must be designed for the benefit of the subject, not for the destruction of the subject, even if the destruction of the subject may benefit another group of human beings. The use of one group of the human family to serve as experimental subjects, or spare parts resources, for another group is exploitative and abusive. The use of human embryos to serve as experimental subjects for the interests of science, creates a group of human individuals that can be used and destroyed for another group of human individuals. This violates the ethical principles of doing no harm, benefiting the subject experimented on, autonomy, justice and the sanctity of human life.[10]

1.20 Stripping the embryo of its humanity for utilitarian purposes would have frightening implications for other vulnerable minority groups.

1.21 Dr Robert Orr and Dr Christopher Hook examine rationales from the historical record used to justify research abuses on human subjects:

> … codes, guidelines, and regulations have been developed specifically for the purpose of bridling this research enthusiasm with ethical principles. One such principle is that human subjects' research is never to result deliberately in the death of a subject, regardless of how much supposed good may result from the investigation.[11]

1.22 Denying the humanity of the human embryo and using it as an experimental tool, would contravene the principles underpinning a number of international human rights instruments including:

- The Nuremberg Code (1947)
- UN Declaration on the Rights of the Child (1959)

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9 Submission 870

10 Submission 1301

11 Submission 156

- The International Covenant on Civil and Political Rights (1966)
- Protocol I Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of International Armed Conflict (1977)
- Convention on Human Rights and Biomedicine (1997)
- Universal Declaration on the Human Genome and Human Rights (1997)
- Declaration of Helsinki (2000)

1.23 Further details of these instruments are given in the Appendix to this report.

1.24 If this Bill is passed, the Australian Parliament will have abrogated the foundational principle of law and public policy regarding the uniform protection of all human life and entrenched in legislation approval for the deliberate destruction of human life for radically utilitarian, commercial purposes.

1.25 The Senate Select Committee on the Human Embryo Experimentation Bill 1985:

> sought guidance in the protective role of the law recognised in the jurisprudence of our legal system as the minimum and for some the only, justification for interference with the freedom of others – in this case the freedom to carry out research on human embryos. It is in this framework that the Committee answers the questions accepted by all as the correct query: what is the respect due to the human embryo?

1.26 The Select Committee recommended "that the principle protecting the embryo from destructive non-therapeutic experimentation be adopted by the Senate in its consideration of this matter."[12]

1.27 The current Bill radically departs from this principle of protection.

1.28 To enshrine in law the destruction of the smallest and most vulnerable members of the human family to obtain marketable human commodities would be inhuman.

The unacceptable precedent

1.29 The Bill will set a dangerous precedent in Australian law where human embryos will be defined as disposable and commodities available for use in research. Dr Warwick Neville for the Australian Catholic Bishops' Conference pointed out this legislation would mean that there would be different levels of respect accorded to the human embryo under different branches of the law:

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12 Senate Select Committee on the Human Embryo Experimentation Bill 1985, *Human Embryo Experimentation in Australia*, Parliamentary Paper 437/1986, p.xiv.

> This legislation will set the unheard-of precedent for the statutory creation of a biological underclass—namely, those unworthy of life but worthy of sacrifice on the commercial slab of experimentation. That is the precedent that would be set by this legislation. And what of the inchoate rights of embryos already recognised by the Supreme Court of Tasmania in the landmark case in 1996 of Re K? The frozen generation will be denied the ultimate right of having those rights ever crystallised.[13]

1.30 Dr Gregory Pike from the Southern Cross Bioethics Institute argues that such a precedent as contained in the Bill may have a significant negative impact on Australians' ethical approach to life and death issues:

> My … point is that we have tried to clarify what we see as a distinction which in one respect we hoped would never have to be made, and that is the distinction between intentional killing and allowing to die. It is a difficult one, but one recognised in ethics in several different arenas. What concerns me most about this particular application of the `they're going to die anyway, so let's use them' approach is that that line of reasoning has been used in other arenas in the past and some of those have been quite disturbing. As often happens in ethics and philosophy, what is a consistent argument in one arena gets transferred into another arena.[14]

Informed consent inadequate

1.31 Concern was raised in submissions that parents of embryos would not be given adequate information or control over the end uses of their embryos. The Feminist International Network of Resistance to Reproductive and Genetic Engineering (FINRRAGE), for example, observed:

> Informed consent is a central issue which we believe has yet to be properly addressed. Will donors be informed of the full implications of the research and the commercialisation of the research undertaken using the embryos they donate? Holland (1996) points out that '…downstream commercialisation is a potent and problematic issue. How to safeguard it ethically and how to keep women from potential exploitation is the rub. The potential profitability of cell lines derived from donated embryos is huge given the promise of regenerative medicine.'[15]

1.32 Dr Tonti-Filippini made a similar observation about this downstream commercialisation:

> Once couples have consented to their embryos being used, they have no further say over what may be done. They do not even have to be informed about what is done with their embryos or their embryonic stem cells. Their legal relationship with their embryos ceases when they give consent.

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13 *Committee Hansard*, 26.09.02, p.215 (Dr Neville)

14 *Committee Hansard*, 17.09.02, p.54 (Dr Pike)

15 Submission 1036.

> The Cloning Bill incorporates the interests of the researchers and their corporate supporters so that the embryonic stem cells become the unencumbered assets of the company. There is no restriction on their use, export or subsequent trade in them. An IVF couple will have no way of knowing what research is being done on their embryonic stem cell cultures, or whether the cell cultures remain identified with the couples and who the end-users might be.
>
> One would expect that couples would be interested in whether
>
> Genomically related information is obtained which is medically relevant to them and to their families
>
> The cultures and their DNA are used as a commercial asset and the couple may have lost an opportunity to profit from that commercial exploitation
>
> the end-uses of their cultures and products derived from them are ethically acceptable to them, and whether they should have exercised greater responsibility in donating their embryos.[16]

Overproduction of human embryos

1.33 The Chair's Report fails to place the current issue of human embryo research into any context. How has it come to pass that thousands of human embryos – with no chance of ever being implanted - have been deliberately created? We are on the verge of establishing a national scheme for capitalising and profiting from a situation which should never have been allowed to develop: more than 70,000 human embryos stored in a frozen state, with no questions asked as to why such a massive stockpile of embryos was allowed to accrue in the first place.

1.34 FINRRAGE argued in its written submission that:

> … this bill will act to cover up for the mistakes of the IVF industry in creating many thousands of so-called spare embryos in the first place.[17]

1.35 The number of human embryos in storage since 1994 has risen from about 22,000 to 72,000[18], a proportion of which are available for use in research.

1.36 Medical and Managing Director of Sydney IVF, Professor Robert Jansen, admitted before the last Senate committee to examine this issue that it was not difficult to manipulate a "surplus" of human embryos. Professor Jansen told the Senate Select Committee on the Human Embryo Experimentation Bill 1985:

> It is a fallacy to distinguish between surplus embryos and specifically created embryos in terms of embryo research. The reason why I say this is that any intelligent administrator of an IVF program can, by minor changes in his ordinary

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16 Submission 86.

17 Submission 1036

18 Submission 981

> clinical way of going about things, change the number of embryos that are fertilised. So in practice there would be no purpose at all in enshrining in legislation a difference between surplus and specially created embryos. It would be but a trifle administratively to make those embryos surplus rather than special.[19]

1.37 Professor Jansen has since attempted to recant this statement by referring unconvincingly to difficulties in collecting human ova rather than the issue of creating surplus human embryos.[20]

Embryonic stem cells for developing therapies

1.38 The research used to 'sell' this legislation in debate has largely been limited to embryonic stem cell research and claims by some researchers that this may lead to cures for conditions such as diabetes and Parkinson's disease.[21] However other scientists were more cautious and some were dismissive.

1.39 Deputy Vice Chancellor (Research) at the Australian National University, Professor John Hearn, warned:

> it is premature to anticipate therapeutic results that will treat patients with Alzheimers, Parkinsons, Diabetes and other disorders. The field is less than five years old. Use of patients in wheelchairs, film stars, and emotional statements from scientists, industry or the media are inappropriate and risk damaging the credibility of research.[22]

1.40 Professor Peter Rowe, Director, Children's Medical Research Institute, Westmead, Sydney said:

> I have an interest in a number of these things that are thrown around in the press, particularly things like Alzheimer's, diabetes and Parkinson's. These are very complex disorders. To say that you will cure them by putting in a few cells is a joke. We do not even know the genetic basis.[23]

1.41 Similar views were expressed by Professors Colin Masters, John Martin, Peter Silburn, Michael Pender and Michael Good.[24]

1.42 Emeritus Professor of Medicine at the University of Melbourne, John Martin, pointed out that there was no 'proof of concept' for embryonic stem cell research:

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19 Senate Select Committee on the Human Embryo Experimentation Bill 1985, Committee Hansard, 26.02.86, pages 391-392 (Dr Jansen)

20 Submission 897

21 Submission 871, 1041; Committee Hansard, 24.09.02, p.144 (Prof Pera)

22 Submission 1300

23 *Committee Hansard*, 19.9.02, p.95 (Professor Rowe)

24 Submissions 84, 87, 162, 614; Committee Hansard, 17.09.02, p.53; Committee Hansard, 19.09.02, p.95; Committee Hansard, 19.09.02, p.89-91.

> All the proponents of human embryonic stem cell research rely ultimately on the one argument – that cures for serious chronic diseases are sure to follow. If that were true it would be difficult to be opposed to it, but there is no evidence to support these claims from appropriate animal experimentation …
>
> Why, then, should we not require a substantial body of evidence to justify destructive research on human embryos? Why do we not have from animal models of disease, ample proof of the principle that, say in diabetes or Parkinson's Disease, prolonged therapeutic benefit can be obtained from the use of ES cells, and that this can be achieved free of the problems of tumour development, and overcoming the immunological barriers? Why do we not have laid out clearly the milestones to be achieved in fulfilling these conditions, and the time-lines required?[25]

Destroying human embryos for research

1.43 The broader range of destructive human embryo research received less attention than embryonic stem cell research. As outlined earlier, the range of embryo research permitted by the Bill includes using human embryos:

- to examine the effectiveness of new culture media used in assisted reproductive technology (ART) practice;
- to assist in understanding embryonic development and fertilisation;
- training clinicians in microsurgical ART techniques;
- transport, observation and storage of embryos;
- micromanipulation, lasering, cutting and dissecting;
- studies in genetic makeup and expression;
- quality assurance testing to ensure that pre-implantation diagnostic tests give accurate results;
- drug testing including toxicology studies on human embryos as well as the destructive extraction of embryonic stem cells.[26]

1.44 The Southern Cross Bioethics Institute noted that the list of research that will be carried out on human embryos is likely to include "toxicology studies on live human embryos, and testing new drugs on humans rather than animals".[27]

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25 Submission 162

26 Committee Hansard, 26.9.02, p.255-256 (Dr Morris)

27 Submission 892, attachment *Human Embryos: A Limitless Scientific Resource?*, page 8-9.

1.45 Dr Tonti-Filippini commented on some of the areas of research which might involve human embryos and human embryonic stem cells:

> We are seeing a whole opening up of this area to unregulated, unrestricted and unsurveyed research on both the stem cells and the embryos. You ask questions like these: who stops the stem cells finishing up in cosmetics and who stops them being sent for biowarfare to one of the less democratic regimes in the world? Remember, they can be sold off. Alan Trounson was talking earlier about buying and selling the stem cells. If he has got products here in Australia within the companies that he is associated with, what stops those companies selling them to anybody?[28]

1.46 The Committee also heard evidence from Sydney IVF Medical Director professor Robert Jansen that "hundreds" of embryos would be needed "in the development of culture medium for meaningful results".[29]

Alternative stem cell sources

1.47 A number of submissions gave references to over one hundred articles published in peer reviewed scientific and medical journals which detail successful therapies now available to patients using adult stem cells. These include treatments to treat patients with stroke, cancer, bone defects, and muscle, gut and retina problems. There have also been promising results published where there have been successful adult stem cell experiments using animal models to treat conditions such as spinal injury, Diabetes and Parkinsons.[30]

1.48 Dr Tonti-Filippini noted that to-date no successful therapies for humans have been published using embryonic stem cells:

> Treatments using a patient's own stem cells have been achieved for many diseases. Claims about treatments of disease using embryonic stem cells are just hype. There just is no such track record for embryonic stem cells. In these circumstances, it is ludicrous to be claiming the development of treatments using embryonic stem cells as a reason for passing a Bill allowing human embryonic experimentation. There is no such necessity. The truth of the matter is that human embryos and embryonic stem cells have many research and industrial uses …[31]

1.49 Adult stem cells have been compared unfavourably with embryonic stem cells on the basis that they do not have pluripotentiality – the ability to produce many types of tissue. However Professor Michael Good, Director of the Queensland Institute of Medical Research has described this limitation as an advantage:

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28 *Committee Hansard*, 24.09.02, p.165.

29 Committee Hansard, 26.9.02, p.211 (Professor Jansen)

30 Submissions 86, 480, 1042, 1571.

31 Submission 86.

> …the ideal cell that you want in a transplantation situation is one that does not have great pluripotency, that cannot differentiate into multiple unwanted tissues, that has a limited tissue differentiating profile and that you have enough of. Those cells are provided by adult stem cells. Furthermore, if they are taken from the patient, you will not have this problem of graft rejection, which to me is the major problem of embryonic stem cell derived tissue."[32]

Communities opposed to destructive embryo research

Aboriginal and Torres Strait Islanders

1.50 The National Aboriginal Community Controlled Health Organisation made a submission to the Committee which drew attention to Aboriginal and Torres Strait Islander people's concern with the Bill. The submission referred to "strong cultural beliefs opposed to the destruction of human life from its earliest stage. Embryonic stem cell research would violate such beliefs and accordingly we could not support such research."[33]

People with disabilities

1.51 A significant number of submissions from people with disabilities opposing the destruction of embryos were received, though none were invited to give evidence before the Committee.

1.52 Diabetics for Ethical Treatment argued that:

> It is unethical, and an insult to the integrity of persons with diabetes, to pursue research into therapies which involve harming or destroying human beings, including human embryos … We firmly believe that an attack on the dignity and well-being of any group of human beings is an attack on human dignity itself. It is a profound insult to people with disabilities and illnesses, including diabetics, to presume that we are willing to accept therapies developed at the cost of other human lives.[34]

1.53 Some families made submissions to the Committee, with Olivia and Vicki Dunne drawing attention to their experience living with Cystic Fibrosis:

> As a sufferer and as a carer, we would submit to the members of the Committee that it is not legitimate to look for those cures at the cost of another human being. We have seen that in embryonic stem cell research the donor is always destroyed. If the price of new lungs and new pancreases for the members of our family is someone else's life then it is too high a price to pay.[35]

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32 Committee Hansard, 19.9.02, p.91 (Professor Good)

33 Submission 1837

34 Submission 1293

35 Submission 1081

1.54 The Sadkowsky family drew attention to the experience of their daughter, who has Rett Syndrome:

> We share both happy and sad times with her, along with our other children, and we are very proud of the progress she has made despite the difficulties imposed on her by Rett syndrome. In the 23 years of her life she has made an immeasurable, positive contribution to our family, our friends and community in general. Over the years, we have met many wonderful people through association with Veronica … Adult stem cells are available in the body, without resorting to the destruction of human embryos … It is our opinion that the resources would be better channelled into this form of research.[36]

1.55 The Archdiocese of Melbourne's also recorded that in the United States:

> … James Kelly, a 45-year-old paraplegic due to spinal cord injury, wrote to US President Bush asking him to support embryonic stem-cell research. Since then he has undertaken a great deal of research into the area himself. He discovered that while adult stem-cells can and have been used safely in humans for various therapies, and are clearly our "brightest hope", the embryo industry has instead promoted embryonic stem-cells. During his US Senate testimony, Mr Kelly stated: "I think it is highly immoral for researchers and others to encourage the sick, crippled and dying to cut their own throats by supporting cloning [and embryonic stem-cell research], a research avenue whose extremely speculative potential lies somewhere in the distant, hazy future, to the detriment of proven avenues that offer more than futile help.[37]

Women

1.56 There were a number of submissions received from women's groups concerned about embryo research and cloning to produce embryos for research or therapies.

1.57 Feminists for Life (ACT) commented that:

> Embryo research raises serious ethical questions about the exploitation of women - especially in regard to the demand for eggs to produce what are now deemed to be surplus embryos or, if some science lobbyists get their way, for the cloning of embryos for research.[38]

1.58 FINRRAGE point out that:

> To justify the research goal, women and people with disabilities are sometimes held up as future beneficiaries of this research. But the debate is being driven by the immediate beneficiaries, the research and biotechnology

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36 Submission 1084

37 Submission 876

38 Submission 1064

> communities, which are determined that this research go ahead. The science lobbyists are intolerant of voices from other communities and in some cases have misled Parliamentarians in their determination to get their way.

1.59 Further, they note that:

> It is ironic that under the proposed legislation, women would not be able to sell their ova or embryos, while researchers are later able to commercialise the results of their experiments and may potentially make substantial sums of money.[39]

Conscientious objection not protected

1.60 Another concern expressed was for the right to conscientious objection of stem cell scientists or students who are opposed to using embryos as research tools, and protection from discrimination because of their position. Conscientious objection is also of concern to potential recipients of drug treatments derived from destructive research on embryos.

1.61 There is a concerted attempt by those supporting embryonic stem cell research to promote the integration of adult stem cell research with embryonic stem cell research either directly or indirectly.[40]

1.62 The use of human embryos and human embryonic stem cells in the testing of drugs and toxicology studies for drug development has major implications for those objecting on ethical grounds.

1.63 Dr David van Gend, representing Do No Harm, argued that if widespread embryo research is allowed to go ahead, Australians will have difficulty exercising their right to conscientiously object or opt out of involvement:

> Conscientiously, people can object from certain practices—abortion, euthanasia, going to war and so on. But if the fabric of medical knowledge is stained, as it were, by knowledge derived from destruction of human embryos, then people will be beneficiaries of that knowledge when they take from their doctor these new drugs. It is a novel predicament. To me, it is an uncivil predicament, because never before have we faced a situation where certain members of society who would conscientiously object from using things like drugs derived from embryos will have no way out. They will not be able to opt out of standard medical care when, as would happen with embryo research, the whole body of pharmaceuticals is tainted with that research.[41]

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39 Submission 1036

40 Committee Hansard, 19.09.02, p.105.

41 Committee Hansard, 24.09.02, page 175 (Dr van Gend)

Cloning still an issue of concern

1.64 The Chair's report does not address the ethical issues surrounding one half of the referred Bill, now called the *Prohibition of Human Cloning Bill 2002*. Human cloning is an area of significant concern and, while there appears to be a very clear Parliamentary majority to support the prohibition of human reproductive cloning, it is important to state clearly what human cloning is and the reasons why it is unacceptable.

1.65 Universal opposition to human cloning cannot be assumed. The Academy of Science, a senior member of the IVF research community and the science adviser to a Cabinet minister are all on the record as not opposed cloning in various forms.

1.66 Dr Thomas Barlow, science adviser to Education, Science and Training Minister, Dr Brendan Nelson, wrote in a column in the UK *Financial Times* (1 September 2001) that he considers human reproductive cloning to be no more serious an issue than "having sex". "Not to beat about the bush, is there any honest reason why we should treat it more seriously, say, than having sex?" he wrote.

1.67 Professor Martin Pera from the Monash Institute of Reproduction and Development, stated that:

> … although the scientific case for the clinical application of therapeutic cloning in man is not compelling at present, basic research on reprogramming in humans may eventually be very important to successful development of adult stem cell based therapies. I therefore endorse in principle the original recommendation of the report of Mr. Kevin Andrews' committee of inquiry for a moratorium, rather than a ban, on this area of research.[42]

1.68 In testimony before the Committee, the Academy of Science reaffirmed its support for cloning embryos so that they could be destroyed for their stem cells, which could then theoretically be used in therapies. This would be achieved by somatic cell nuclear transfer.

1.69 Distinctions are frequently drawn between cloning for reproduction and cloning where the embryo is destroyed to produce therapies, there is little difference in the basic process.

1.70 The House of Representatives report *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*, employed this distinction when it summarised the most common arguments against cloning for reproductive purposes as:

- A lack of any medical need for cloning for reproductive purposes;

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42 Submission 873

- Cloning for reproductive purposes would constitute an infringement of human dignity;
- Cloning for reproductive purposes would have a negative effect on the family and personal relationships;
- Cloning for reproductive purposes would undermine individuality and identity;
- It would be unsafe;
- Cloning for reproductive purposes would potentially pose a threat to human diversity and run the risk of reintroducing notions of eugenics; and
- It would raise the potential for coercion of women.[43]

1.71 However, when asked whether somatic cell nuclear transfer was cloning, whether or not the embryo was placed in a woman's uterus or in a petri dish for experiments, Professor John White from the Academy of Science agreed it was the same process:

> … I am glad to agree with you. It certainly is cloning, and the academy has never resiled from that point of view. It is the method, which was used to produce the sheep "Dolly", that can actually allow the DNA from any particular donor to be expressed in embryonic stem cells. The only virtue of it from the point of view of future science is that that particular potential is the only way we know to go about the point. So, of course, it is destructive cloning – I am afraid I have to agree with you.[44]

1.72 One particular danger of accepting human cloning – the danger of women being exploited - was raised by a number of groups including FINRRAGE (Australia):

> Women's bodies are central to the hopes and aspirations of scientists determined to work in the embryonic stem cell area. Without access to women's bodies to harvest their ova, scientists would not be able to produce the surplus of embryos we are being asked to release to scientific research. Women's eggs don't drop out of the ether. They come from a woman's ovary which is in a woman's body. The ovary has to be hyper-stimulated with dangerous drugs and the egg cells mechanically extracted.[45]

1.73 FINRRAGE notes that:

> If therapeutic cloning were to go ahead - and there is no doubt the pressure for it will only intensify - the scientists would then need to work out ways to harvest thousands more ova from women. Scientists undertaking this

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43 Human Cloning, pages 77-78.

44 Committee Hansard, 19.09.02, p.125

45 Submission 1036. See also submission 1046.

> research therefore need the cooperation of women to produce the embryos they need for experiments.[46]

1.74 FINRRAGE also pointed out that one US source estimates that if cloning was allowed to produce compatible tissue for therapies:

> … if embryonic stem cells were to provide up to 1.7 million therapies per year, this would require a minimum of 5 – 8 million ova each year. This estimate generously assumes that it would only take between three and five embryos to produce one embryonic stem cell culture.[47]

1.75 The Australian Catholic Bishops' Conference also raised the issue of the quality of frozen embryos and whether the call of some biotech companies for access to 'fresh' embryos, which may be a future pressure for cloned embryos:

> There is growing evidence that children born from IVF suffer from a range of adverse medical conditions. Presumably IVF practitioners have selected for implantation those embryos which are deemed the "best of the crop." If that is so, it would mean that those embryos now deemed "spare" or "excess" might well be of a second order in quality. One might ask, from the prevailing utilitarian perspective, whether researchers would really want, or should be allowed, to use embryos of perhaps inferior quality? If not, would there not then be a push for the need for and use of "fresh" embryos? This has already been suggested in the debate by some of the biotech companies. How would a pro-research licensing committee resist such an application? [48]

The Bill

1.76 A large range of problems with the Bill were raised in submissions and in the Senate Committee hearings. This evidence pointed to major flaws and gaps in the Bill in the areas of regulation, monitoring, reporting requirements, accountability, absence of guidelines and lack of independence in oversight bodies.

1.77 In his written submission, Dr Tonti-Filippini also pointed out that there was no regulation of industrial and other uses of human embryonic stem cell cultures:

> Human embryonic stem cell cultures fall outside existing ethical guidelines because they are not considered human tissue. They are considered not to have been removed from a human body but generated in the laboratory from human embryos. For ethics committees the stem cells do not constitute a human subject and hence are not within their jurisdiction. The Bill contains no restriction on the use of human ES cells.[49]

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46 Submission 1046

47 Submission 1046

48 Submission 981

49 Submission 86

1.78 Clause 10 deals with the offence of intentionally importing or exporting a human embryo clone. Dr Morris from the NHMRC advised the Committee that there is nothing to prevent a person from taking stem cells from a human embryo and then selling them for profit overseas:

> The use of cells derived from any tissue would be permitted to be sent overseas … [The legislation] does not prohibit any uses of embryonic stem cells.[50]

1.79 Among other interesting omissions in the Chair's Report is the fact that literature from biotechnology academics has noted the relevance of other statutory regimes concerning the regulation of matters relevant to ART. Other relevant regimes include not only the Trade Practices Act, but matters relating to intellectual property.

1.80 In further evidence before the Committee, Dr Neville argued that given that the legislation provides for the concealment of confidential commercial information, other ways of keeping the embryo research industry accountable to the public might include the Trade Practices Act and anti-discrimination legislation.[51]

1.81 Concern was expressed that the Bill was being considered when the new NHMRC guidelines referred to in the Bill had not yet been sighted:

> … those guidelines were published in 1996 and they are the subject of review at the moment. So, again, it only adds to the speculative nature and, therefore, also the difficulty of this committee and the parliament to enact legislation when, as it were, all of the balls are still in the air. [52]

1.82 In relation to clause 28, which establishes the NHMRC Licensing Committee, there was evidence given to the Committee that it was inappropriate for the Licensing Committee to be located within the administration of the NHMRC. The ACF GeneEthics Network commented that:

> The NHMRC is impenetrable and effectively answerable to no-one outside. GTRAP and AHEC are examples of NHMRC with whom we have attempted to engage over many years, with very little success. We propose that this licensing function be vested in the Office of Gene Technology Regulator who has statutory responsibilities and authority commensurate with the importance of this licensing work, and has processes and mechanisms to engage with the interested and general publics.[53]

1.83 Dr Tonti-Filippini drew attention to inappropriateness of having the National Health and Medical Research Council as the parent body for the licensing authority:

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50 Committee Hansard, 26.09.02, p.256-257 (Dr Morris)

51 Committee Hansard, 26.09.02, p.216 (Dr Neville)

52 Committee Hansard, 26.09.02, p.220 (Dr Neville)

53 Submission 1843

> We do have a culture here with the Human Research Ethics Committee and the NHMRC, and now the licensing authority … There is not openness in reporting or stringent reporting requirements, so you have got no reporting of, for instance, the Human Research Ethics Committee's decisions or anything like that. The public does not have access to those. So we have got a fairly secretive culture, a non-consultative culture. In fact, the institutions will defend that in terms of their own commercial interests and so on and also their interests in not having public scrutiny."[54]

Conclusion

- The Bill sets an unacceptable and profoundly disturbing precedent in committing for the first time destructive experiments on human embryos. A certain class of human life will be considered expendable for profit. The Bill will entrench the commercialisation and commodification of human life.

- The scope of the legislation is so broad as to facilitate a wide range of destructive research on human embryos of which stem cell research will be a minor part. None of these areas of human embryo research were the subject of the original COAG agreement.

- The embryonic human being has inherent dignity and equal and inalienable rights due to membership of the human family.

- The Bill contravenes the body of human rights law on human experimentation in using one section of the human family to serve as experimental subjects or spare parts resources for another group.

- Stripping the embryo of protection for utilitarian purposes has frightening implications for other vulnerable minority groups.

- The consent process for donating embryos to research is inadequate. The Bill contains no restriction on embryonic stem cell use, export and subsequent trade. Once couples have consented to their embryos being used they have no further say in how their embryos will be used.

- More than 70 000 human embryos are currently in storage. The Chair's report fails to address the crucial question as to why such a massive stockpile of embryos were allowed to accrue in the first place.

- Prominent scientists have cast significant doubt on the overblown claims of pro embryonic stem cell research advocates.

- No successful therapies using embryonic stem cells have been published. A number of submissions gave references to more than 100 articles published in

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54 Committee Hansard, 24 September 2002, p.165.

peer reviewed scientific and medical journals detailing successful therapies using adult stem cells.

- A number of specific communities, among them indigenous people, people with disabilities, and women expressed specific concern about destructive embryo experimentation. Some people with disabilities stated that it was unethical and an insult to their integrity to pursue research which involved harming other human beings.

- The right to conscientious objection is threatened by this Bill.

- The Chair's report does not properly address the ethical issues surrounding one half of the Bill. A number of scientists have publicly expressed their support for cloning embryos so they could be destroyed for their stem cells. There is no distinction between cloning for reproduction and so-called therapeutic cloning.

- Regulation and licensing has been shown to be inadequate. There is no regulation of industrial and other uses of human embryonic stem cell cultures.

- If this Bill is not rejected the Australian Parliament will have abrogated the foundational principle of law and public policy regarding the uniform protection of all human life and will entrench in legislation the deliberate destruction of human life for radically utilitarian, commercial purposes.

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Senator Brian Harradine (Ind, Tas.)

Appendix

International human rights and medical research

The International Covenant on Civil and Political Rights (1966)

Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life (Article 6(1)).

"sentence of death … shall not be carried out on pregnant women" (Article 6 (5)).

UN Declaration on the Rights of the Child (1959)

Governments are obliged "to provide appropriate legislative protection for the child, before as well as after birth." (preamble)

"every child [ie before as well as after birth] has the inherent right to life" (Article 6)

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation (Article 7).

The Nuremberg Code

Principle 1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

Principle 5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

Protocol I Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of International Armed Conflict, 8 June 1977

Article 11 - Protection of persons

1. The physical or mental health and integrity of persons who are in the power of the adverse Party or who are interned, detained or otherwise deprived of liberty as a result of a situation referred to in Article 1 shall not be endangered by any unjustified act or omission. Accordingly, it is prohibited to subject the persons described in this Article to any medical procedure which is not indicated by the state of health of the person concerned and which is not consistent with generally accepted medical standards which would be applied under similar medical circumstances to persons who are nationals of the Party conducting the procedure and who are in no way deprived of liberty.

2. It is, in particular, prohibited to carry out on such persons, even with their consent:

(a) physical mutilations;

(b) medical or scientific experiments;

(c) removal of tissue or organs for transplantation, except where these acts are justified in conformity with the conditions provided for in paragraph 1.

3. Exceptions to the prohibition in paragraph 2 (c) may be made only in the case of donations of blood for transfusion or of skin for grafting, provided that they are given voluntarily and without any coercion or inducement, and then only for therapeutic purposes, under conditions consistent with generally accepted medical standards and controls designed for the benefit of both the donor and the recipient.

Convention on Human Rights and Biomedicine (1997)

The European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, also known as the Convention on Human Rights and Biomedicine of 4 April 1997. Council of Europe.

Article 2 – Primacy of the human being

The interests and welfare of the human being shall prevail over the sole interest of society or science.

Article 16 – Protection of persons undergoing research

Research on a person may only be undertaken if all the following conditions are met:

…

(ii) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research,

(iii) the research project has been approved by the competent body after independent examination of its scientific merit, …

(v) the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Article 17 – Protection of persons not able to consent to research

Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:

1…

iii research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

iv the necessary authorisation provided for under Article 6 has been given specifically and in writing; and

v the person concerned does not object.

2 Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:

i the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition;

ii the research entails only minimal risk and minimal burden for the individual concerned.

Article 18 – Research on embryos *in vitro*

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

2 The creation of human embryos for research purposes is prohibited.

Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Subjects

World Medical Association

October 2000

5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.

17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

Universal Declaration on the Human Genome and Human Rights

This declaration was adopted unanimously and by acclamation at the twenty-ninth session of UNESCO's General Conference on 11 November 1997. The following year, the United Nations General Assembly endorsed the Declaration.

Article 5

e) If according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights.

Article 10

No research or research its applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.

Article 11

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.

APPENDIX 1

LIST OF PUBLIC SUBMISSIONS, TABLED DOCUMENTS AND OTHER ADDITIONAL INFORMATION AUTHORISED FOR PUBLICATION BY THE COMMITTEE

The following is a listing of those organisations and individuals who made submissions to the inquiry. The Committee secretariat had difficulty in determining the exact spelling of names and addresses in some handwritten material. In addition it was unclear in some cases whether a submission was provided in an individual capacity or on behalf of an organisation. Therefore there may be some minor inaccuracies in the recording of submissions.

ORGANISATIONS

1047 ACCESS - Australia's National Infertility Network (NSW)
Supplementary information
- Response to questions following public hearing, dated 27.9.02 and 1.10.02

1843 ACF GeneEthics Network (VIC)

672 Anglican Diocese of Sydney, Social Issues Executive (NSW)
Tabled at hearing on 24.9.02
- References documenting the scientific advances in 'adult' stem cell research

Supplementary information
- Additional information from public hearing, received 15.10.02

1473 Apostles for Life (NSW)

361 Assemblies of God in Australia (NSW)

1045 AusBiotech (VIC)

893 Australasian Spinal Research Trust (NSW)
Tabled at hearing on 17.9.02
- Email dated 11.9.02 on visiting US scientists

Supplementary information
- Response to questions following public hearing received 25.9.02

1219 Australia & New Zealand Society for Cell and Developmental Biology (SA)

1044 Australian Academy of Science (ACT)

981 Australian Catholic Bishops Conference (ACT)
- Part 2 of submission, dated 13 September 2002

Supplementary information
- Provided at public hearing 26.9.02, *Sample lead studies: Exploitation of Women*
- Response to questions from public hearing 26.9.02, dated 9.10.02

1402 Australian Christian Lobby (ACT)

866 Australian Family Association (VIC)

986 Australian Family Association - Geelong Branch (VIC)

1029 Australian Family Association - Newcomb Branch (VIC)

1099 Australian Family Association - NSW (NSW)

983 Australian Family Association - The Bayswater/Boronia Branch (VIC)

811 Australian Family Association SA (SA)

1040 Australian Federation of Right to Life Associations (ACT)

1239 Australian Research Council (ACT)

1035 Australian Youth Alliance, The (VIC)

1263 Biotechnology Australia Division (ACT)
Supplementary information
- Provided at public hearing 26.9.02, copy of article by R. Boyd et al *generation of a complete thymic microenvironment by MTS24 thymic epithelial cells,* published online
- Additional information from public hearing 26.0.02, dated 15.10.02

1030 BresaGen Limited (SA)
Supplementary information
- Additional information following public hearing, dated 20.9.02
- List of references which question adult stem cell plasticity, dated 24.9.02
- Supplementary information from hearing, dated 2.10.02
- Article re plasticity of stem cells, Experimental Hematology 30 (2002) 848-852

1006 Burnie-Devonport Lutheran Parish (TAS)

280 Caroline Chisholm Centre for Health Ethics (VIC)

876 Catholic Archdiocese of Melbourne (VIC)

968 Catholic Association of Sydney Tamils (NSW)

1009 Catholic Doctors Association of WA (WA)

987 Catholic Health Australia (ACT)

765 Catholic Medical Guild of St Luke (QLD)

882 Catholic Women's League Australia Inc (ACT)

1046 Catholic Women's League Australia-NSW Inc (NSW)

1005 Catholic Women's League of Victoria & Wagga Wagga (VIC)

989 Catholic Women's League of Victoria & Wagga Wagga Inc (VIC)

268 Catholic Women's League, Leeton NSW Branch (NSW)

658 Christian Reformed Churches of Australia - Classis WA (WA)

564 Christian Traders (NSW)

895 Coalition for the Advancement of Medical Research (CAMRA) (NSW)
Tabled at hearing on 17.9.02
- Article from *Cell,* vol 110, 9.8.02, pp.385-397

Supplementary information
- Additional information following public hearing dated 23.9.02

868 Coalition for the Defence of Human Life (WA)

1032 Council for Marriage and the Family (VIC)

764 Council for the National Interest - Western Australian Committee (WA)

849 Country Women's Association of NSW (NSW)

1293 Diabetics for Ethical Treatment (WA)

1598 Disability Action Group (ACT)

1042 Do No Harm - Australians for Ethical Medical Research (QLD)
- Attachment to submission, 13 September

Tabled at hearing on 24.9.02
- Human Embryo Forum (Video) - held at Toowoomba, 8 August 2002
- Corrections to submission and info on an AusBiotech meeting

Supplementary information
- Response to a question following public hearing, dated 1.10.02

1048 Do No Harm – NSW Branch (NSW)

211 Do No Harm – South Australian Branch (SA)

880 Do No Harm – WA Branch (WA)

1235 Don't Cross the Line (NSW)
Tabled at hearing on 24.9.02
- Replacement submission
- Information on the membership of the US President's Council on Bioethics

1025 Endeavour Forum (VIC)

1039 ES Cell International Pte Ltd (VCI)

1062 Family Council of Queensland (QLD)

1033 Family Council of Victoria (VIC)

1482 Fatherhood Foundation (NSW)

1036 Feminist International Network of Resistance to Reproductive and Genetic Engineering (FINRRAGE) (VIC)

1064 Feminists for Life ACT (ACT)

1073 Festival of Light (SA)

382 Fulton J. Sheen Society of Perth Western Australia Inc (WA)

667 Human Life International (Australia) (NSW)

982 Humanist Society of Victoria (VIC)

1826 Infertility Treatment Authority (ITA) (VIC)

896 Juvenile Diabetes Research Foundation (NSW)

1070 Knights of the Southern Cross NSW (NSW)

984 L J Goody Bioethics Centre (WA)

736 Members of Queensland Right to Life Rockhampton Branch (QLD)

477 Monash Institute of Reproduction and Development, Centre for Early Human Development (VIC)

1007 Monash IVF (VIC)

843 Motor Neurone Disease Association, Dr Paul Brock (NSW)

1837 National Aboriginal Community Controlled Health Organisation (NACCHO) (ACT)

1067 National Civic Council - NSW (NSW)

1056 National Civic Council - Queensland Branch (QLD)

282 National Civic Council (WA) (WA)

23 National Health and Medical Research Council (ACT)
Supplementary information
- Responses to questions following public hearing 29 August 2002, dated 13.9.02
- Response to questions re HRECs, dated 26.9.02
- Response to questions re consent, dated 2.10.02
- Additional information re IVF concerns, dated 15.10.02
- Responses to questions from public hearing on 26.9.02, received 16.10.02
- Response to questions after hearing, dated 18.10.02

1234 National Stem Cell Centre (VIC)
Supplementary information
- Additional information presented at public hearing 24.9.02
- Response to question after public hearing, dated 26.9.02

219 NSW Doctors for Life (NSW)

891 NSW Government (NSW)

969 Our Lady of Lourdes Parish (WA)

302 Pauline Association (TAS)

1292 Peter MacCallum Cancer Institute, Members of the Stem Cell Program (VIC)

690 Presbyterian Church of Eastern Australia Church and Nation Committee (VIC)

510 Presbyterian Church of Queensland (QLD)
1069 Presbyterian Church of Victoria, Church and Nation Committee (VIC)
1570 Pro-Life Victoria (VIC)
870 Queensland Bioethics Centre (QLD)
1500 Queensland Government (QLD)
1037 Queensland Right to Life Associations (QLD)
1054 Renal Regeneration Consortium (QLD)
1031 Right to Life Association (NSW) (NSW)
1028 Right to Life Association (NSW) - John Haseler Branch (NSW)
1003 Right to Life Australia (VIC)
508 Right to Life Australia Queensland Office (QLD)
1034 Royal Australasian College of Surgeons (VIC)
1502 Salt Shakers – A Christian Ethics Group (VIC)
1503 Social and Political Youth Study Club from the Free Reformed Churches (WA)
892 Southern Cross Bioethics Institute (SA)
Supplementary information
- Additional information following public hearing, dated 26.9.02
- Response to questions from public hearing, dated 2.10.02

611 St Paul's Anglican Church, Parish of St Helens (TAS)
1483 St Vincent's Hospital Sydney (NSW)
1012 Stem Cell Sciences Ltd (VIC)
541 Survivors of Abortion Ltd (TAS)
1049 Thomas More Centre, Sydney (NSW)
223 Thomas More Social Action Group, Hawthorn (VIC)
1442 Veritas Young Adults Group Normanhurst (NSW)

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1571 Abboud, Dr Amin (NSW)
1584 Abramowicz, Mrs K (WA)
797 Addlem, Ms Cara (VIC)
755 Addlern, Ms Sheryl (VIC)
1184 Adeney, Mr Warwick (QLD)
1181 Adeney, Ms Michele (QLD)
104 Adkins, Ms Margaret (TAS)
642 Adolphe, Mr Paul (NSW)
551 Agius, Ms Antoinette (VIC)
1577 Ahrens, Mr Bill (NSW)
1110 Ahronson, Mrs Mavis (VIC)
728 Aitken, P (VIC)
328 Akers, Miss R (VIC)
1581 Alack, Mr Ron (WA)
242 Aldous, Mr Geoffrey C (WA)
1546 Alford, Ms Margaret (NSW)
1438 Allan, Ms Diana (QLD)
1776 Allchurch, Ms Emma (VIC)
975 Allen, Mr Bryan & Mrs Margaret (QLD)
562 Allen, Mrs A (NSW)
1829 Allen, Mrs Clare (WA)
1817 Allen, Ms Betty (VIC)
1192 Allman, Mrs Mary (VIC)
1611 Allman, Ms Emily (VIC)
640 Alonso, C (NSW)
139 Alp, Miss Nicola (VIC)
138 Alp, Mr A (VIC)
125 Alp, Mr James (VIC)
134 Alp, Mrs R (VIC)
132 Alp, Ms Stephanie (VIC)
358 Altham, Mrs Veronica (NSW)
609 Althaus, J & O'Connor, Mrs M (QLD)
814 Althaus, Mr AG (QLD)
195 Althaus, Mrs Margaret (QLD)

850 Althaus, Ms Anne-Maree (QLD)
47 Althaus, Ms Catherine (QLD)
452 Amato, Mrs Lila (WA)
808 Ambrose, Ms Carolyn (WA)
1401 Anbeek, Mr A & Mrs D (VIC)
1093 Anderson Family (NSW)
1730 Anderson, H (VIC)
598 Anderson, Ms Faye (WA)
741 Andrealla, M (NSW)
904 Andreallo, Ms Pamela (VIC)
241 Andrews, Mr Michael (VIC)
176 Andrews, Ms Linda (SA)
1058 Andrews, Professor Peter (QLD)
832 Anglo, Ms Grace (NSW)
1530 Anstey, Ms Lynn (QLD)
1791 Antonello, M (WA)
455 Antunovic, N (WA)
740 Apelt, C J (QLD)
158 Appleby, Mr Jerome (SA)
1426 Arms, Ms Cecily (TAS)
1393 Armstrong, Mr N & Ms K (NSW)
1558 Arnold, Mr Philip (VIC)
1557 Arnold, Ms Nola (VIC)
780 Arragon, Mr & Mrs (NSW)
40 Ash, Mr Robert (NSW)
90 Ashkar, Mr Rimon & Mrs Ellen (QLD)
254 Aslett, Mrs Imelda (WA)
1670 Asphar, Mr Jim (WA)
1855 Atherton, Mr Philip (QLD)
10 Austen, Mr Steven (QLD)
22 Austin, Mr Patrick (VIC)
1852 Ayres, Mrs Elizabeth (QLD)
1853 Bacon, Mr Paul (NSW)
709 Bagguley, C (VIC)
912 Bagguley, Mr Charles (VIC)
1652 Bagguley, Mr Damien (VIC)
770 Bagguley, Mrs Marianne (VIC)
484 Bagus, Mr Marlo (NSW)
1288 Bailey, Mr Larry & Ms Beverley (NSW)
707 Bajuk, Ms Julie (WA)
407 Baldwin, Ms Monique (NSW)
1662 Baldwin, S (VIC)
363 Baleriola, Dr Cristina (NSW)
1299 Ball, Ms Jenny (ACT)
4 Ballesteros, M P (NSW)
24 Ballesteros, M P (NSW)
304 Balogh, Ms Sarah (QLD)
660 Balzevic, Ms Julie (NSW)
668 Barber, Rev Peter (QLD)
1561 Barbero, RV & PJ (NSW)
459 Baric, Ms Marina (WA)
354 Barich, Mr John (WA)
453 Barnes, Dr Doris (NSW)
454 Barnes, Dr John (NSW)
827 Barnes, Mr Ian & Ms Mary (NSW)
1615 Barnes, Ms P Barnes (VIC)
15 Barnes, Rev Dr Peter (NSW)
1087 Barrett, Mr Glenn (QLD)
357 Barrett, Ms Heather (NSW)
841 Barry, Dr Jerard (NSW)
1623 Barry, Ms Angela (VIC)
723 Bassi, Mrs R (VIC)
380 Bastoli, Mr Elias & Ms Sandra (NSW)
1290 Bates, Ms Christie (em)
612 Bath, Tony (NSW)
1106 Batteccio, Mrs Anna (NSW)
788 Batten, Ms Catherine (NSW)
1209 Beale, Mrs J (VIC)
1514 Beer, Mr Troy (QLD)
994 Beevers, Mr Craig & Mrs Andrea (QLD)
1119 Behiels, Mr Andre & Mrs Nicole (WA)
16 Bell, Ms Thea (NSW)
1767 Bennett, Mrs Betty (QLD)
329 Bennett, Ms Catherine (NSW)
1359 Bennett, Ms Dorothy (WA)
1124 Benson, Mrs Moya (VIC)
1527 Benson, Mrs Victoria (QLD)
1624 Benson, Ms Jenny (VIC)
767 Bentley, L (NSW)
570 Berger, Mr H & Mrs E (TAS)
419 Best, Dr Megan (NSW)
333 Beswick, Mrs Pat (WA)
1486 Biddell, Mr Dale (QLD)
1494 Bignold, Mr Charles (em)
398 Billing, Mr Ralph (NSW)
1654 Bionti, B (VIC)
1698 Bird, Ms Kathleen (VIC)
698 Black, Dr W & P, Dr Joseph (WA)
415 Black, Mr Keith & Ms Betty (QLD)
1819 Blackman, P (VIC)

647 Blackmore, Mr Garnet (NSW)
514 Blair, Mr Jack & Ms Nanette (NSW)
1280 Bland, Mr David (QLD)
1279 Bland, Ms Sandra (QLD)
997 Blee, Ms Jessie (QLD)
204 Blevins, Ms Dianne (WA)
859 Bloomfield, Ms Lesley (QLD)
355 Blythe, Mrs N (WA)
910 Bobbin, A A (NSW)
739 Boersma, Mr Jeffrey (WA)
815 Boettcher, Ms Kerry (QLD)
619 Bohan, Mr John (VIC)
1588 Bohan, Mr Leo (VIC)
930 Bolar, Ms Ruth (WA)
106 Boller, Sister Beatrice (NSW)
516 Bom, Mr Robert (QLD)
1357 Bond, Mr W J (VIC)
1574 Bond, Mrs Ruth (WA)
1394 Bond, Ms Kathleen (VIC)
542 Boneham, Mr Gavin (NSW)
1457 Bonner, Ms Catherine (TAS)
1665 Booker, Ms Mary (VIC)
1543 Borham, Mr Barry (NSW)
1454 Bosel, Ms Patricia (QLD)
691 Bosotti, Ms C & Mr M (NSW)
53 Bourke, Dr Kevin (NSW)
759 Bourke, E M (VIC)
791 Bourke, Mr Basil (NSW)
1718 Bourke, Mr Paul (VIC)
860 Bourke, Mrs Elizabeth (VIC)
711 Bourke, Ms H (VIC)
3 Bourne, Mr Roger (NSW)
852 Bowden, Miss K M (QLD)
474 Bowden, Mr Ivan (QLD)
1469 Bowden, Ms Sarah (QLD)
1051 Bowman, Dr Mark (NSW)
250 Bowyer, Mr Ian (NSW)
1773 Boyce, Ms Anne (NSW)
661 Boyd, Mr A & Mrs C (VIC)
590 Boyers, G T (NSW)
389 Boyle, Mr Alan (VIC)
1150 Boylson, Mr Michael Gregory (WA)
1612 Bradbury, Mr Neil (VIC)
322 Bradford, Mr Don (NSW)
344 Bradford, Mr Noel (NSW)
50 Brady, Frank & Rosemary (NSW)
1329 Braeside, Rev Jack (WA)
78 Bramston, Dr Brian A (WA)
1375 Bray, Rev R A (NSW)
561 Breen, The Hon Peter (NSW)
249 Brennan, Mr Gerard A (WA)
284 Brennan, Mr Martin (SA)
73 Brewer, Mrs Anne (TAS)
359 Briggs, Mr William (TAS)
1445 Bright Ms Maureen (WA)
97 Brinkman, Mrs Donielle D (AZ)
121 Broadhurst, Ms Jane (WA)
1091 Broadwater, Mr Donald (QLD)
716 Broberg, Ms Ann (VIC)
1741 Broberg, Ms Meg (VIC)
1781 Bronts, Mrs Bev (VIC)
68 Brooks, Ms Louise (QLD)
48 Brophy, John and Patricia (WA)
472 Brosnan, John, Marie, Elizabeth (NSW)
1657 Brown, H (VIC)
1458 Brown, Mr Kevin (QLD)
734 Brown, Mr T (NSW)
401 Brown, Ms Irene (QLD)
482 Brown, Ms Monica (NSW)
746 Browne, Mrs M (WA)
1247 Brydon, Mr R & Ms D (QLD)
1162 Buckle, Ms Helen (QLD)
1831 Buckley, Ms Carolyn (WA)
1575 Bugg, Mr Malcom (VIC)
1113 Buhaglar, Mr J & Mrs M (NSW)
1137 Buhler, M (VOC)
1733 Bulich, Ms Anne (WA)
448 Buller, J (WA)
1019 Bullock, Mr Geoffrey (QLD)
186 Buman, Mr Jacob (VIC)
146 Buman, Mrs Alison (VIC)
28 Burfitt, Mr James (NSW)
190 Burgandy, Mr D (WA)
350 Burns, M (QLD)
937 Burns, Mr Miles Blake (NSW)
85 Burns, Mrs Beth (QLD)
1027 Burrow, Mr Barrie (NSW)
766 Burton, Dr E (NSW)
1380 Butcher, Ms Shelly (WA)
1152 Byl, Miss Janet (WA)

414 Byrnes, SC & KM (QLD)
1134 Bywater, Ms Bev (NSW)
1696 Cahill, Ms Margaret (VIC)
924 Cain, Mr Des (WA)
317 Cameron, Mr Don (NSW)
332 Cammock, Mr R & Mrs L (WA)
437 Campbell, Mr C M & Mrs J (NSW)
103 Campbell, Mrs M (NSW)
247 Campbell, Ms Dana (SA)
208 Campbell, Ms Sandra (VIC)
233 Campbell, Ms Vera (SA)
1715 Candwell, M (VIC)
1613 Cann, K (VIC)
370 Canny, Mrs Margaret (VIC)
572 Cantwell, A J (VIC)
120 Cappello, Mr Anthony (VIC)
775 Carboni, Mrs Clara (NSW)
27 Carolan, Mr Joseph (NSW)
837 Carr, Ms Bethany (VIC)
627 Carter, Ms Margaret (WA)
89 Casanova, Mr Michael (VIC)
272 Casey, Mr Len (NSW)
1535 Casey, Mr Peter and Ms Yvonne (NSW)
546 Casey, Ms Mary (em)
1250 Cassar, Mr Joe (NSW)
166 Castieau, Mr Brian (WA)
754 Casuso, Ms Loreto (NSW)
1116 Cathro, Mr L & Mrs L (NSW)
39 Cattell, Mrs Wendy (NSW)
1468 Cavanagh, Mrs Colleen (NSW)
246 Cencic, Ms Maxene (WA)
1244 Challacombe, Mr Jeffrey (QLD)
1245 Challacombe, Ms Judith (QLD)
1111 Chamber, K (VIC)
1147 Chamber, Mr Jack (TAS)
1112 Chandler, Ms Mary (VIC)
200 Chandler, Ms Rosemary (WA)
673 Chandrasegaran, Mr Suryan (VIC)
131 Chandrasegaran, Mrs Therese (VIC)
1397 Chant, Ms Sheila (NSW)
1556 Chapman, Mr Phil (em)
1772 Chapman, Mrs Lynn (WA)
1476 Chapman, Ms Julie & Mr Ashley (NSW)
29 Chase, Mr Andrew (QLD)
1282 Chayna, Ms Viviane (NSW)
922 Chedid, Ms Marie-Francoise (WA)
1440 Chegwidden, Ms Joy (QLD)
1267 Chellew, Ms Joy (VIC)
836 Chiang, Mr Paul (QLD)
737 Chicherio, Ms Mary (NSW)
49 Chigwidden, Ms Barbara (NSW)
1800 Childs, Mr Michael (WA)
393 Childs, Ms Karen (NSW)
575 Chivers, Mr Peter (NSW)
235 Chong, Ms Janet (NSW)
1672 Chris, N (VIC)
1474 Christie, Mr Dave (QLD)
1771 Cicholas, Mr Bruno (WA)
1770 Cicholas, Mrs Luise (WA)
461 Cikara, S (WA)
928 Clamp, Mr H & Mrs R (WA)
189 Clancy, Mr B & Mrs B (NSW)
1320 Clancy, Mr Paul (VIC)
886 Clapinski, Mr Daniel (VIC)
150 Clarke, Mr B & Mrs M (NSW)
631 Clarke, Mr Leslie (NSW)
1501 Clarke, Mr Owen (SA)
621 Clarke, Mrs B (TAS)
1223 Clarke, Ms Berlinda (VIC)
1423 Clarke, Ms Caroline (VIC)
1520 Clarke, Ms Carolyn (TAS)
1202 Cleary, Mr William (VIC)
311 Clifford, B E (WA)
20 Close, Ms Andrea (QLD)
70 Clune, Mr Paul (WA)
1793 Cobai, C (WA)
1746 Cobai, Ms Anne (WA)
468 Cobanov, H (QLD)
1480 Cochrane, Ms Deborah (QLD)
952 Cocilova, Mr E & Mrs M (NSW)
1324 Cocilova, Mr E & Mrs M (NSW)
1695 Cock, K (VIC)
1750 Cockrell, Mrs Helen (WA)
889 Cocks, Ms Jade (QLD)
1758 Coffell, Mrs Mary (WA)
550 Coffield, Mr Hugh (VIC)
1725 Coleman, C (VIC)
1719 Coleman, Mr James (VIC)
974 Colgan, Mr Mark J (VIC)
202 Colin, Mrs Joanna (NSW)

141 Colla, Ms Michelle (VIC)
1739 Collier, Ms Doreen (VIC)
191 Collins, Mr D & Mrs E (NSW)
580 Collins, Mr Wayne (SA)
636 Collins, Mrs Patricia (SA)
1759 Collins, Ms Catherine (QLD)
947 Colreavy, Mr M & Mrs E (NSW)
278 Colwell, Mr Matt (TAS)
339 Coman, Dr Brian (VIC)
1297 Combridge, Rev Daniel (TAS)
1763 Compton, Mr and Mrs Roger (NSW)
1309 Conder, Mr Raymond (WA)
1448 Conis, Ms Kerrie (QLD)
447 Conlan, Br Gerard (VIC)
900 Conlan, Miss Teresa (NSW)
995 Conlan, Mr Denis (WA)
1158 Conlan, Mrs Colleen (WA)
655 Connolly, Mrs Mary (WA)
1417 Connor, Mrs Ann (NSW)
1088 Consen, Ms Linda (TAS)
1682 Cook, Ms Pauline (VIC)
1220 Cook, Ms Sally-Anne (WA)
17 Coombs, Mrs L (NSW)
914 Cooney, M (VIC)
587 Cooney, Ms J (VIC)
1610 Cooper, M (VIC)
1351 Corben, Mrs Muriel (NSW)
323 Corbett, Ms Margaret (NSW)
1522 Corcoran, Mr Jim (VIC)
1363 Corcoran, Mr Tom and Mrs Marg (WA)
179 Cornish, Ms Celia (WA)
1261 Corry, Ms Anna (NSW)
753 Cotter, Mr J including 2 signatures (NSW)
1518 Cotton, Ms Catherine (NSW)
548 Coupland, Mr Bryan (NSW)
567 Courtney, Mrs Kathleen (WA)
312 Coutinho, Ms Bessie (WA)
792 Cowell, Ms Margaret (ACT)
663 Cox, Mr John (VIC)
840 Cox, Ms B & McMonagle, Ms J (QLD)
99 Crane, Mrs Mavis (QLD)
1685 Crane, S (VIC)
1395 Crittenden, Ms Elizabeth (NSW)
128 Crogan, Mrs D M (WA)
82 Crogan, T N (NSW)
579 Crowe, Mrs Margaret (QLD)
298 Cudmore, Ms M & Mr F (NSW)
613 Cullen, Ian (WA)
506 Cummins, Mr Alan (QLD)
1143 Cummins, Mrs C M (NSW)
1190 Cummins, Sr Marie (NSW)
1745 Czydel, Mr Chester (VIC)
1648 Czydel, Mrs Diana (VIC)
499 d'Alessandro, Mr Joseph (WA)
238 D'Arcy, M (NSW)
1237 D'Costa, Mr W & Ms C (NSW)
927 D'Silva, Mr & Mrs A (WA)
1175 D'Souza, Miss Violet (VIC)
869 D'Urso, Ms Maria (NSW)
108 Dabbs, Ms Therese (WA)
1777 Dagman, Y J (VIC)
164 Dalle-Nogare, Ms Margot (SA)
863 Dallin, Mr Ray (WA)
794 Dalwood, Mrs J (SA)
309 Daly, Ms Mary (WA)
1774 Daniell, Ms Anita (SA)
314 daSilva, M A (WA)
713 Dattilo, Mr & Mrs (WA)
1795 Daurdson, J R (WA)
334 Davidson, Mr J & Mrs J (WA)
1433 Davidson, Mr Peter (QLD)
1808 Davidson, T J (WA)
1416 Davies, Mr B & Ms J (QLD)
600 Davis, Dr V E (NSW)
471 Davis, Mr John (NSW)
1023 Davis, Mr Ken (VIC)
349 Dawson, Mrs Norma (NSW)
844 de Boer, Rev Jan Pieter (VIC)
1498 de Bruijn-Trapnell, Mr Gerard (VIC)
495 de Castella, Ms Rosemary (VIC)
1213 de Groot, Mr Ron (VIC)
199 De Gruchy, Mrs P (WA)
1254 de Haan, Sita (TAS)
1041 de Kretser, Professor David (VIC)
1495 de Rooy, Mr Frank (WA)
1481 de Souza, L J (NSW)
949 De Vries, Mr John (TAS)
950 De Vries, Ms Mieke (TAS)
485 dela Cruz, Mrs Libby (NSW)
973 Delaney, Mrs Elizabeth (VIC)

532 Delhanty, Pastor Terry (em)
1311 Della-Bora, Ms Jeanette (WA)
165 Dennis, Ms Alison and Mr Nic (NSW)
279 Dent, Mr L J (SA)
831 Derrick, Jaki (QLD)
787 Devitt, Mr S (WA)
1193 Devitt, Ms Angela (WA)
168 Dew, Mr Peter (WA)
717 Dezaayer, Ms Helen (VIC)
463 Di Zoro, E (WA)
813 Dickman, Mr Max & Ms Ros (QLD)
810 Dickman, Ms Lauren (QLD)
818 Dickson, Ms Karen (TAS)
236 Dilley, Mrs Mary (NSW)
43 Dinel, Mr Yves A (NSW)
52 Dodd, Mr Neville (NSW)
826 Doe, Mr Keith (NSW)
237 Doherty, J T (WA)
1596 Doherty, Ms Judy (VIC)
913 Dolahenty, J V (NSW)
11 Dolan, Mr Peter (NSW)
1676 Donahoe, Mr Terence (VIC)
101 Donjerkovic, Mr Daria (NSW)
102 Donjerkovic, Ms Mary (NSW)
932 Donovan, Mr Charles (WA)
293 Doolan-Roche, Mr Richard (QLD)
42 Dooley, Ms Clare (QLD)
381 Dopheide, Dr Theo (VIC)
666 Dopheide, Marlis (VIC)
1619 Doud, Fr Frank (VIC)
1096 Doueihi, Mr Elias (NSW)
1079 Doust, Mr Geoff (WA)
442 Downey, Mr K & Mrs K (NSW)
1072 Downey, Mr Matthew (QLD)
1232 Doyle, Mr Louis C (NSW)
628 Doyle, Mr T & Mrs S (NSW)
295 Doyle, Mrs Lyn (WA)
1201 Doyle, Mrs Norma (NSW)
1127 Dozzi, Mr E & Mrs M (NSW)
1374 Drake, Mrs Margaret (NSW)
1680 Drew, J (VIC)
291 Drum, Ms Nola (NSW)
1222 Drum, Ms Rosemary (QLD)
1407 Drumore, Ms Catherine (NSW)
758 Duckett, Ms Winifred (WA)
105 Duffy, Mr Patrick (WA)
137 Duggan, Miss Eileen (WA)
955 Duke, C (WA)
1668 Dullard, P (VIC)
92 Duncan, Mr Paul (NSW)
1315 Duncan, Ms Billie (VIC)
786 Dunne, Mr Dermot (NSW)
1081 Dunne, Ms Vicki & Ms Olivia (ACT)
1177 Dunning, Ms Margaret (WA)
346 Duynelam, Mr Peter (VIC)
1332 Dwyer, Mr Don (VIC)
595 Dwyer, Mr J & Mrs F (VIC)
71 Dwyer, Mr Noel (QLD)
320 Dwyer, Mr Noel (QLD)
118 Dwyer, Mrs Georgina (WA)
1643 Dwyer, Ms Christa (VIC)
1721 Dwyer, S (VIC)
634 Eansythe, M B (NSW)
230 Earle, R (VIC)
1540 Eastlake, Ms Danielle (VIC)
198 Easton, Mr H & Mrs J (WA)
1208 Edgar, Mrs Sheila (VIC)
990 Edney, Ms Evelyn P (VIC)
1663 Egan, B (VIC)
1026 Egerton-Warburton, B & E (NSW)
1587 Egmolesse, Mr T & Ms B (WA)
462 Eletich, M (WA)
1218 Elias, Mr Phillip (NSW)
352 Elliott, Mrs J (WA)
856 Elliott, Ms Samantha (QLD)
412 Ellis, Mr Ronald (NSW)
1366 Ellis, Mrs Kim (NSW)
1342 Ellyard, Mr F R (WA)
1813 Elphick, M (WA)
1716 Elston, T (VIC)
714 Emanuele, Mr & Mrs (WA)
1545 Enderby, Mr L & Ms J (QLD)
1551 Enderby, Mr Samuel (QLD)
14 Endo, Mr Hiroaki (NSW)
1847 England, L (WA)
1191 English, Fr Tom (NT)
325 Evans, Mr Michael (WA)
300 Evans, Mr Paul (QLD)
353 Evans, Mr T R (NSW)
521 Evans, Ms Catherine (em)

172 Evans, Ms Peta (QLD)
1090 Evans, Ms Rachael (QLD)
1275 Evans, Ms Rebecca (QLD)
1622 Everard, C (VIC)
774 Faehrmann, Mr R & Mrs M (NSW)
1266 Fagan, Mr Mike & Ms Sylvia (NSW)
1406 Fahey, Mr Neil (NSW)
549 Fairbrother, Ms Margaret (VIC)
222 Fairley, Mr J (WA)
586 Fajardo, Ms M (NSW)
368 Fallon, Mr & Mrs F; Calkin, Mrs J; Lane, Mrs C (NSW)
845 Farquhar, Mr Jim & Ms Hilary (WA)
1760 Farrell, Mr Bill (WA)
582 Farrell, Mr Jack (NSW)
111 Farrell, Mrs Z (NSW)
1766 Fauazzi, Ms Lita (WA)
648 Fay, Miss Mary (NSW)
1240 Felton, Mr Doug (ACT)
1408 Fennell, Mr Kevin T (NSW)
1200 Fergusson, Ms Kristin (QLD)
1683 Fermio, M (VIC)
194 Fernandes, Mr C J (WA)
1018 Fernandez, Mr Duane (NSW)
1489 Fernandez, Ms Averil (NSW)
1149 Fernandez, Ms Elizabeth (WA)
1260 Fernando, Ms Shelanah (NSW)
706 Ferrante, Mr & Mrs (WA)
1225 Field, Mr Christopher (NSW)
1478 Field, Ms Susan (NSW)
1427 Fife, Mrs J (NSW)
184 Finlay, Ms Veronica (WA)
486 Firth, Mr Reg (WA)
830 Fisher, Mrs Anna (SA)
555 Fisher, Ms Alice (NSW)
729 Fitzgerald, J (VIC)
1671 Fitzgerald, S (VIC)
1414 Flader, Fr John (NSW)
1400 Flanagan, M (VIC)
679 Flanagan, Mr Terry & Ms Jan (NSW)
32 Flanagan, Mrs E (VIC)
1103 Flanagan, Ms Mary (VIC)
1816 Flannery, A (WA)
771 Flesher-McNamara, Ms Maud (WA)
13 Fleurant, Ms Rachel (NSW)
946 Flood, Mr Roger Joseph (NSW)
699 Floris, Pastor Lynn (VIC)
1606 Fogarty, Mr Trevor (VIC)
1534 Fogarty, Ms Tess & Mr Ray (VIC)
1593 Fohrig, Ms Louise (VIC)
292 Foong, Dr Andrew (NSW)
921 Forrest, Mr Anthony (WA)
376 Fowler, Mr Richard (NSW)
1601 Francis, Mr Josh (QLD)
865 Francis, Ms Heidi (QLD)
1415 Franke, Ms Chantelle (QLD)
528 Fraser, Ms Dianne (em)
74 French, Mr B & Ms C (NSW)
229 French, Ms Anne C (VIC)
1653 French, Ms Karen (VIC)
206 Frisina, Ms Betty (WA)
1525 Frohling, Ms Annette (NSW)
1638 Fruiti, M (VIC)
1384 Fry, Mrs Lorraine (QLD)
762 Fullerton, S (NSW)
88 Fung, Mr Jimmy (VIC)
1703 Fyfe, Ms Leonie (VIC)
533 Gadsby, Mrs Betty (QLD)
1630 Gallagher, S (VIC)
1532 Gane, Mr Mathew (TAS)
243 Gardner, Mr W & Ms M (WA)
675 Gartlan, Mrs Pat (TAS)
224 Garwood, Mr N & Ms L (TAS)
1798 Gates, J (WA)
1214 Gawler, Dr David M (NT)
1838 Gawler, Ms Isobel (NT)
535 Geluk, M P (WA)
539 Gemmell, Ms Patricia (NSW)
872 Geoghegan, Dr Jannene (NSW)
1756 Gerrmas, N G (VIC)
513 Gesling, Mr Brian (QLD)
1131 Gibbins, R W (NSW)
1693 Gibellini, F (VIC)
798 Gibson, Ms Margaret (NSW)
479 Giddens, Mrs Mary (VIC)
752 Gifford, Mrs G (WA)
625 Giles, Mr Paul (NSW)
1076 Gillam, Ms Sara (QLD)
1754 Gillman, Ms Judith (WA)
9 Gilmore, Mrs Imelda (NSW)

1295 Gilson, Matthew S (ACT)
534 Gimeno, Mr Conchi (NSW)
1550 Girod, Mr Hugh (WA)
751 Glass, Mr Gregory Charles (NSW)
597 Gleich, Mr Heinz (TAS)
1271 Glen, Mr Phil (QLD)
1270 Glen, Ms Helen (QLD)
687 Glynn, Ms Amy (em)
680 Glynn, Ms Susanne (VIC)
992 Goeyle, Ms Betty (VIC)
394 Goiran Family (WA)
530 Goiran, Mr Nick (WA)
287 Goldsmith, Jan & Brett (em)
677 Goldsworthy, M F (NSW)
1318 Gomm, Miss E A (WA)
979 Gonzaga, Ms Josie (NSW)
94 Gonzalez, Mrs G & Mr M (WA)
935 Good, Mr Adrian (WA)
614 Good, Professor Michael F (QLD)
816 Gooden, Mr Gerald (NSW)
588 Gooden, Mr Peter (NSW)
593 Gooden, Mrs Jean (NSW)
671 Goodhew, Ms Alison (QLD)
1302 Goodwin, Ms Angela (QLD)
18 Goonan, Mr Des F (NSW)
256 Gordon, Ms Beryl (WA)
1706 Gordon, Ms Beryl (WA)
440 Gordon, Ms Ruth (WA)
1655 Gordonson, B (VIC)
1836 Gormon, Mrs Barbara (NSW)
367 Goss, Ms Margaret (VIC)
1724 Gotts, Mr John (VIC)
19 Gough, Mr Scott (NSW)
1159 Gould, Mr Syd & Mrs Meryl (QLD)
155 Goutarini, Ms Eugenia (WA)
1465 Grace, Mr Andrew (VIC)
30 Grainger, Mr David (NSW)
1291 Grant, Mr Colin (VIC)
335 Grant, Mrs Meg (NSW)
173 Grant, Ms Patricia (NSW)
1786 Graven, A M (VIC)
1790 Gravener, Ms Marianne (VIC)
1691 Gray, B (VIC)
1677 Gray, M (VIC)
1389 Gray, Mr Allan (VIC)
719 Gray, Mr Anthony (VIC)
1736 Gray, Mr Brian (VIC)
378 Gray, Mr David (QLD)
1362 Gray, Mr Jim (VIC)
1565 Gray, Mr Les (VIC)
553 Gray, Mrs Joan (VIC)
1649 Gray, Ms Vera (VIC)
963 Gray, P (VIC)
1635 Gray, Pat (VIC)
1639 Gray, R (VIC)
1678 Gray, S (VIC)
1722 Gray, W (VIC)
801 Greef, Mr Chris (NSW)
397 Green, Mr Jono (VIC)
812 Green, Ms Anne (VIC)
817 Green, Ms Sarah (VIC)
1823 Greening, Mr LA & Mrs EM (NSW)
606 Grier, Mr H (WA)
727 Griffin, M (VIC)
1303 Griffin, Miss M (VIC)
875 Griffin, Mr Anthony (NSW)
135 Griffin, Mr John (WA)
1182 Griffiths, Mr A W (VIC)
1157 Griffiths, Mr K & Mrs M A (WA)
1215 Grigg, Ms P R (em)
722 Grnnow, Mrs D (VIC)
1647 Grocock, Mr H (VIC)
512 Grocott, Dr Dianne (QLD)
881 Groenensteyn, Mrs R (SA)
596 Gross, Mr E (NSW)
1262 Groundwater, Ms Dianne (QLD)
1154 Groutsch, Mr E & Mrs J (WA)
285 Groves, Mr Paul (QLD)
342 Grybaitis, F P (ACT)
170 Gundry, Mr Steve (VIC)
703 Gunn, Ms Jennifer (VIC)
122 Gurry, E (WA)
196 Gurry, J (WA)
1248 Haavisto, V P & M A (NSW)
1569 Hackett, Ms Kathleen (VIC)
696 Hackett, Ms Pamela (QLD)
1673 Hackwell, Mr Gavan (VIC)
1747 Hackwell, Ms Valda (VIC)
1521 Hagan, Mr Peter and Ms Gaysley (QLD)
1409 Hagan, Mr Tom & Ms Janette (QLD)

421 Haggar, Mr Colin (NSW)
1627 Haggard, B (VIC)
1679 Haggert, Ms Margaret (VIC)
779 Haggerty, Ms Annette (NSW)
769 Haggett, Ms Margaret (VIC)
1398 Haire, F (VIC)
959 Hall, D (WA)
83 Hall, Dr George (NSW)
449 Hall, G (WA)
956 Hall, G (WA)
1794 Hall, Mr Denis (WA)
140 Hall, Mr G J (NSW)
594 Hall, Ms Mary (NSW)
1060 Hall, Professor Wayne (QLD)
1301 Hallen, Dr Katrina (VIC)
489 Halpin, Mr FR (TAS)
386 Halpin, Mr Julian (TAS)
458 Halusek, Mr D & Mrs T (WA)
964 Hamer, J (VIC)
1020 Hamilton, Mr Ian (TAS)
1603 Hamilton, S (VIC)
192 Hampson, Mr R & Mrs J (WA)
1447 Hancock, Mrs Jan (WA)
954 Hanna, Mr (WA)
858 Hanna, Mr Tobin (QLD)
851 Hannah, Mrs L R (WA)
1371 Hannan, Mr Peter (WA)
853 Hannigan, Ms Diana & Mr Peter (NSW)
552 Hanratty, Ms Raelene (VIC)
1650 Hanratty, S (VIC)
1444 Hans, Mr Anthony (NSW)
1360 Hanson, Mr Jim (WA)
252 Hanson, Ms Margaret (NSW)
505 Hanstock, J & M & Seymour, Ms S (NSW)
525 Harding, Mr Terry (QLD)
12 Harding-Davis, Paul & Annette (NSW)
883 Hargrave, Ms Nancy (NSW)
1775 Hargraves, Ms Mary (VIC)
1634 Harkin, Ms Mary (VIC)
436 Harling, Ms Ann (WA)
953 Harold, G (VIC)
503 Harris, Fr Doug (WA)
846 Harris, Mr Ian & Ronda (QLD)
203 Harris, Mr Paul (WA)
69 Harris, Ms Bridget (QLD)
425 Harris, Ms Joyce (QLD)
522 Harris, Rev Keith (QLD)
1353 Harrison, Mr P & Ms L (VIC)
940 Harrison, Ms Ann (WA)
608 Harrup, Ms Dorothy (VIC)
1594 Harte, Rev E J (VIC)
181 Hartley, Mr Dunstan (WA)
847 Hartnett, Dr John (WA)
894 Hartwig, Dr Arthur (QLD)
926 Harvey, Mr Trevor (WA)
923 Harvey, Mrs Brenda (WA)
1567 Harvey, Mrs I (SA)
919 Harvey, Mrs P (WA)
1834 Harvey, Mrs Patricia (SA)
1515 Hastie, Mr Peter (NSW)
1257 Haydon, Mr Michael (WA)
1253 Haydon, Mr Philip (WA)
1641 Hayes, Ms Patricia (VIC)
26 Hayter, Mr Neil (SA)
5 Head, Fr Adrian (SA)
240 Healey, M L (WA)
1071 Healy, Mr Patrick (VIC)
906 Healy, Sr Valerie (QLD)
1300 Hearn, Professor John P (ACT)
296 Heaslip, Ms Sue (NSW)
573 Heaton, Ms Olive (WA)
1197 Heesh, Mr John (NSW)
44 Helgeson, Mr Simon (SA)
1702 Helmke, Ms Leandra (VIC)
684 Hemetsberger, Mr James (QLD)
343 Hendriksen, Mr Freddie (WA)
1310 Hengeveld, Mr Steven & Ms Myrna (VIC)
1148 Henry, Fr Lionel (WA)
1441 Henson, Mrs Isabel (NSW)
399 Hersey, Ms Karen (WA)
340 Hertherington, Ms Kathleen (NSW)
299 Hibberd, Ms Heidi (QLD)
178 Hibble, Mr Larry (WA)
93 Hickey, Mr Frank & Mrs Norma (QLD)
1856 Hickey, Mr F M (QLD)
1625 Hickey, Mr Michael (VIC)
45 Hickey, Ms Bernadette (NSW)
712 Higgins, L (VIC)
112 Higgins, Mr Kevin (NSW)

1720 Higgins, Pat (VIC)
1396 Hilder, Mr Colin and Ms Helen (NSW)
961 Hill, J (WA)
428 Hill, Mrs Anne (WA)
1338 Hill, Ms Joan (NSW)
1568 Hill, Ms Mary (VIC)
1203 Hillman, A (WA)
1372 Hind, Mrs Hazel (NSW)
544 Hirvi, Mr Ben (em)
1566 Hoare, Miss Pat (VIC)
307 Hoare, Ms Emily (NSW)
1511 Holland, Mr Mark (NSW)
1243 Holland, Mrs Mary (NSW)
1333 Holley, Pastor Ron (QLD)
1331 Holloway, Mr J T (NSW)
313 Holohan, Dr Aidan (WA)
641 Honkin, Mrs Marie (VIC)
1726 Hopkins, H (VIC)
1737 Hopkins, Ms Mary (VIC)
1734 Horan, Mr Pat & Mrs Elsa (VIC)
965 Horton, H (TAS)
945 Hosking, Mr John (VIC)
1231 Houlihan, Mr Liam (VIC)
498 Howard, Mr Peter (QLD)
1667 Howard, Ms Marie (VIC)
854 Howarth, Ms Rebekah (QLD)
1132 Howe, Mr Anthony (VIC)
1761 Howe, Mrs Joan (NSW)
1328 Howe, R J (WA)
1812 Howell, Ms Lesley (WA)
1563 Hoysted, Mr Alan (VIC)
1669 Hug, Ms Rosemary (VIC)
277 Hughes, Miss Olwen (WA)
1376 Hughes, Mrs Therese (VIC)
470 Hughes, Ms Dorothy (NSW)
490 Hungerford-Morgan, Ms Carola (TAS)
867 Hunt, Ms Kerryn (QLD)
931 Hunter, W H (WA)
1316 Hurley, Ms Elizabeth (VIC)
1555 Hurley, Ms Susan (VIC)
1708 Hutcheon, Mr Rod (QLD)
944 Hutchin, Ms Pauline (VIC)
1101 Hutchinson, Ms Catherine (VIC)
878 Huxtable, Ms Marg (VIC)
592 Hyde, A J (NSW)
1675 Idelops, S (VIC)
496 Ielasi, Ms Carmel (WA)
1554 Ilott, Ms Denise (VIC)
1491 Inkster, Ms Brooke (VIC)
1854 Innes, Mrs Myriam (NSW)
785 Ireland, Ms Rose Marie (NSW)
1233 Irvine, Mr Philip (NSW)
543 Iscel, Mr Zeliha (em)
1169 Izzo, Ms Maria (WA)
1849 Jackson, Fr M (NT)
446 Jackson, Mr Anthony (WA)
795 Jackson, Mr Ray (WA)
445 Jackson, Mrs Maria (WA)
700 Jackson, Mrs R (VIC)
79 Jaeger, W, M, A, E, E (SA)
1337 Jago, Dr Arnold (VIC)
1014 Janetzki, Peter (QLD)
708 Jansak, Mr D (WA)
294 Jansen, Mr Chris (VIC)
151 Jansen, Mr J & Ms J (WA)
897 Jansen, Professor Robert (NSW)
Supplementary information
- Response to questions following public hearing, dated 1.10.02 and 15.10.02

265 Jaques, Mrs & Mr (WA)
566 Jarman, L (NSW)
315 Jarvis, Ms Judith (WA)
456 Jasa, Emila (WA)
742 Jefferys, Mrs R (WA)
1560 Jelleyman, Mr Paul (NSW)
1507 Jetmar, Mr Frank (VIC)
365 Jocson, Ms Danilo (NSW)
646 Johnson, Mr Robin (VIC)
1008 Johnson, Ms Paula (QLD)
669 Johnson, Pastor Robin J (VIC)
1074 Johnston, Mr Adam (NSW)
331 Johnston, Mrs Shiela (WA)
1022 Johnston, Ms Suzan (VIC)
1166 Jones, Mr T & Mrs J (WA)
1130 Jones, Mrs Harriet (NSW)
80 Jones, Mrs M J (TAS)
1684 Jongebloed, K (VIC)
231 Jongen, Ms Rosemary (VIC)
1462 Joseph, Mr Gerard (ACT)
599 Joseph, Mrs Jeanette (QLD)
1053 Joseph, Ms Rita (ACT)

1061 Joshua, Dr Philomene (VIC)
1167 Joyce, Dr P R (WA)
119 Joyce, Mr B & Mrs C (WA)
1284 Jurgens, Mr William (WA)
1492 Kaaye, Ms Beverley (VIC)
531 Kady, Mr Elias (NSW)
1842 Kain, C (NSW)
605 Kain, Mr V & Mrs E (WA)
327 Kane, Mrs Rita (VIC)
1632 Keane, Ms Annie (VIC)
1126 Kearney, Mrs C M (VIC)
1325 Keen, Mrs Veronica (QLD)
635 Keenan, Dr D & Mrs A (SA)
391 Keep, Mr Denis (NSW)
390 Keep, Ms Emily (NSW)
1785 Keller, J (VIC)
1805 Kelly, M P (NT)
1674 Kelly, Ms Penny (NT)
823 Kendrick, Mrs Lee (NSW)
1484 Kenneally, Mr Desmond (VIC)
63 Kennedy, A T (NSW)
934 Kennedy, Mr Patrick (WA)
1183 Kennedy, Mr Phillip (WA)
1749 Kennedy, Ms Aileen (VIC)
1429 Kennedy, Ms Lillian (QLD)
574 Kenter, Mr John (VIC)
1194 Kenter, Ms Catherina (VIC)
1211 Keogh, Mrs Patricia (NSW)
1369 Keogh, Ms E (NSW)
1825 Kerlin, P (QLD)
205 Khorry, Ms Danielle (NSW)
1120 Kide, Mr P (VIC)
999 Kiely, Ms Judy (VIC)
1832 Kiely, Ms Mary (NT)
1016 Kierath, the Hon Graham (WA)
1714 Killeen, J (VIC)
1710 Killeen, Ms Denise (VIC)
1251 Kimnes, Ms Eva (VIC)
61 Kinasz, Mr Michal (TAS)
630 King, Mr Ronald (VIC)
783 King, Mrs Fay (NSW)
431 King, Ms Elizabeth (VIC)
1102 Kingman, Mr Gregory (VIC)
1188 Kingman, Ms Janet (VIC)
1516 Kingsmill, Mr John (NSW)
432 Kinsman, Mr Arthur (SA)
1618 Kinzenga, Ms C (VIC)
920 Kirby, Ms Mary E (WA)
1471 Kirk, Ms Moira (WA)
81 Kirkpatrick, Ms Juliet (NSW)
1815 Kirkwood, W (WA)
651 Kirway, Mr K & Mrs M (NSW)
1378 Kitchen, Dr Theodore (WA)
348 Kitthe, Fr Don (WA)
1277 Klein, Mr Glen & Ms Christy (QLD)
1294 Klein, Mr Jamie & Ms Sharon (QLD)
1179 Knight, Ms Aileen (NSW)
1839 Knuckey, Ms Rose (WA)
260 Koelen, Mrs Jenny & Mr John (WA)
879 Kohlhardt, Mr Jim & Ms Marie (QLD)
1298 Kohlhardt, Mr Phil (QLD)
1467 Kohlhardt, Ms Kelly (QLD)
1217 Kolhardt, Ms Sharon (QLD)
6 Kolos, Mr Michael (NSW)
1289 Koniuszko, Ms Lidia (VIC)
372 Koontz, Ms Marilyn (WA)
1164 Kos, Ms Ruth (NSW)
1216 Krivacic, Ms Sonia (NSW)
1123 Kroeze, Mr & Mrs (WA)
1508 Krueger, Mr Ron & Ms Glenda (QLD)
418 Kuo, Ms Angela (NSW)
583 Kwok, Pastor Frank (NSW)
802 Kwong, Ip (NSW)
1742 Kyne, Ms Eileen (VIC)
1488 Ladd, Mrs Atala (VIC)
1010 Lamont, Dr Amanda (WA)
656 Landers, Mr F & Mrs D (NSW)
36 Lane, Ms Andrea A (NSW)
901 Lane, P J (QLD)
1308 Lane-Mullins, Mr David (NSW)
649 Lannen, Mr Paul (NSW)
1466 Lansdown, Mr Andrew (WA)
1313 Lansdown, Mr Colyn (WA)
1493 Lansdown, Mr David (VIC)
77 Lanzon, Mr Michael (QLD)
1748 Lappin, Mrs Monica (VIC)
1221 Laracy, Mrs Elaine (ACT)
966 Laredo, Mr Shane (TAS)
1435 Lau, Ms Jason (VIC)
373 Laudenbach, Mr Darren (ACT)

1460 Law, Ms Lina (em)
601 Lawless, Mr Peter (VIC)
1744 Laws, Ms Joan (VIC)
560 Lawton, S (NSW)
451 Leach, Mr Aaron (WA)
957 Leach, Mr Callan (WA)
1542 Leach, Ms Jeannette (NSW)
226 Leach, Ms Renee (WA)
66 Ledger, Mr Kevin (WA)
916 Lee, Mr Frank (VIC)
375 Lee, Mr John L (VIC)
1697 Lee, Mr Michael (VIC)
1764 Lee, Ms Alicia (VIC)
1343 Lee, Ms Josephine (NSW)
1321 Lee, Ms Margaret (VIC)
1336 Lee, Ms Margaret (VIC)
918 Lehane, Mr B & Mrs S (NSW)
643 Lehmann, Mr Dieter (WA)
301 Leipoldt, Mr Erik (WA)
297 Lennon, Dr Richard (NSW)
1388 Leong, M N (WA)
925 Leoni, Dr Emilio (WA)
1651 Lesley, J (VIC)
1156 Leslie, Brother James (NSW)
257 Lesque, Ms Margaret (WA)
972 Lesse, Dr Paula (VIC)
197 Leurs, L A (WA)
319 Lewis, R D (SA)
1541 Liackman, Mr Gill (NSW)
193 Lighter, Mrs Pauline (WA)
207 Lim, Dr Philip (NSW)
1085 Limbers, Ms Mary (NSW)
985 Linaker, Mr Peter (VIC)
387 Lincoln, Ms Stephanie (NSW)
1140 Lindeman, Mrs A (NSW)
819 Liszewski, Mr Martin (QLD)
1276 Liszewski, Ms Eva (QLD)
1274 Liszewski, Ms Joanna (QLD)
644 Lithgow, E (VIC)
1055 Little, Assoc Professor Melissa (QLD)
559 Livingstone, Mr Steve (QLD)
885 Loader, Mr Daniel (QLD)
603 Logan, Mr B & Mrs E (NSW)
377 Logan, Mr Jonathan (QLD)
64 Long, Mr and Mrs A (WA)
1505 Long, Ms Dorothy (VIC)
1160 Longshaw, Mr Peter (VIC)
67 Lopez, Mr Joe (NSW)
1428 Lorimer, Mrs Dominica (ACT)
1129 Loring, J (QLD)
404 Lorrain, Mr Erhard (NSW)
1755 Lou, M (VIC)
733 Louise, Mr Michael (Vic)
259 Lowe, G (WA)
960 Lowe, G (WA)
1352 Lowry, Mrs Margaret (WA)
1068 Loy, Dr Thomas (QLD)
410 Lubgans, Mr R & Ms M (NSW)
460 Luburic, L (WA)
726 Luscombe, A (VIC)
1349 Luscombe, Mr Bill (VIC)
626 Lydon, Mrs Edna (WA)
1195 Lye, Mrs Eileen (NSW)
877 Lynch, Dr Johanna (QLD)
1236 Lynch, Dr T B (QLD)
7 Lynch, Mr Justin (NSW)
1136 Lynch, Mr P & Mrs M (NSW)
1432 Lynch, Mrs Elizabeth (NSW)
1065 Lynch, Ms Rosina (NSW)
426 Lynch, P A (NSW)
571 Lynn, P (WA)
1704 MacDonald, Ms Carolyn (VIC)
1840 Madaffari, Ms Grace & Mr Rocco (WA)
54 Madden, Mr Gerard (NSW)
55 Madden, Ms Jenny (NSW)
1848 Magennis, Mr Des (VIC)
337 Mahoney, Mr Ron (NSW)
768 Makin, Mrs P (NSW)
1789 Malady, S (VIC)
1637 Malkic, Ms Anna (VIC)
1727 Mallace, M (VIC)
1107 Mansbridge, Ms Jean (Vic)
887 Mansfield, Mrs Kerrie (QLD)
1256 Mapa, Mr Roland (NSW)
545 Marffy, Mr Michael (em)
1097 Markham, Mr C & Ms A (WA)
807 Marks, Mr Roger & Ms Anne (VIC)
750 Marotta, Mr Robert (NSW)
1472 Marsh, Mr W & Ms A (em)
803 Marsh, Ms Paulette (NSW)

234 Marsh, N P (WA)
457 Marsic, S (WA)
261 Martin, J L & S M (NSW)
161 Martin, Mrs Lyn (NSW)
171 Martin, Ms Carl (NSW)
58 Martin, Ms Teresa (QLD)
1281 Martin, Ms Teresa (QLD)
162 Martin, Professor T. John (VIC)
316 Martin, R D (NSW)
1692 Mason, G (VIC)
1446 Massam, Mr John (WA)
87 Masters, Professor Colin L (VIC)
478 Mataitini, Tahirih (QLD)
136 Mauro, Ms Josie (VIC)
1125 Maxey, Mr Clive (VIC)
1609 May, Ms Dulcie (VIC)
1171 Maynard, Mr James (WA)
1172 Maynard, Mrs Miriam (WA)
682 McArthur, Mr Colin (WA)
615 McArthur, Ms Patricia (VIC)
1146 McCarthy, E V (VIC)
720 McCarthy, M B (VIC)
688 McCarthy, Mr Anthony (VIC)
654 McCarthy, Ms Margaret (WA)
228 McCarthy, Ms Marie (VIC)
1403 McCaughan, Dr James B (NSW)
890 McClarty, Mr Doug (QLD)
21 McClarty, Ms Rebecca (ALD)
1258 McConaghy, Ms Elaine (QLD)
1411 McCorkell, Mr W & Ms L (QLD)
213 McCormack, Mr John (VIC)
41 McCormack, Mr Luke (QLD)
1344 McCormack, Mrs Margaret (VIC)
212 McCormack, Ms Lorna (VIC)
529 McCorry, Mr H & Mrs W (NSW)
1614 McCowan, Ms Carmel (VIC)
589 McCray, Mr Douglas (NSW)
480 McCullagh, Dr Peter (NSW)
1809 McDonald, D (WA)
1335 McDonald, E (VIC)
1196 McDonald, Ms M (VIC)
1334 McDonald, Ms Philomena (VIC)
163 McDonnell, Mr T & Ms R (WA)
1358 McDonnell, Mrs Dorothy (WA)
941 McDonnell, Ms Helen (WA)
1485 McEachran, Mrs Jennifer (QLD)
1350 McEwan, Mrs Patricia (NSW)
1304 McFadden, Mr Tom (NSW)
75 McGivern, John & Violet (WA)
1788 McGovern, Mr Michael (WA)
1658 McGrath, B (VIC)
607 McGrath, Mrs Erica (VIC)
210 McGregor, Mr Brian (NSW)
148 McGuane, Ms Catherine (WA)
1459 McGuire, Mr Ken (VIC)
1265 McHardy, Mrs Jeanette (VIC)
187 McHugh, Br Michael (NSW)
269 McHugh, Ms Edwardine (WA)
1385 McKenna, Mr Keith (VIC)
547 McKitrick, Mr Erik (TAS)
1269 McLeod, Ms Justine (WA)
705 McLernon, D (WA)
796 McLinden, Ms Therese (VIC)
1017 McLindon, Dr Luke (VIC)
1443 McLoughlin, Dr Samantha (NSW)
1646 McLure, Ms Cathy (VIC)
464 McMahon, J W (NSW)
1806 McMahon, P E (VIC)
1585 McMaster, Ms Mary (VIC)
1273 McMenamin, E (NSW)
604 McMullan, Ms Joy (WA)
326 McNeil, Mrs Diana (NSW)
1249 McPherson, Mr K & Ms C (QLD)
515 McPherson, Ms Katja (NSW)
569 McRae, Ms Dorothy (NSW)
434 McSevich, Mr Joseph (WA)
509 Medland, Anne-Louise (QLD)
1108 Meese, Dr A (VIC)
911 Meese, Ms Lesa (VIC)
1255 Meijer, Mr Joe (TAS)
264 Mellor, Mr Brian (WA)
848 Melville, Mr Brent (QLD)
839 Merrick, Pastor Noel (QLD)
1135 Metral, Mr Gerard (VIC)
1173 Micallef, Mr H & Mrs A (VIC)
1787 Miford, Mrs (WA)
225 Miguel, Mr Leon (WA)
1285 Miller, Mr H E & family (WA)
1814 Miller, Mr John (WA)
518 Miller, Mr Leonard (em)

1529 Millican, Laural (QLD)
400 Millican, Mr Paul (QLD)
1139 Millie, Mr David (VIC)
1807 Mills, J (WA)
1133 Milne, Mr T (WA)
1364 Milne, Mrs M (WA)
538 Milross, Dr John (NSW)
1186 Milroy, Mrs Thelma (VIC)
1549 Mir, Mr Leo (NSW)
784 Mirabito, Ms Ann (NSW)
1681 Mircon, Mr Mike (NT)
408 Mitchell, Mr Brett (VIC)
1114 Mitchell, Mr Roger (NSW)
683 Miyashiro, Mr Maki (NSW)
1118 Mkoka, Mrs A (QLD)
1510 Mohr, Ms V, Mr G & Mr J (QLD)
420 Moller, Mr Scott & Ms Catrina (QLD)
1021 Monk, Professor Marilyn (UK)
581 Mooney, Mr P & Mrs G (NSW)
1844 Moore, Dr Susan (NSW)
760 Moore, Mr B & Mrs M (VIC)
369 Moore, Mr Gary (NSW)
266 Moore, Mr Gregory D (WA)
1238 Moore, Ms Margaret (NSW)
385 Moran, Ms Emma (WA)
1523 Moreau, Ms Irene Mara (QLD)
1830 Morel, A (WA)
96 Morgan, Mr Barry (WA)
466 Morgan, Mr Ben (em)
1346 Morgan, Mrs B (TAS)
488 Morgan, RH (TAS)
1326 Morham, Mrs Lucia (VIC)
308 Moriarty, Mr Mark (NSW)
271 Morris, Mr John (WA)
1356 Morris, Ms Marian (WA)
188 Morris, Rev K W (WA)
1645 Morrison, J (VIC)
1115 Morrison, Ms Margaret (NSW)
1621 Morrison, Ms Margaret (VIC)
790 Morrissey, Mr Frank (NSW)
65 Mortimer, Ms Patricia (NSW)
1602 Moulton, M (VIC)
1607 Moulton, Mr Philip (VIC)
34 Moussa, Mr Youssef (NSW)
144 Moylan, Mr Joe (WA)
622 Moylon, Ms Maureen (VIC)
1592 Moynihan, Mr Thomas (WA)
366 Muir, Mr Andrew (ACT)
577 Muir, Mrs Irene (ACT)
324 Mulcahy, Mrs E (NSW)
1322 Muldoon, Dr Dennis (NSW)
1078 Mulhearn, Mr R & Mrs V (NSW)
38 Mulholland, Mr John (NSW)
1207 Muling, Mr Gil (VIC)
632 Mullens, Mr Patrick (NSW)
113 Mulry, Mr Patrick (WA)
1845 Murphy, Mr Matthew (NSW)
1373 Murphy, T (NSW)
1490 Murray, Mr Peter (VIC)
473 Napper, Mr Arthur (QLD)
694 Napper, Ms Melissa (em)
276 Nash, Mr G (WA)
500 Nash, Ms Marie (NSW)
60 Nathan, Mr Peter (NSW)
1381 Neale, M (WA)
1180 Nebauer, Mr R & Mrs S (NSW)
347 Neille, Mrs L (WA)
929 Newbold, Mr E A (WA)
898 Newell, Dr Christopher (TAS)
1098 Neyen, Ms Tess ()
1287 Nguyen, Anh (VIC)
1038 Nibbs, Mrs Marie (TAS)
1586 Nicholson, Ms J (NSW)
1686 Nicolao, Mr Angelo (VIC)
1538 Nielsen, Mrs Janine (NSW)
424 Nielson, Mr Andrew (TAS)
1548 Nightingale, Mr Warren (VIC)
1547 Nightingale, Ms Karen (VIC)
1666 Nikolajew, A (VIC)
1636 Nixon, Ms Janice (NT)
1153 Noble, Mr Phillip (WA)
591 Noon, Ms M & Gooley, Ms M (NSW)
1174 Noonan, A G (WA)
288 Noonan, Mr Kevin J (VIC)
289 Noonan, Ms Margaret E (VIC)
1165 Norman, Mrs P (WA)
1314 Noronha, Ms Agnes (WA)
1835 Norris, Mrs Carol (WA)
977 Novy, Mr David (WA)
704 O'Brien, C (VIC)

1707 O'Brien, C (VIC)
1661 O'Brien, M (VIC)
789 O'Brien, Miss P (NSW)
905 O'Brien, Mr Brendan (NSW)
1080 O'Brien, Mr Edward (SA)
724 O'Brien, Mr P & Mrs J (VIC)
1729 O'Brien, Ms Ann (VIC)
1757 O'Brien, Ms Kath (VIC)
610 O'Brien, Ms P (NSW)
1604 O'Brien, P (VIC)
1348 O'Callaghan, Mr Des (VIC)
1387 O'Callaghan, Ms Kathleen (VIC)
416 O'Connor, Mr Michael (NSW)
1367 O'Dwyer, Mr James (NSW)
645 O'Flaherty, Mrs S (NSW)
670 O'Keefe, Hon Mr Justice Barry (NSW)
650 O'Leary, K (NSW)
263 O'Leary, Ms Denis (SA)
1818 O'Loughlin, C (VIC)
123 O'Neill, A G (WA)
384 O'Neill, Mr Terence (WA)
1185 O'Neill, Ms Betty (WA)
383 O'Neill, Ms Margaret (WA)
1341 O'Rourke, Mr T J (WA)
413 O'Rourke, Mr Terence (TAS)
1553 O'Shannessy, Ms Carolyn (VIC)
201 O'Sullivan, Mrs H (WA)
909 O'Sullivan, Ms Jill (NSW)
735 Oldmeadow, Dr Hary (VIC)
475 Oliver, Mr Edward (VIC)
907 Olsen, Mr Benedict (NSW)
1272 Olsen, Mr Jim (WA)
1144 Ong, Mrs Andrea (VIC)
51 Opdam, Ms Maree (NSW)
435 Opie, Mr Nick (WA)
253 Orchard, Mrs J M (WA)
156 Orr, Dr Robert D (USA)
1089 Ortega, Ms Maria (NSW)
970 Ortolan, Mr F & Mrs B (TAS)
748 Ovalle, Dr Ximena (NSW)
761 Owen, Mrs Jill (SA)
701 Owen, Ms J (VIC)
1846 Paar, Mr Arthur (VIC)
1330 Packer, Mr Tim and Ms Kay (QLD)
993 Packer, Mrs Carolyn (NSW)
1537 Paff, Mr Stephen (NSW)
1599 Paglia, Ms Judith (NSW)
517 Parish, Mr M & Ms E (QLD)
793 Park, Ms Susan (VIC)
1163 Parker, Miss Jo (NSW)
481 Parkes, Mr Todd (QLD)
1450 Parkes, Ms Heidi (QLD)
275 Pass, Mr Colin & Ms Phyllis (WA)
1296 Paterson, Mr Matthew & Ms Kym (SA)
1769 Patrick, Mrs E (QLD)
1449 Patterson, Mr Ron (WA)
623 Patton, Ms Patricia (VIC)
624 Paul, Ms Rosalie (VIC)
988 Paulovics, Mr Stephen (TAS)
281 Pavia, Ms Carmen (NSW)
738 Payne, Ms Judy (NSW)
1176 Payton, Ms Judith (WA)
1801 Peachey, Ms Maree (WA)
1633 Peavey, M (VIC)
1664 Peavey, R (VIC)
1827 Peers, Dr Robert (VIC)
1513 Pega, Ms Carmen (VCI)
763 Pendal, Mr Phillip MP (WA)
84 Pender, Professor Michael (QLD)
873 Pera, Assoc Professor Martin F (VIC)
Supplementary information
- Response to questions after public hearing , dated 26.9.02 and 11.10.02

1230 Percy, Mr Les (QLD)
402 Perez, Mr Chito (NSW)
902 Perez, Ms Chito (NSW)
330 Peters, Mrs Jannette (WA)
537 Peterson, Ms Janne (NSW)
1422 Petrie, Ms J & Hammond, Mr & Ms M (NSW)
1628 Phelan, Ms C (VIC)
639 Phelan, Ms Pauline (VIC)
652 Phemister, Mrs P (NSW)
1822 Philips, Ms A (WA)
1100 Phillip, Mr Tom & Mrs Barbara (VIC)
996 Phillips, Mr G & Mrs C V (WA)
1410 Phillips, Mr Stephen (QLD)
395 Phillips, Mr Wayne (VIC)
1015 Piercy, Dr Mathew (VIC)
1122 Piercy, P (VIC)
290 Piggott, Mr Greg (NSW)
776 Pike, Mrs Veronica (NSW)

1765 Pike, Ms Anne-Marie (WA)
1583 Pile, Mrs Jan (NT)
76 Pillar, Mr Rob (SA)
154 Pirhonen, Mrs Raili (WA)
681 Pirola, Ms Teresa (NSW)
126 Pittari, Mr Adrian (VIC)
133 Pittari, Mr Stefan (VIC)
584 Pittari, Ms C (VIC)
1121 Plant, Ms Mavis June (VIC)
773 Playdon, Mrs Maureen (NSW)
306 Playsted, Mr Stewart (NSW)
270 Pleming, Ms Jill (NSW)
1496 Plustwik, Mr Stephen (VIC)
227 Podgorczyk, Mr P & Mrs L (NSW)
1059 Polak, Dr Max (TAS)
405 Poland, Mr James (TAS)
685 Pollard, Dr Brian (NSW)
558 Pollard, Mrs Patricia (VIC)
422 Pollard, Ms B & Mr J (QLD)
1013 Pollnitz, Dr Robert (SA)
1858 Pollnitz, Dr Robert (em)
1391 Pommer, Mr Denis (NSW)
1307 Pompeus, Mrs D (VIC)
1688 Ponaba, C (VIC)
861 Pons, Ms Sylvia (TAS)
1001 Pope, Dr Adrianne (VIC)
Supplementary information
- Response to questions following public hearing, dated 2.10.02 and 15.10.02

1317 Poullin, Mrs M J (VIC)
1430 Powell, GV & JR (TAS)
215 Powell, Mr Ron (WA)
1413 Pratt, Ms Sandra & Mr Bill (WA)
1052 Prentice, Dr David A (USA)
1512 Price, Ms Christine (VIC)
1323 Prichard, Ms Carol (TAS)
1552 Proud, Mr Steve (em)
362 Proudley, Mr Craig (QLD)
662 Purcell, K J (WA)
149 Pynenburg, Ms Theresa (WA)
450 Quadros, Fr Benedict (WA)
933 Quesnel, Mr Gerard (WA)
1370 Quigley, Ms Helen (NSW)
1155 Quinlan, Brother John (NSW)
1660 Quinn, G (VIC)
757 Quinn, G E (NSW)
1497 Quinn, Mr Peter (VIC)
1246 Quinn, Ms Anne-Maree (NSW)
1024 Quirk, Professor Patrick (QLD)
494 Rael, Mr Isagani (NSW)
1141 Ralls, Mrs Glenys (VIC)
976 Rasenberger, Rev F & Mrs A (QLD)
782 Ratcliffe, Miss Margaret (NSW)
665 Rayment, Mr John (NSW)
1170 Rayney, Ms Yolanda (WA)
1419 Reddick, Ms Rebecca (QLD)
388 Redgen, Mr Wesley (QLD)
406 Reeves, Ms Rachel (NSW)
536 Reichel, Dr Alex (NSW)
1227 Reinikka, Mr V R (QLD)
1461 Resce, Ms Meredith (SA)
491 Rice, Mr Peter (NSW)
1452 Richardson, Mr Robin (WA)
1425 Richardson, Ms Geraldine (TAS)
565 Richardson, Ms Kathleen (NSW)
1451 Richardson, Ms Yvonne M (WA)
1576 Richens, Mrs G (NSW)
1456 Ridley, Mr Francis (em)
1475 Ridley, Ms Therese (NSW)
1105 Rieniek, Ms Carmel (VIC)
1524 Rigby, Mr Denly (VIC)
1629 Riggall, J (VIC)
409 Riley, Ms Lonnie (QLD)
127 Rink, Mr Laurie (WA)
686 Ritson, Ms Melinda (QLD)
497 Rix, Mr Ron & Ms Bonnie (QLD)
692 Roberts, Dr N & Mrs B (TAS)
109 Roberts, Mrs M (WA)
1000 Roberts, Ms Judie (VIC)
1857 Roberts, Stuart (QLD)
169 Robinson, Mr Mark ()
220 Robinson, Ms Julie (QLD)
772 Robinson, Ms Sylvia (SA)
1198 Roebik, Ms Geraldine (VIC)
217 Rofe, Mrs Mary (QLD)
31 Rogers, Mr Michael (NSW)
1305 Rogers, Mrs Judy (QLD)
91 Rolls, Mr Mark (NSW)
1802 Rosa, Mr J (VIC)
114 Rose, Mr Graham (WA)

1753 Rose, Ms Anne (WA)
1797 Rose, Ms Patricia (WA)
1283 Ross, Mr Rein Jaan (em)
1347 Ross, Mrs Jocelyn (WA)
1094 Ross, Ms Merle (QLD)
777 Roth, Mrs Mary (NSW)
439 Rowe, Mr J H & Mrs V I (WA)
822 Rowe, Ms Glynise (SA)
1470 Rowney, Mr K, Ms V & Mr S (NSW)
1783 Rowney, Mrs Veronica (NSW)
1424 Roy, Ms Caitlin (QLD)
743 Rule, Ms Catherine (WA)
1 Russell, Mr Mel (SA)
379 Russell, Ms J (NSW)
1082 Russell, Ms Sue (NSW)
1477 Russo, Mr Gary & Ms Peta (WA)
884 Ryan, Dr Neil E (VIC)
1437 Ryan, Mr Craig (VIC)
1379 Ryan, Mr John & Ms Norma (WA)
1312 Ryan, Mr Peter (VIC)
1327 Ryan, Mrs Marita (VIC)
33 Ryan, Mrs Patricia (NSW)
274 Ryan, Ms Edna (TAS)
1506 Ryan, Ms Veronica (WA)
1084 Sadkowsky, Mr K & Ms M (ACT)
1086 Saha Family (em)
1600 Sainsbury, Mr Francis (VIC)
1487 Sainsbury, Mr Frank (TAS)
1780 Salkeld, Mr L (NSW)
756 Salkin, Ms Vicki (ACT)
829 Samuels, Ms Janine (QLD)
617 Sandhu, B (WA)
799 Sandral, Mr P & Mrs H (NSW)
1168 Sangiolo, L (VIC)
1011 Santamaria, Dr Joe (VIC)
1539 Saparamado, Mr Mario (NSW)
1784 Sarah, Mr and Mrs Ian (NSW)
286 Sartori, Ms Michelle (NSW)
778 Saul Mrs Marie (NSW)
721 Saunders, M (VIC)
962 Saverimutta, Mrs M P (NSW)
1803 Scara, Mr Carl (NSW)
1057 Schepers, Goslik (QLD)
527 Schlatter, Mr Victor (em)
1616 Scholtes, Mr Henry (VIC)
1659 Scholtes, Ms Annette (VIC)
321 Schou, Mrs Carmel (NSW)
37 Schwartz, Rev Rudi (SA)
175 Scurry, Ms Lyn (WA)
216 Seager, Ms Katie (TAS)
467 Searle, Mr Peter (ACT)
62 See, Ms June (NSW)
244 See, Richard E (NSW)
1833 Seeber, Mrs Kaye (WA)
180 Sefton, Mrs Glenys (WA)
258 Sellars, Mr P (WA)
46 Selwyn, Adrian (NSW)
95 Sertori, Mr J G (NSW)
1092 Shah, G & A (em)
1228 Shallvey, Mr John (NSW)
585 Sharah, Mr Alex (NSW)
124 Sharman, Mrs Kath (WA)
1189 Sharpe, Mrs J (VIC)
1066 Shave, Ms Michelle (WA)
578 Shaw, Miss Helen (QLD)
616 Shaw, Mr Bernard (VIC)
267 Shaw, Mrs Pam (VIC)
351 Shaw, Ms Joyce (NSW)
1782 Shayse, Mrs J (VIC)
1712 Sheehey, C (VIC)
444 Sheeran, Mr Paul (NSW)
174 Shepherd, Mr L E & Mrs C M (NSW)
1210 Sherry, Mr & Mrs (NSW)
633 Shiel, Mr Gerald (VIC)
1735 Shiels, (VIC)
1738 Shingles, Mr Gary (VIC)
1743 Shingles, Ms Catherine (VIC)
1597 Shipway, A (NT)
1821 Sibclose, M (WA)
273 Siebert, Ms Betty (SA)
1226 Silvius, Ms Emmy (NSW)
1620 Simm, Ms Francis (VIC)
1242 Simmonds, Pastor Phil (QLD)
1851 Simpson, Mr George (VIC)
360 Slade, Mr Phil (QLD)
1709 Slattery, Ms Margaret (VIC)
153 Slee, M J (VIC)
142 Slee, Mr Jacob (VIC)
356 Slee, Ms Christeena (NSW)
130 Slee, Ms Pieter (VIC)

72 Sloane, Mrs Sundai (NSW)
441 Slocum, Mrs Teresa (VIC)
806 Small, Dr Garrick (NSW)
117 Smallwood, Mrs R (WA)
1241 Smith, G J (QLD)
1694 Smith, L (VIC)
620 Smith, Mr A & Smith Mr W (VIC)
1536 Smith, Mr Adrian (QLD)
1268 Smith, Mr Allan (NSW)
1340 Smith, Mr Christopher (NSW)
167 Smith, Mr Kevin & Ms Lyn (QLD)
1142 Smith, Mrs Cynthia (VIC)
1850 Smith, Mrs Margaret (VIC)
1533 Smith, Ms Ann (em)
998 Smith, Ms Carol R (VIC)
1700 Smith, Ms Cecilia (VIC)
476 Smith, Ms Claire (NSW)
1690 Smith, P (VIC)
1608 Smithers, W (VIC)
232 Smolenaars, M A (VIC)
1740 Smolenaars, Mr Theo (VIC)
971 Smyth, Mr Eris (TAS)
1187 Smyth, Mr Peter (VIC)
1319 Smyth, Mr Stephen (TAS)
1689 Smyth, Mrs Dorothy (VIC)
147 Snell, C A (VIC)
1828 Snell, Ms P & Mr J (NSW)
1104 Soldlem, Ms Jackie (VIC)
283 Sorbara, Mr D & Ms C (NSW)
1383 Soumbasis, Ms Mary (VIC)
1804 Spadaccini, Mr Fred (WA)
1792 Spadoccini, Ms M (WA)
1752 Speekman, Father John (VIC)
1644 Speekman, Ms Mary (VIC)
1591 Spellman, Ms Mary (WA)
469 Spencer, Ms Kirsty (QLD)
1063 Spoelstra, Mr Gerard (WA)
917 Spongberg, Ms Cath (NSW)
177 Spring, Ms Patricia Anne (WA)
1418 Srdarev, Ms Marie (WA)
1824 Staer, Ms Debby (WA)
115 Staker, Mrs Norma (WA)
978 Stamm, Mrs Pamela (VIC)
1229 Stanley, Mr Tom (NSW)
674 Starling, David & Nicole (NSW)
520 Steele, Mr Brian (QLD)
504 Steele, Mr Peter & Ms Amanda (VIC)
1436 Steele, Ms Rosanne (QLD)
143 Stewart, Mr J & Mrs C (VIC)
251 Stewart, Mr Ron (VIC)
1431 Stewart, Ms Jennifer (QLD)
1564 Stewart, Ms Veronica (VIC)
1562 Stillone, Ms Amanda (NSW)
1573 Stinson, Mr Paul (NSW)
1762 Stirton, Mrs Liza (WA)
862 Stocks, Mr Bernie & Ms Helen (VIC)
1617 Stoddart, C (VIC)
730 Stoddart, R (VIC)
1778 Stokes, B J (WA)
1779 Stokes, M (WA)
1499 Stokes, Mr Peter (VIC)
903 Stoodley, Mr Paul & Mrs Ruth (NSW)
697 Storey, Mr Geoff (WA)
828 Storrs, Mr Andrew (QLD)
1404 Strachan, Ms Judith (QLD)
1223 Street, Mr Mark & Ms Sheilah (NSW)
715 Strickland, R (WA)
1453 Strohbeck, Ms Jeannine (VIC)
1306 Sullivan, B E (NSW)
563 Sullivan, Mr J & Mrs E (WA)
1365 Sullivan, Mr Leslie (NSW)
749 Sullivan, Mrs B P (NSW)
1528 Sullivan, Ms Elizabeth (em)
1841 Supan, Mr Louie (NSW)
430 Sutton, Mr A W (WA)
1264 Sutton, Mr Brian (WA)
1811 Swan, G T (WA)
1504 Swan, Mr Paul (QLD)
554 Sweeney, P M (VIC)
1526 Swire, Mr William Michael (NSW)
338 Sworder, Dr Roger (VIC)
568 Sykes, Sr M C (NSW)
1109 Szondi, Rev E (NSW)
747 T'Hart, Mr C & Mrs T (WA)
214 Tadj, Dr Armin (TAS)
824 Tai, Pastor Alfred (VIC)
511 Tait, Mr M & Ms A (em)
524 Tamme, Mr N & Ms D (NSW)
888 Tan, Mr Greg (NSW)
526 Tan, Mr Jin (NSW)

1582 Tanzi, Mrs Beryl (VCI)
35 Taouk, Ms Miriam (NSW)
899 Tate, Rev Professor Michael (TAS)
1590 Taylor, AM & BW (WA)
1463 Taylor, Dr Andrew (WA)
427 Taylor, Dr Annette (TAS)
695 Taylor, Mr Geoff & Ms Kerri (QLD)
1640 Taylor, Mr John (VIC)
341 Taylor, Mr T J (NSW)
1145 Taylor, Mrs Margaret (VIC)
310 Taylor, Mrs Maureen (WA)
1286 Taylor, Ms Patricia (WA)
396 Taylor, Ms Rachel (VIC)
429 Taylor, Pastor Paul
including 12 signatures (SA)
820 Telford, Mr Brian & Ms Helen (TAS)
1128 Templeton, Mr K (VIC)
1382 Ter Horst, Mrs J (WA)
8 Terkes, Mr Damir (NSW)
1810 Tester, Ms Margaret (WA)
1117 Thomson, Rev Ian (QLD)
1642 Thornhill, M (VIC)
1713 Thornhill, WJ (VIC)
507 Thorpe, Mr Michael (NSW)
465 Thuip, C (WA)
637 Thuip, H (WA)
1420 Tighe, Mr Kevin (TAS)
958 Tilley, Mr Peter John (WA)
492 Tilsley, Mr Andrew (NSW)
1434 Timmins, Ms Susannah (VIC)
423 Todd, Mrs Alex (QLD)
221 Tome, Mr Michael (QLD)
182 Tomlinson, Mr Kevin (WA)
183 Tomlinson, Ms M (WA)
86 Tonti-Filippini, Dr Nicholas (VIC)
Supplementary information
- Response to questions after public hearing, dated 26.9.02 and 17.10.02

1345 Tosh, Mr Gary (QLD)
493 Triffett, Mrs Maree (TAS)
1043 Trounson, Professor Alan (VIC)
Tabled at hearing on 24.9.02
- Information including Nobel Laureates letter and Journal web articles on stem cells

Supplementary information
- Response to question following public hearing, dated 26.9.02
- Additional information dated 30.9.02 and 4.10.02
- Article, Science vol 297, 27.9.02
- CV including list of publications

908 Truscott, Mr G & Mrs P (QLD)
871 Tuch, Professor Bernie (NSW)
Supplementary information
- Response to questions following public hearing, dated 17.9.02

110 Tunnard, Mr Keith (WA)
1595 Tunzi, Mr Peter (VCI)
1578 Turner, Mr George (NSW)
1579 Turner, Mrs Judith (NSW)
1572 Twomey, Mr Ray (NSW)
731 Twyford, Ms Suzanne (NSW)
438 Tyler, Dr Edward (NSW)
336 Tyndall, Dr Anne (VIC)
1479 Tyson, Mr Alan & Ms Helen (SA)
1631 Uyen, Mr John & Ms Anna (WA)
417 van Brummelen, Mr G & Ms R (NSW)
433 Van de Velde, W (NT)
1705 Van den Bogert, Mrs P and Mrs J (WA)
100 van der End, Mr Alex (VIC)
374 Van der Heijde, Mr John ()
1138 Van der Velden, Mrs Lien (VIC)
874 van der Wel, Mr Neil & Ms Jo (VIC)
689 van der Wel, Mr Simon (VIC)
519 van der Wel, Ms M & Santibanez, Ms L (VIC)
618 van Dreven, Ms Liz (VIC)
1278 van Duyn, Ms Kina (WA)
1509 van Geyzel, Mr Mark (WA)
152 van Rensburg, Mr Gavin (VIC)
145 van Rensburg, Ms Rebecca (VIC)
834 Vanderkolk, Mr G & Ms M (NSW)
1355 Vandermark, Mr J & Mrs J (WA)
1354 Vandermark-Baba, M (WA)
1095 Vanderstoep, Mr C & Mrs H (WA)
98 Vanderstoep, Mr Tim (VIC)
855 Vanderstoep, Ms Ingrid (VIC)
943 Vardy, Ms Patricia (VIC)
1717 Varker, K (QLD)
1377 Vassallo, Mrs Mary (NSW)
556 Veal, Ms Georgina (WA)
1390 Venier, Shane (NSW)
1723 Vermailin, Mr John (VIC)

821 Vermeulen, Ms Karina (WA)
804 Vermeulen, Ms Rosemarie (WA)
1799 Vernon, R (WA)
659 Vetter, Mr Paul (NSW)
411 Vieira, Mrs Michele (NSW)
938 Virgona, Miss M & Miss P (NSW)
1820 Virgona, S (VIC)
805 Vishnu, Lord Maitreya Surya (WA)
255 Vladich, Mrs Glenice (WA)
116 Vo, Mr Gia Hien (WA)
209 Vodola, Fr Max (VIC)
239 von Perger, Ms Margaret (WA)
678 Wagenaar, Mr M & Ms S (WA)
1656 Wake, R (VIC)
159 Wakefield, Mr Peter (VIC)
160 Wakefield, Mrs Lucia (VIC)
129 Walawski, S (WA)
262 Waldock, Ms Miriam (WA)
318 Wales, Mr Anthony (NSW)
1517 Walker, Mr Gregory (VIC)
1199 Walker, Ms Ellen (NSW)
364 Walker, Ms Kathleen (WA)
1077 Wallace, Mr Malcolm (NSW)
833 Wallace, Ms Catriona (NSW)
1711 Wallee, Ms Julianne (VIC)
1699 Wallen, Mr Paul (VIC)
1626 Wallen, Mr Peter (VIC)
1421 Walsh, Dr F (QLD)
732 Walsh, Mr Damer (NSW)
842 Walsh, Ms Marilyn (QLD)
602 Walter, Dr Derek (TAS)
345 Ward, A M (WA)
725 Ward, Ms Audrey (VIC)
245 Ward, Ms Cath (VIC)
951 Ward, Rev Maurice (VIC)
502 Ware, Mr Phillip (QLD)
936 Waterhouse, Mr Timothy (WA)
800 Waterhouse, Mrs Jenny (WA)
1206 Waters, E (VIC)
1455 Watts, Mr Charles (TAS)
638 Way, Mr David (QLD)
305 Wearmouth, Mr Lance (QLD)
835 Webb, Mr Mark & Ms Phillipa (WA)
1732 Webster, Ms Rosemary (VIC)
1361 Welch, Mr Maurie (WA)
939 Welch, Mrs Dorsi Ruth (WA)
1252 Werth, Mr John (QLD)
1083 West, Dr Michael D (USA)
1544 West, Mr Peter (QLD)
1439 Whalley, Ms Maureen (QLD)
1559 Whatley, Mrs Jennifer (WA)
629 Whawell, Mrs J (WA)
702 Whelan, Ms Margaret (VIC)
1731 Whelan, P (VIC)
185 White, L J (TAS)
107 White, Mr Francis & Mrs Veronica (WA)
443 White, Mr Peter (WA)
1399 White, Ms Veronica (NSW)
59 Whiteley, Ms Emma (NSW)
1728 Whiting, J R (WA)
487 Whitney, Mr Peter (QLD)
218 Whitton, Ms Georgie (QLD)
1178 Whyte, Ms Maureen (VIC)
942 Wicks, Ms Lyn (WA)
1075 Wiedersehn, Mr William (NSW)
1386 Wieske, Mr John & Ms Jannet (WA)
56 Wilkinson, Mr Tom (NSW)
57 Wilkinson, Ms Noelene (NSW)
657 Willemsen, Fr Michael (VIC)
1412 Willersdorf, Mr Ian & Ms Julie (NSW)
1405 Williams, Mr David (NSW)
403 Williams, Mr Guy & Ms Mandy (VIC)
781 Williams, Mrs Patricia (NSW)
1701 Williams, Ms Dianne (VIC)
991 Williams, Ms Theresa (VIC)
1050 Williamson, Dr Peter (WA)
857 Williamson, Ms Yvonne (QLD)
1002 Williamson, Professor Bob (VIC)
838 Wills, Ms Renee (QLD)
664 Wilson, B (VIC)
1161 Wilson, Ms Julie (VIC)
710 Wilson, Ms Moira (VIC)
2 Wise, Mr Tom & Ms Win (NSW)
371 Wiseman, Mr Andrew (QLD)
1605 Withell, Ms Irene (VIC)
1212 Wong, Pastor Stephen (VIC)
1464 Wood, Ms Rana (NSW)
248 Wood, Ms Sarah (NSW)
1519 Wood, Robert (em)
1204 Woodhead, Mr L F (VIC)

1205	Woodhead, Ms Joy (VIC)	1768	Young, Miss Bev (QLD)
676	Woodley, Mark (em)	557	Young, Mr Graeme (VIC)
745	Woodrow, Mrs L (NSW)	744	Young, Mr Peter (NSW)
693	Woolridge, Ms P & Mr J (TAS)	1392	Young, Mr Phillip (VIC)
1339	Worthington, Ms Althea (VIC)	501	Young, Ms Athalie (QLD)
1751	Wright, Miss Glenyse (WA)	1259	Young, Ms Beverley (QLD)
1580	Wright, Miss Lyn (VIC)	653	Young, Ms Janet (VIC)
1151	Wright, Mr Anthony (VIC)	576	Young, Ms Thelma (VIC)
540	Wright, Mr John (VIC)	980	Zacest, Mrs Cynthia (SA)
809	Wright, Mrs Maureen (NSW)	718	Zaffina, Mrs Sylvia (VIC)
864	Wright, Ms Heather (NSW)	483	Zapanta, Mr Alberto (NSW)
1531	Wu, Ms Lee (em)	1368	Zeh, Mrs Veronica (WA)
915	Yap, Mr Darrell (VIC)	523	Zeiger, Ms Cathy (QLD)
157	Yih Shing Phang, Ms Elaine (NSW)	1687	Ziouane, Ms Doris (VIC)

Additional information

Australian Government Solicitor Advice dated 13.2.02 and 30.4.02, provided through the Committee Chairman, Senator Sue Knowles

Professor Perry Bartlett - tabled at public hearing 19.9.02 a graph titled Degree of Difficulty

Professor Peter Illingworth:
- Provided at public hearing 26.9.02, IVF presentation
- Response to questions following public hearing, dated 27.9.02 and 16.10.02
- Clarification of evidence given at public hearing 24.9.02, re: abnormal embryos, dated 8.10.02

Dr Peter Jonson - correspondence dated 2.10.02 responding to comments made by Senators during the hearing on 26 September

Parkinson's New South Wales - Letter dated 26.9.02

Professor Douglas Saunders:
- Tabled at public hearing 24.9.02, RTAC and other IVF information
- Response to question following public hearing, dated 26.9.02

Statistical summary

Total number of submissions received		1851
Number of submissions received from organisations		100
Number of submissions received from individuals		1751
Number of submissions received as a form letter*		289
Number of submissions opposed to the Bill**		1803
Number of submissions in support of the Bill		48
Number of pages of submissions	1-2 pages	1724
	3-10 pages	107
	> 11 pages	20

Note:

* The number of form letters received may well be considerably higher as there were a number of versions of text received as form letters by the Committee. Many of these were handwritten rather than in printed text and included the rewriting of a 'sample submission'.

** These figures set out the basic position of those making submissions, as interpreted by the secretariat. The numbers listed as opposed to the Bill are opposed to the human embryo research aspects of the Bill. No figures were compiled on the cloning issue, as many of the submissions made no reference to that part of the Bill. Reasons for opposition varied and have been canvassed in the text of the report.

The Committee also received a further 65 printed or handwritten letters expressing views opposed to human embryo research that had an illegible signature or no identifiable name or address.

APPENDIX 2

WITNESSES WHO APPEARED BEFORE THE COMMITTEE AT PUBLIC HEARINGS

Thursday 29 August 2002

Parliament House, Canberra

National Health and Medical Research Council
Professor Alan Pettigrew, Chief Executive Officer
Dr Clive Morris, Executive Director, COAG Implementation Taskforce
Ms Andrea Matthews, Consultant, Matthews Pegg Consulting

Tuesday 17 September 2002

Parliament House, Canberra

BresaGen Limited
Dr Christopher Juttner, Senior Vice President

Professor Bernie Tuch, Director, Diabetes Transplant Unit, Prince of Wales Hospital

Stem Cell Sciences
Mr Hugh Ilyine, General Manager

Southern Cross Bioethics Institute
Dr Greg Pike, Deputy Director

Dr Peter Silburn, Neurologist, Princess Alexandra Hospital and Spokesman, Scientific Committee Parkinson's Australia

Right to Life Australia
Ms Margaret Tighe

Coalition for the Advancement of Medical Research Australia (CAMRA)
Juvenile Diabetes Research Foundation (JDRF)
Ms Sheila Royles, Spokesperson (CAMRA) and Chief Executive Officer (JDRF)
Mr James Shepherd, Youth Ambassador (JDRF)

Australasian Spinal Research Trust
Mr Bob Turner, Honorary CEO
Ms Johanna Knott, Director

Motor Neurone Disease Association
Mr Kevin Langdon, NSW President

Thursday 19 September 2002
Parliament House, Canberra

Professor Michael Good, Director, Queensland Institute of Medical Research

Associate Professor Paul Simmons, Head, Stem Cell Laboratory, Peter MacCallum Cancer Institute

Professor Perry Bartlett, Chairman of Molecular Biology, Uni of Queensland and Walter and Eliza Hall Institute

Professor Peter Rowe, Director, Children's Medical Research Institute, Westmead

Professor John Hearn, Deputy Vice Chancellor (Research), ANU

Australian Academy of Science
Professor Sue Serjeantson, Executive Secretary
Professor John White, Academy Spokesperson on Human Cloning
Professor John Shine, Secretary, Biological Sciences

AusBiotech
Dr Tony Coulepis, Executive Director

Tuesday 24 September 2002
Parliament House, Canberra

Monash Institute of Reproduction and Development:

Professor Alan Trounson, Director, Centre for Early Human Development, Deputy Director MIRD and CEO Designate National Stem Cell Centre

Associate Professor Martin Pera, Co-Director, CEHD

Dr Andrew Elefanty, Senior Research Fellow, Laboratory Head, CEHD

Dr Edouard Stanley, Senior Research Fellow

National Stem Cell Centre
Mr Bob Moses, Chairman

Professor Douglas Saunders, Chair, Reproductive Technology Accreditation Committee of the Fertility Society of Australia

Anglican Diocese of Sydney
Dr Megan Best, Member, Archbishop's Social Executive Committee

Dr Nicholas Tonti-Filippini

Dr Peter McCullagh

Do No Harm
Dr David van Gend, Queensland spokesperson

Dr Amin Abboud, Director, Australian Bioethics Information

Australian Family Association
Mr Bill Muehlenberg, National Vice President

Don't Cross the Line
Mr Rocky Mimmo, Convenor

Thursday 26 September 2002

Parliament House, Canberra

Associate Professor Peter Illingworth, Westmead Fertility Clinic

ACCESS – Australia's National Infertility Network
Ms Sandra Dill, Executive Director

Monash IVF
Dr Adrianne Pope, Director of Laboratory Services

Sydney IVF
Professor Robert Jansen, Medical and Managing Director

Australian Catholic Bishops Conference
Archbishop Philip Wilson, Archbishop of Adelaide
Dr Warwick Neville, Research Fellow
Ms Marcia Riordan, Executive Officer, Respect Life Office,
Archdiocese of Melbourne

Catholic Health Australia
Mr Francis Sullivan, Chief Executive

Catholic Women's League Australia
Mrs Mary Uhlmann, National Bioethics Convenor
Ms Aileen Solowiej, Communications Officer

Queensland Bioethics Centre
Mr Ray Campbell, Director

Rev Professor Michael Tate AO, former Chairman, Senate Select Committee on Human Embryo Experimentation

Biotechnology Australia
Ms Kerri Hartland, Executive General Manager
Dr David Swanton, Manager, Industry Development

Australian Research Council
Mr Greg Harper, Deputy Chief Executive Officer
Professor Bill Sawyer, Executive Director, Biological Sciences and Biotechnology

National Health and Medical Research Council
Dr Clive Morris, Executive Director, COAG Implementation Task Force
Ms Andrea Mathews, Consultant, Matthews Pegg Consulting

Australian Health Ethics Committee
Dr Kerry Breen, Chair

APPENDIX 3

COUNCIL OF AUSTRALIAN GOVERNMENTS COMMUNIQUE – 5 APRIL 2002

The following extract relating to human cloning, assisted reproductive technology (ART) and related matters is from the COAG communique dated 5 April 2002.

INTRODUCTION

The Council of Australian Governments (COAG) today held its 11th meeting in Canberra. The Council, comprising the Prime Minister, Premiers and Chief Ministers and the President of the Australian Local Government Association (ALGA), had wide ranging discussions on important areas of national interest.

This Communique sets out the agreed outcomes of the discussions.

HUMAN CLONING, ASSISTED REPRODUCTIVE TECHNOLOGY (ART) AND RELATED MATTERS

The Council agreed that the Commonwealth, States and Territories would introduce nationally-consistent legislation to ban human cloning and other unacceptable practices. The Council noted the Commonwealth intends to introduce legislation by June 2002.

The Council agreed that research involving the use of excess assisted reproductive technology (ART) embryos that would otherwise have been destroyed is a difficult area of public policy, involving complex and sensitive ethical and scientific issues. Having noted the range of views across the community, including concerns that such research could lead to embryos being created specifically for research purposes, the Council agreed that research be allowed only on existing excess ART embryos, that would otherwise have been destroyed, under a strict regulatory regime, including requirements for the consent of donors and that the embryos were in existence at 5 April 2002. Donors will be able to specify restrictions, if they wish, on the research uses of such embryos.

The regulation restricting the use of embryos created after 5 April 2002 will cease to have effect in three years, unless an earlier time is agreed by the Council. The Council also agreed to establish an Ethics Committee with membership jointly agreed by the Council to report to the Council within 12 months on protocols to preclude the creation of embryos specifically for research purposes, with a view to reviewing the necessity for retaining the restriction on embryos created on or after 5 April 2002. The Council also agreed to request the National Health and Medical Research Council (NHMRC) to report within 12 months on the adequacy of supply and distribution for research of excess ART embryos which would otherwise have been destroyed.

The Council agreed that research involving the destruction of existing excess ART embryos be permitted under a strict regulatory regime to enable Australia to remain at the forefront of research which may lead to medical breakthroughs in the treatment of

disease. It was further agreed that the regulatory regime governing the use of excess ART embryos that would otherwise have been destroyed will be reviewed within three years. Research would need to have approval from an ethics committee and be in accordance with NHMRC and Australian Health Ethics Committee guidelines. This arrangement will be administered by the NHMRC as the national regulatory and licensing body.

Details of the agreed arrangements on the bans on human cloning and other unacceptable practices and the regulatory regime governing research involving the destructive use of existing excess ART embryos are attached.

….

Council of Australian Governments
5 April 2002

ATTACHMENT

ARRANGEMENTS FOR NATIONALLY-CONSISTENT BANS ON HUMAN CLONING AND OTHER UNACCEPTABLE PRACTICES, AND USE OF EXCESS ASSISTED REPRODUCTIVE TECHNOLOGY (ART) EMBRYOS

The Council agreed that the Commonwealth, States and Territories would introduce nationally-consistent legislation to ban human cloning and other unacceptable practices. The Council noted the Commonwealth intends to introduce legislation by June 2002.

It is also intended that this legislation establish a national regulatory regime in relation to the use of excess ART embryos. Given the pace of scientific developments in this area, the Council also agreed that arrangements for research using excess ART embryos will be reviewed within three years.

The arrangements agreed by the Council are as follows.

A nationally-consistent ban on the cloning of a human being

1. The following wording is to be used as the basis for a nationally-consistent ban on the cloning of a human being:

1.1 A person must not:

a) create, or attempt to create, a human clone by means of a technological or other artificial process; or

b) cause a human embryo clone to be placed in the body of a human or animal for any period of gestation.

1.2 For the purposes of establishing that a human clone or human embryo clone is a genetic copy:

a) it is sufficient to establish that the set of genes in the nucleus of the human cell has been copied; and

b) it is not necessary to establish that the copy is an identical genetic copy.

1.3 It is not a defence that the human clone or human embryo clone did not or could not survive.

“Human clone” means a human that is a genetic copy of another living or dead human.

“Human embryo clone” means a human embryo that is a genetic copy of a living or dead human.

“Embryo” is a developing organism from the completion of fertilisation, or initiation of development by any other means, until eight weeks when the organism becomes known as a foetus.

Nationally-consistent regulation of certain unacceptable practices

2. The following practices are unacceptable and should be prohibited in Australia.

2.1 A person must not create or develop an embryo outside the body of a woman:

a) for purposes other than assisted reproduction; or

b) by a process other than the fertilisation of a human ovum by human sperm.

2.2 A person must not create or develop an embryo for assisted reproduction that contains genetic material from more than two people.

2.3 A person must not create or develop an embryo for assisted reproduction that uses any precursor cells of eggs or sperm from an embryo or foetus.

2.4 A person must not maintain an embryo outside the body of a woman after the 14th day of its development excluding any time in which its development has been suspended.

2.5 A person must not alter the genome of a cell of a human being or in vitro embryo such that the alteration is inheritable.

2.6 A person must not conduct embryo flushing.

3. A person must not:

a) create or develop a hybrid embryo; or

b) place a hybrid embryo in the body of a human or animal for any period of gestation.

“Hybrid embryo” means a single living organism which has a mixed genetic origin as a consequence of combining cells derived from humans and other species.

3.2 A person must not:

a) place a human embryo in an animal or in any human body cavity other than the female human reproductive tract; or

b) place an animal embryo in a human for any period of gestation.

3.3 A person must not give or offer valuable consideration to any person for donation of gametes or embryos of that person or of any other person.

“Valuable consideration” includes a discount or priority in the provision of a service but does not include the disbursement of any reasonable expense incurred by a person in connection with a donation of his or her reproductive material.

4. The prohibited practices will be comprehensively reviewed within three years of nationally consistent legislation taking effect, taking into account changes in technology, the potential therapeutic uses for such technology and any changes in community standards.

A nationally-consistent approach to research involving human embryos

5. Research involving human embryos should be regulated through nationally-consistent legislation.

6. The following principles should underpin nationally-consistent legislation:

6.1 legislation should ensure appropriate ethical oversight of research involving embryos based on nationally-consistent standards;

6.2 the nationally-consistent standards should be clear, detailed and describe the ethical issues to be taken into account, research which may be permitted and the conditions upon which it may be permitted (that is, the "rules" to be observed by researchers undertaking work with embryos) and should be based on National Health and Medical Research Council (NHMRC) guidelines as devised by the Australian Health Ethics Committee (AHEC);

6.3 these national standards should be applied consistently throughout Australia, recognising that jurisdictions may use different mechanisms to establish that proposals comply with the national standards;

6.4 the system should provide for public reporting of research involving embryos so as to improve transparency and accountability to the public; and

6.5 the system should enable appropriate monitoring of compliance with the national standards and provide legislated penalties for non-compliance.

7. There is a range of legislative options that could meet these principles including systems of accreditation, licensing or mandating of compliance with the revised AHEC guidelines.

A nationally-consistent approach to the development and/or use of embryos for the derivation of stem cells

8. Research with existing stem cell lines will be permitted to continue in Australia subject to observance of conditions set by NHMRC/AHEC.

9. Research and possible therapeutic applications which involve the destruction of existing excess ART embryos (or which may otherwise not leave the embryo in an implantable condition) will be permitted in accordance with the regulatory regime at Appendix 1.

10. The ban on the development of embryos for purposes other than for assisted reproduction will be maintained and reviewed within three years taking into account the implications for therapeutic use of embryonic stem cells (as detailed in the Health Ministers' report, Chapter 4).

A nationally-consistent approach to ART

11. Accreditation by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia should provide the basis for a nationally-consistent

approach to the oversight of ART clinical practice in Australia, noting that compliance with the NHMRC/AHEC Ethical Guidelines on ART is a key requirement of RTAC accreditation.

12. Individual jurisdictions may choose to mandate RTAC accreditation in legislation or supplement requirements for RTAC accreditation with an additional layer of oversight (for example, through a system of licensing or accreditation of ART service providers).

13. Non-legislative measures should be implemented to improve clarity regarding the role of Human Research Ethics Committees in relation to innovative practice and to increase public reporting of research and innovative practice (as detailed in the Health Ministers' report, Chapter 5).

APPENDIX 1

REGULATORY REGIME CRITERIA FOR RESEARCH USES OF EXCESS ASSISTED REPRODUCTIVE TECHNOLOGY (ART) EMBRYOS

Governments agree to put in place a strict regulatory regime under nationally-consistent legislation and administered by the National Health and Medical Research Council (NHMRC) as the national regulatory and licensing body. The NHMRC would issue a licence for a person to use an excess embryo from an ART programme for research or therapy that damages or destroys the embryo. A licence would only be issued where that project has the approval of an ethics committee established, composed and conducted in accordance with NHMRC guidelines, and that the approval is given on a case by case basis that:

- there is a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed procedure;
- the significant advance in knowledge or improvement in technologies could not reasonably be achieved by other means;
- the procedure involves a restricted number of embryos and a separate account of the use of each embryo is provided to the ethics committee and the national licensing body;
- all tissue and gamete providers involved and their spouses or domestic partners, if any, have consented to research for each embryo used, including by specifying restrictions, if they wish, on the research uses of such embryos; and
- the embryo had been created prior 5 April 2002.

These regulations will be reviewed within three years.

The regulation restricting the use of embryos created after 5 April 2002 will cease to have effect in three years, unless an earlier time is agreed by the Council.

- The Council also agreed to establish an Ethics Committee with membership jointly agreed by the Council to report to the Council within 12 months on protocols to preclude the creation of embryos specifically for research purposes, with a view to reviewing the necessity for retaining the restriction on embryos created on or after 5 April 2002.

- The Council also agreed to request the NHMRC to report within 12 months on the adequacy of supply and distribution for research of excess ART embryos which would otherwise have been destroyed.

5 April 2002