7

The ethics of research and therapy

INTRODUCTION

7.1 As foreshadowed in Chapter 5, this chapter focuses on the ethical issues raised by research involving the use of stem cells and cloning techniques involving embryos and the possible application of such techniques to treat illness and disease. The overwhelming majority of the evidence concentrated on that matter.

7.2 The discussion in this chapter will canvass only ethical issues relating to whether research involving the use of stem cells, embryos and cloning technologies should be permitted and, if so, in what circumstances. The Committee's recommendations for appropriate regulation of this research are outlined in Chapter 12.

7.3 As noted in Chapter 5, the use of cloning technology for implantation, gestation and the birth of a whole human being is not the only aspect of research involving cloning technology that has aroused passionate comment. Related practices such as the use of embryonic stem cells, the prospect of the creation of embryos by somatic cell nuclear transfer for research or therapy, and the use of surplus embryos from assisted reproductive technologies for research purposes (such as the derivation of embryonic stem cells) have also aroused great interest and concern.

7.4 Chapter 5 also discussed the approach taken by the AHEC report to ethical issues and the Committee's approach to ethical issues arising from the application of cloning technologies to human beings. The AHEC report's discussion of ethical issues focused primarily on those associated with cloning techniques involving the use of human embryos. That report considered the possible objectives for cloning techniques involving human embryos, the circumstances in which such cloning might take place, the

significance of such cloning and the public policy issues associated with either permitting or prohibiting such cloning. AHEC concluded that '[o]verall, it has been suggested that the more convincing, weighty and cogent arguments support constraints on the use of cloning techniques which involve human embryos'.[1] The Committee notes the AHEC report did not focus on the issue of embryonic stem cells, which are now central to the debate, because human embryonic stem cell lines had only just been isolated at the time AHEC concluded its report.[2]

What Is The Main Issue?

7.5 At the centre of the Committee's deliberations is the question: is there any benefit in conducting this research or in the application of any cloning technologies to human beings? If there is, what use of cloning techniques is permissible to achieve the benefit or benefits? For what purposes would such use be permitted? At the heart of these questions is the degree to which it is ethical to conduct research involving cloning techniques that destroy embryos.

Summary Of The Ethical Issues

7.6 The ethical acceptability of research involving the use or creation of embryos generated polarised comment. Those opposed on ethical grounds to research involving embryos held firmly that the moral status assigned to the embryo as the beginning of potential human life precluded its use or destruction in research. This view did not change no matter what the source of the embryo. As with reproductive cloning, people holding this view focused on the ethical significance of the research involving cloning technologies, not on its context or sources of material.

7.7 An equally strong view was expressed by others that the ethical imperative lies in permitting and facilitating research involving embryos. These people argued that if the research that could assist them were prohibited many people would continue to suffer or die.

7.8 AHEC's *Ethical Guidelines on Assisted Reproductive Technology* state:

> Research involving early human embryos raises profound moral and ethical concerns. There are differences of opinion amongst

1 AHEC report, Chapter 3, paragraph 3.33

2 Human embryonic stem cell lines were isolated in 1998 – see paragraph 2.46 of this report. The AHEC report did discuss embryonic stem cells—see AHEC report Chapter 2, paragraphs 2.16-2.20. Professor Saunders, the Chairman of the NHMRC, stated that AHEC does not have a formal position on embryonic stem cells, Professor Nicholas Saunders, *Transcript*, p.192

> Australians regarding the moral status of the human embryo, particularly in its early stages of development.
>
> Some believe that there is the same obligation to refrain from harming an embryo as that which is recognised in relation to human subjects in general. If so, then any destructive or other harmful experimentation would be morally unacceptable to researchers or gamete donors with this belief. Others believe that research which may potentially harm the embryo may be justified where it is undertaken for the direct benefit of other embryos. Still others believe that research which is harmful to embryos may be justified on the basis of advancing knowledge or improving technologies for treatment.
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> These differences of opinion were understood and reflected in the discussions which led to the development of these guidelines. At the present time these differences cannot be resolved.[3]

7.9 While there is a range of issues about which the Committee agrees, a single position could not accommodate the full range of views on these matters. The distance between the two principal positions expressed in the evidence to the inquiry is illustrated in the following paragraphs.

7.10 Dr Pike of the Southern Cross Bioethics Institute posed the ethical dilemma faced by this Committee:

> …can we be sure what is being traded here? Are some of the deep values and principles guiding human conduct worth surrendering for possible medical treatment? The promise of therapy seems exciting and full of hope, but if, in the process, something quite fundamental has been exchanged, our humanity may be significantly compromised and diminished and with the risk of further diminishing steps, the consequences of which cannot at this stage be fully known.[4]

In the same vein Archbishop Hickey of the Australian Catholic Bishops Conference stated:

> Human life is never disposable at any stage of its development. It should never be seen as a commodity … nor is its worth and claim to protection dependent on age or utility to others …

3 NHMRC, *Ethical Guidelines on Assisted Reproductive Technology*, Guideline 6

4 Dr Gregory Pike, *Transcript*, p.32

> …it is the view of the Catholic Church in Australia that it is unethical to collude with or participate in the harvesting and use of ES cells.[5]

7.11 Professor Marilyn Monk from the Monash Institute of Reproduction and Development emphasised:

> …the immense medical potential of the research… The possibility of transplantation of tissue arising from embryonic stem cells in the treatment and cure of disease is the greatest and most exciting medical breakthrough I can envisage in the future. For it to happen, research into embryonic stem cells derived from human embryos is needed…
>
> …these few cells of an embryo, destined to be discarded, do not possess a greater potential value than the embryonic stem cell line they could generate with the potential to be used in tissue transplantation to save lives and alleviate suffering.[6]

7.12 Professor Pettit posed different ethical considerations:

> When we come to the matter of what does ethical consideration require of us in regard to allowing something of this kind, then we have got to realise that ethics does not belong to those of any particular group with any particular set of metaphysical views. The ethics that should guide our deliberations is an ecumenical ethics—an ethics that is pluralist, that recognises that it involves the sorts of principles to which any goodwilled, clear-headed people can at least come to understand and be moved by.[7]

The Committee's Approach To The Issue

7.13 The most important preliminary question is: will any benefit flow from conducting this research or applying cloning technologies to human beings? The Committee asserts that this question must be addressed before considering the ethical issues.

7.14 The evidence outlined in Chapter 3 indicated the significant potential of this research for human medicine. The ethical issues arise principally in the way the research is conducted and the source of the material. Most discussion in this chapter will canvass these issues.

7.15 Evidence indicated ethical considerations could arise from the use of the following sources of material for research involving cloning techniques:

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5 Archbishop Barry Hickey, *Transcript*, p.91

6 Professor Marilyn Monk, *Submissions*, pp.S805-806

7 Professor Philip Pettit, *Transcript*, p.107

- adult stem cells;
- embryonic stem cells;
- embryos that are surplus to assisted reproductive technology requirements;
- embryos deliberately created for research purposes;
- embryos deliberately created by somatic cell nuclear transfer using a patient's own tissue for therapy for individual patients; and
- cells, such as embryonic stem cells imported from overseas (that is, cells obtained in one of the ways above and imported into Australia).

The Committee's Use Of The Term 'Embryo'

7.16 The meaning of the term 'reproductive cloning' was discussed in Chapter 6. Many people interpreted the term to include the use of cloning techniques to produce an embryo even where there was no intention to produce a whole human being. Reasons for producing such an embryo might include the conduct of research or its use as part of medical treatment.

7.17 The Committee is aware that the definition of 'embryo' and the moral status attached to the human embryo have been canvassed on many previous occasions.[8]

7.18 Some scientists discussed whether to call what is derived from the somatic cell nuclear transfer process an 'embryo'. Professors Williamson and Short, regarded the term 'embryo' as only being applicable to the product of the union of an egg with sperm.[9] Professor Trounson described the products of a somatic cell nuclear transfer process as 'embryos':

> …my scientists call cloned embryos, cloned embryos… That does not mean to say that they believe they are the same as a fertilised embryo…[10]

7.19 These differences may reflect either a substantive difference of view or merely a difference in terminology. The evidence from others was presented on the assumption that the product of a somatic cell nuclear transfer process was an 'embryo'. The Committee accepts for the purposes of the discussion of ethical issues that these are 'embryos'—or as Dr

8 The report of the Senate Select Committee on the Human Embryo Experimentation Bill 1985, 8 October 1986, provides an example of the work of a parliamentary committee on this issue

9 Professor Robert Williamson, *Transcript*, p.8 and Professor Roger Short, *Transcript*, p.7

10 Professor Alan Trounson, *Transcript*, p.28

Norman Ford from the Caroline Chisholm Centre for Health Ethics described them—'artificially constructed embryos'.[11]

7.20 For the purposes of its discussion of research involving the use of embryos, the Committee intends the term 'embryo' to apply to embryos in whatever way they are created. A definition of 'embryo' can be found in the Glossary. For the sake of clarity the Committee emphasises that its use of the term in this chapter includes embryos created:

- naturally;
- as a result of artificial reproductive technologies (including *in vitro* fertilisation); and
- by asexual reproduction such as by somatic cell nuclear transfer for the purpose of research or (in the future) possible use in medical treatment.

As noted earlier the key issues for the Committee are the ethical issues associated with the sources of material necessary for cloning research and the use of cloning technology. This chapter will therefore focus on the source and use of embryos.

POTENTIAL BENEFIT IN THE APPLICATION OF CLONING TECHNOLOGIES TO HUMAN BEINGS

7.21 The potential benefits for human health from developments in stem cell research and somatic cell nuclear replacement were outlined in Chapter 3.

7.22 The AHEC report outlined the benefits to be anticipated from embryonic stem cell research as including:

> … *in vitro* studies of normal human embryogenesis, abnormal development (through the development of cell lines with targeted gene alterations and engineered chromosomes), human gene discovery, and drug and teratogen testing, and as a renewable source of cells for tissue transplantation, cell replacement and gene therapies. To these might be added the acquisition of new information about nuclear-cytoplasmic interactions relevant to studies of ageing and cancer.[12]

7.23 The AHEC report commented that 'the thrust of scientific endeavour is towards applying technology relating to cloning to achieve goals other than producing new persons'[13] and hence that its discussion of the ethical

11 Dr Norman Ford, *Transcript*, p.17

12 AHEC report, Chapter 2, paragraph 2.27

13 AHEC report, Chapter 2, paragraph 2.1

issues 'associated with the use of cloning techniques' is focused on 'the use of cloning techniques involving whole human entities, in particular embryos'.[14]

7.24 The Committee sees merit in AHEC's comment that in 'order to provide a framework for subsequent consideration of the ethics of human cloning, identification of the ends that may be sought, and the means likely to be employed to attain them, provides a useful reference point'.[15]

7.25 The possible development of tissues for therapy for serious diseases such as Parkinson's disease and Alzheimer's disease have been the most discussed benefits of cloning research. The potential benefit to a wide range of people was broadly accepted throughout the evidence, including by many of those who raised ethical objections to it.

7.26 Associate Professor Martin Pera added to the list of possible benefits contained in the AHEC report. He listed four applications for research involving embryonic stem cells:

> …basic research into human development and disorders thereof, including birth defects and certain types of childhood embryonal tumours; secondly, the discovery of novel protein factors which may be used to drive tissue regeneration and repair if administered therapeutically; thirdly, the development of *in vitro* human cell models for drug discovery and toxicology in the pharmaceutical industry; and fourthly, the development of tissue for transplantation, which has really attracted the most attention.[16]

Associate Professor Pera went on:

> … the first three of those applications really by and large do not require any access to cloning technology whatsoever. They can be achieved pretty much with stem cell lines derived from embryos… It is only the fourth one where the cloning technology really comes into play. It might be that for the third application we might want to use the cloning technology to make cell lines from individuals with particular genetic susceptibility to disease but, by and large, for much of the research cloning really is not required.[17]

7.27 Although he acknowledged the potential benefits Professor Roger Short sounded a cautionary note:

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14 AHEC report, Chapter 3, paragraph 3.4

15 AHEC report, Chapter 2, paragraph 2.7

16 Associate Professor Martin Pera, *Transcript*, p.5

17 Associate Professor Martin Pera, *Transcript*, p.5

> If therapeutic cloning is to be transformed from a dream into a reality, an enormous amount of basic research will be necessary to establish the safety and efficacy of the technique. But the potential rewards would be enormous, comparable to the discovery of antibiotics…[18]

7.28 At this stage attempts at cloning embryos in animals by means of somatic cell nuclear transfer usually fail to yield embryos or usually yield embryos with fatal abnormalities. Hundreds of attempts are made to yield one viable embryo. The process requires a large supply of eggs. In animals that supply may be found readily. However in humans the process of obtaining a supply of eggs is much more complicated.[19]

7.29 The Committee emphasises that the scientific evidence before it indicates that some of the above discussion of the potential benefit in the application of cloning technologies to human beings may be premature. In some respects discussion on this matter proceeds as though the benefits are immediately available or will be shortly. However many of the mooted benefits have long time frames and in some cases may be unobtainable.

Ethical Issues

Evidence from scientists and doctors

7.30 The great potential of the research to improve health led some to argue that it would be unethical to prohibit or restrict the research. Professor Williamson, for example, stated:

> …there are very great potential benefits in continuing research into ways in which somatic cells from living individuals can become totipotent. These benefits are most clear in the field of transplantation medicine. … If it were possible to take a cell from an individual … and dedifferentiate / redifferentiate this cell into a bone marrow cell with normal properties, these problems would be solved. This is such a stunning prospect that it would be highly unethical NOT to pursue it [emphasis in original].[20]

7.31 Professor Short agreed with this view of the ethical considerations and stated '…we should not be considering the ethics of whether we should be

18 Professor Roger Short, *Submissions*, p.S661. Dr Robert Loblay also submitted that there are 'compelling reasons' to support the research, *Submissions*, p.S677; see also BresaGen, *Submissions* p.S822

19 The process for obtaining eggs is described in Chapter 2 at paragraph 2.20

20 Bob Williamson, *Submissions*, p.S347

using therapeutic cloning; we should regard it as highly unethical to ban it'.[21]

7.32 BresaGen Ltd submitted that research involving the generation and use of embryonic stem cells should be able to be conducted with appropriate oversight and regulation.[22]

7.33 The AMA argued that 'using the cloning techniques to therapeutic ends is an ethical procedure which should be permitted to occur in this country under suitable ethical frameworks'.[23]

7.34 Dr Rogers of the Human Genetics Society of Australasia agreed that:

> The potential benefits from research in this area in terms of birth defects, malignancy and transplantation, to name a few of them, are enormous. We feel that it is critical that this research be facilitated within Australia, although properly regulated…and perhaps there is an ethical imperative that this research proceeds.[24]

Evidence from others

7.35 Several members of the public, themselves suffering from, or diagnosed with, severe or potentially debilitating illness urged the Committee strongly to support the continuation of this research work because of its potential medical benefit. Ms June Hearn submitted:

> Any research, development and assistance which may be gained by human cloning for disabled, injured or diseased people must be undertaken…I believe it is unethical to deny any person who is in any way challenged the opportunity for an improved life.[25]

7.36 Mr Peter Williamson also stressed that:

> … the stem cell research is showing great promise of providing a cure for Parkinson's disease and diabetes, diseases that afflict millions of people worldwide…

21 Professor Roger Short, *Transcript,* p.8. The Humanist Society of Victoria also took this view, Mrs Halina Strnad, *Transcript*, pp.34-35

22 BresaGen, *Submissions,* p.S822

23 Dr Sandra Hacker, *Transcript*, p.35. The Executive Council of Australian Jewry also believed there were significant benefits in the research, Mr Earle Hoffman, *Transcript*, p.96

24 Dr John Rogers, *Transcript*, p.37

25 Ms June Hearn, *Submissions,* p.S40. See also Ms Robyn Doyle who was 'particularly concerned that barriers not be put in the way of research that may lead to the alleviation of disorders such as that from which I suffer', *Submissions,* p.S837

> It would be shameful and of horrendous consequence to sufferers of diseases such as Parkinson's and diabetes if the stem cell research was swept up in any move to limit human cloning.[26]

7.37 Ms Anne van Zeist urged:

> The potential to benefit those condemned to suffering from Parkinson's disease and other illness should be considered. We take blood transfusions for granted these days, however, in its infancy blood transfusion was very controversial. All inventions, medical research or technological advancements through out time have been controversial.[27]

7.38 Ms Naomi Kronenberg likewise submitted:

> …in considering the ethical implications of cell development, you take account of the ethical responsibilities to those people facing huge odds in dealing with neurological disease. I urge you to consider society's ethical obligation to these people, as well as to ensuring that all stem cell harvesting occurs with the consent of donors or their guardians …[28]

7.39 As a relative of a person suffering from Parkinson's disease, Mr David Williamson stressed the 'importance of current research being carried out into the use of embryonic stem cells as the therapeutic agents for several of the major diseases affecting men and women in our community.' Mr Williamson urged the Committee to support the work, saying 'the potential benefits to humankind of the research are obvious …'[29]

7.40 Ms Leonie Maher argued that 'the fact [is] that it will be my own cells and embryos that they use to help me. They are not someone else's cells, and they are not making a copy of me, just the cells I need to stop the degeneration in my brain and spinal cord.'[30]

7.41 The potential benefits from this scientific research were also accepted by many of those who went on to express opposition to it on ethical grounds.[31]

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26 Mr Peter Williamson, *Submissions,* p.S832. See also *Submissions,* p.S869

27 Ms Anne van Zeist, *Submission*s, p.S827

28 Ms Naomi Kronenberg, *Submission*s, p.S865. See also submissions from Mrs W. Modra, *Submissions,* p.S850; Mr J.A Dickinson, *Submissions,* p.S851; V.G White, *Submissions,* p.S852; and Ms Maree Wragg, *Submissions*, p.S894

29 Mr David Williamson, *Submissions*, pp.S825-826

30 Leonie Maher, *Submissions,* p.S838

31 The Caroline Chisholm Centre for Health Ethics, for example, noted that while cloning technology may be used ethically for gene therapy or autologous transplants, for example stem cells for blood or bone marrow, the Centre does not support unethical methods of

7.42 Anne and Ian Whittingham submitted that embryonic stem cell research is:

> … revolutionary research that has enormous potential to save human lives and to mitigate human suffering for thousands of patients for whom stem cell treatment offers their first ray of hope…
>
> … Provided the embryos are not created for the purpose of the research but sourced from those generated for fertility treatments and in excess of clinical needs, we believe it is immoral to not pursue the tremendous scientific and medical potential benefits from embryonic stem cell research…[32]

7.43 Dr Hacker of the Australian Medical Association (AMA) stated that the AMA:

> …supports a view that using the cloning techniques to therapeutic ends is an ethical procedure which should be permitted to occur in this country under suitable ethical frameworks …
>
> …we must continue this work because we have to turn off machines. I have to sit with the young people who are losing their parents and with the parents who are losing their children because we do not have enough organs. The research that can come out of this work clearly has enormous benefit…. There are huge issues related to the possible outcomes of the work that are equally ethically demanding.[33]

7.44 Professor Savulescu also argued it would be morally remiss to neglect such research:

> Let me take you forward to one possible future in 30 years time. My three-year old daughter is now 33 and she has leukaemia. She is bleeding from her mouth and vomiting litres of blood each day. She needs a bone marrow transplant if she is to be cured. She has no compatible donor. Scientists are working on and are very close to developing a drug which would cause one of her healthy skin cells to turn into a bone marrow cell and in fact be able to repopulate her bone marrow and cure her leukaemia.[34]

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obtaining these benefits for example by destroying embryos to gain embryonic stem cells, *Submissions,* p.S490

32 Anne and Ian Whittingham, *Submissions*, p.S898

33 Dr Sandra Hacker, *Transcript*, pp.35-36

34 Professor Julian Savulescu, *Transcript*, p.114

In the light of this example Professor Savulescu argued that he would think:

> …it is not only morally permissible for scientists to engage in such research but actually morally required that they engage in research to develop such a drug. If such a drug was available, it would be negligent of doctors not to use it in treating my daughter. That is what is potentially on offer. The question is not whether therapeutic cloning should be allowed in Australia but why we are not doing it now and actually encouraging it.[35]

THE SOURCE OF MATERIAL FOR CLONING RESEARCH AND THERAPEUTIC APPLICATIONS

Adult Stem Cells

7.45 The use of adult stem cells in research and their potential for providing significant medical breakthroughs was described in Chapters 2 and 3. Using adult cells and seeking to reprogram them to apply them therapeutically to patients with disease would avoid the need to pass through the stage of creating an embryo (as the somatic cell nuclear transfer technique does) and would not require the use of embryos in conducting research.

7.46 Associate Professor Martin Pera described the process:

> …transdifferentiation or dedifferenciation, taking an adult cell of one tissue type and somehow reprogramming it to form a different desired type of tissue for transplantation.[36]

7.47 Work using this source of material was greeted with enthusiasm by many because it avoids the need to create or destroy embryos.

7.48 Dr George Owen, the President of the Spinal Cord Society of Australia gave evidence concerning research the Society is funding into the use of adult neuronal stem cells.[37] He noted the importance of this research not only as a doctor and President of the Society but also as the father of a quadriplegic child.[38]

7.49 The Catholic Archdiocese of Melbourne pointed out:

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35 Professor Julian Savulescu, *Transcri*pt, p.114

36 Associate Professor Martin Pera, *Transcript*, p.6

37 See Chapter 3, paragraph 3.57

38 Dr George Owen, private meeting, 27 October 2000

> Some scientists have chosen to avoid the ethically contentious issues of cloning human embryos and using human ES cells and instead are working with ordinary body cells like skin, blood, nerve, muscle and bone cells to try to isolate 'pluripotent' adult stem cells…[39]

The Archdiocese went on:

> …adult stem cells or de-differentiated somatic cells would have all the therapeutic advantages of ES cells but not require the generation and dismembering of cloned human embryos. …
>
> The Archdiocese strongly supports work of this kind as long as there is appropriate information giving, consent, and impartial and competent review to ensure the safety of human research subjects and respect for human dignity.[40]

7.50 Drs Fleming and Pike of the Southern Cross Bioethics Institute suggested:

> Perhaps the seemingly obvious outcomes of ES cell research could be supplanted by more effective and morally acceptable research using adult stem cells. …
>
> When it comes to alternatives, there is an ethical imperative to first pursue those avenues that are morally less problematic.[41]

7.51 Dr Eloise Piercy also submitted that 'research should be focused … upon efforts to culture adult stem cells eg. blood stem cells, skin cells and so on, in order to alter their type for use in tissue transplantation. There have already been some promising results in this area.'[42]

7.52 In relation to the possibility of partial reversal or differentiation of a person's adult cells to form regenerative stem cell types the Academy of Science recognised:

> … this is an approach preferred, from certain religious viewpoints, to the complete reprogramming of adult cells using cloning techniques. This route will not be available until a great deal more is known about cell growth factors and their receptors, and, even then, may not be available for all types of tissue repair.[43]

7.53 As noted in Chapter 3, the scientific evidence is that the partial reversal or differentiation of a person's adult cells to form regenerative stem cell types

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39 Catholic Archdiocese of Melbourne, *Submissions*, p.S524

40 Catholic Archdiocese of Melbourne, *Submissions*, p.S524

41 Dr John Fleming and Dr Gregory Pike, Southern Cross Bioethics Institute, *Submissions*, p.S563

42 Dr Eloise Piercy, *Submissions*, p.S585

43 Australian Academy of Science, *Submissions*, p.S249

is not yet possible. Many scientists consider it is necessary at this point to continue to undertake research using embryonic stem cells.[44]

Embryos Surplus To Assisted Reproductive Technology Programs

7.54 In assisted reproductive technology programs (including IVF) more embryos are often created than will be required to achieve children for those undergoing treatment. Under the legislation or guidelines applicable to work in this area[45] such embryos are usually stored for a certain period of time and may then be discarded if unused. There are currently more than 65,000 embryos in storage in Australia.[46]

7.55 It has been suggested that these 'surplus' embryos be used for research purposes. The most common use for such embryos, as outlined in Chapter 2, would be as a source of embryonic stem cells which are being studied to determine how they develop into specific tissues and organs. This has potential for new therapies in medicine. The extraction of the cells, however, destroys the embryo. Professor Trounson from the Monash Institute of Reproduction and Development described the process (not currently undertaken in Australia):

> What happens in the derivation of embryonic stem cells is that you actually take embryos that are no longer required by the patients—that is, at the end of their interest in IVF treatment—and you would normally either donate those embryos to other patients, if that is a possibility, or you would use them for research if that is a possibility, or you would discard them, you would throw them away in some sort of way…[47]

7.56 Professor Williamson of the Murdoch Institute for Research into Birth Defects supported a limited number of procedures (subject to rules of consent) being permitted on embryos surplus to assisted reproductive technology procedures that would otherwise be destroyed to allow methods to be developed which can yield cells for transplantation from somatic cells.[48]

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44 Chapter 3 paragraphs 3.62-3.64 and 3.70-3.72

45 See Chapters 8 and 9 for details

46 Tara Hurst and Paul Lancaster, *Assisted Conception Australia and New Zealand 1998 and 1999,* Australian Institute of Health and Welfare National Perinatal Statistics Unit and the Fertility Society of Australia, AIHW National Perinatal Statistics Unit, Sydney, 2001, p.7. The number of embryos that are frozen each year exceeds the number thawed so the total number of embryos in storage continues to increase. The number of embryos in storage has nearly trebled since 1994 from 22,280 in 1994 to 65,518 in 1999

47 Professor Alan Trounson, *Transcript*, p.4

48 Bob Williamson, *Submissions*, p.S348. Professor Williamson added the caveats that the usual rules of consent should apply and the procedures not lead to reproductive cloning

7.57 Professor Savulescu of the Murdoch Institute for Research into Birth Defects also supported the use of embryos that are surplus to assisted reproductive technology requirements.[49]

7.58 The Humanist Society of Victoria argued that '[f]rozen embryos no longer required for IVF should be used (with owners' consent) for research rather than discarded. This should proceed to day 14 of embryonic development.'[50] The Society does:

> … not believe the early embryo is a sentient being (before day 14 of development) nor a person or a moral agent.
>
> The research carried out on a cluster of cells that may, or may not develop into a human being, offers major clinical and therapeutic benefits for the present and future generations…
>
> We believe there is a moral and societal obligation to promote such research.[51]

7.59 A significant number of submissions specifically opposed the use of embryos that were surplus to assisted reproductive technology requirements.[52]

7.60 The Caroline Chisholm Centre for Health Ethics submitted:

> Non-therapeutic, destructive or harmful research on human embryos, be they naturally conceived embryos, IVF embryos or cloned embryos, is absolutely unethical and should be legally banned. The same applies to a cell or group of cells which is probably an embryo.[53]

7.61 The Anglican Church of Australia opposed the use of embryos that were surplus to assisted reproductive technology programs.[54] The Social Responsibilities Committee of the Anglican Diocese of Melbourne argued that the fact the:

> …tissue sources may come from "spare" embryos or unwanted tissue does not alter the ethical status of that tissue. If a tissue exists or we have access to it we do not have a moral obligation to use it and there is no ethical imperative to ignore the source of tissue to achieve the ends desired.[55]

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49 Professor Julian Savulescu, *Submissions,* p.S655

50 Humanist Society of Victoria, *Submissions,* p.S150

51 Humanist Society of Victoria, *Submissions,* p.S151

52 See submission numbers 199, 240, 243, 250, 269, 276, 284, 417, 418, 423, 426, 432, 448, 452, 461, 468

53 The Caroline Chisholm Centre for Health Ethics, *Submissions,* p.S778

54 Anglican Church of Australia**,** *Submissions,* p.S343

55 Social Responsibilities Committee, Anglican Diocese of Melbourne, *Submissions,* p.S307

7.62 Ridley College argued:

> Using the language of ES cell lines serves to mask the fact that the earliest form of human embryo, the blastocyst, must be destroyed in order to obtain these ES cells, which are extracted from the inner cell mass… One does not need to adopt the view that the early embryo has the same moral status as a developed human being, to nevertheless deny that it has no moral status and is not entitled to any protection or any respect.[56]

7.63 Ridley College also raised another issue: whether the requirement for embryos as a source for embryonic stem cells might influence the numbers that are created in assisted reproductive technology programs.[57] The College also suggested there is a significant distinction between:

> … using existing embryos or foetuses which, for other reasons, are not destined to develop into human beings, and deliberately creating such early humans with the intention of sacrificing them.[58]

Embryos Created Deliberately

7.64 The deliberate creation of embryos for research purposes is another possible source of material for research involving cloning technologies. Embryonic stem cells could then be extracted from such embryos. As noted above, the extraction would destroy the embryos.

7.65 Embryos could be created deliberately in the course of assisted reproductive technology programs or could be created by the use of other techniques such as somatic cell nuclear transfer.

7.66 The Committee received little evidence concerning the deliberate creation of embryos in the course of assisted reproductive technology programs. This was presumably due to the emphasis on 'cloning' techniques which resulted in a focus in much of the evidence on somatic cell nuclear transfer techniques. The recent announcement in the United States of the deliberate creation of embryos for research purposes using conventional assisted reproductive technology techniques[59] indicates that this is a possibility that should be considered. The Committee considers the issues raised by the deliberate creation of embryos for research purposes are similar regardless of the technique used.

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56 Ridley College, *Submissions*, p.S35

57 Ridley College, *Submissions*, p.S35

58 Ridley College, *Submissions*, p.S36

59 See Chapter 4, paragraph 4.4. (The Jones Institute of Reproductive Medicine)

7.67 A consideration for the Committee is that, given the large number of surplus embryos resulting from assisted reproductive technology programs, the deliberate creation of more embryos seems unnecessary.

7.68 The prospect of using somatic cell nuclear transfer techniques to create embryos for research involving cloning techniques evoked very strong opposition from most who gave evidence although most of the arguments used would seem equally applicable to embryos deliberately created for research purposes during assisted reproductive technology programs. This opposition was founded primarily on the view that research involving the creation and destruction of embryos transformed human life into a commodity or a 'manufactured product' created to serve the purposes of others. The projected benefits did not lessen the opposition to this form of research—the argument being that the end of improved health outcomes does not justify means of research that involve the destruction of embryos.

7.69 The Council for Marriage and the Family noted 'with concern the support in some scientific circles for research involving somatic cell nuclear transfer and the development of embryonic stem cell lines for purposes other than cloning of human beings'.[60] The Council:

> … opposes these practices regardless of the intention associated with them. It is not relevant that the cloning is done with the intention of creating one or more "viable" human beings destined to be allowed to develop normally, or whether it is to derive stem cells for the replication of specific human tissues, or other purposes. In each case human life is generated as a manufactured product to serve the purposes of another.[61]

7.70 Pro-Life Victoria submitted:

> If human beings are created for the purpose of experimentation and then destruction, this creation is itself most objectionable and shows flagrant disregard for human rights and the value of human life.[62]

7.71 The Social Responsibilities Committee of the Anglican Diocese of Melbourne submitted:

> Any material made using ethically unacceptable methods is still ethically unacceptable no matter what the proposed usage. The

60 Council for Marriage and the Family, *Submissions*, p.S493

61 Council for Marriage and the Family, *Submissions*, p.S494. See also Youth Concerned with Cloning, *Submissions*, p.S545

62 Pro-Life Victoria, Submissions, p.S669. See also Queensland Right to Life, *Submissions* p.S265; Coalition for the Defence of Human Life, *Submissions*, p.S271

> good end does not justify the wrong means of reaching the ends.[63]…
>
> Most arguments advanced for use and experimentation on embryonic material proceed from an implicit position about embryonic status. … The Church's position is that the moment of fertilisation should be considered as the unique human beginning.[64]

7.72 Several members of the public agreed. Mrs Madge Fahy, for example, submitted that:

> … while we would all agree that eliminating diseases would be a great achievement, we do not have the right to experiment with human embryos or creating them to remove their stem cells so that we might be without disease. Stem cell research should only be allowed if it can be done without involving the killing of human beings, including embryos.[65]

Mr Garrick Small likewise rejects 'the justification that it may provide solutions to medical problems on the grounds that there are other means of addressing these problems that do not carry the ethical complications of cloning.'[66]

Use of Embryos Created Deliberately By Asexual Reproduction in Therapy

7.73 This process would use the somatic cell nuclear transfer technique for the therapeutic benefit of particular individuals suffering from diseases which require transplantation of tissues or cells. At present this scenario is speculative but it could involve the use of the somatic cell of an ill person to create an embryo by means of somatic cell nuclear transfer. Such a procedure would also involve a donated egg. Embryonic stem cells would then be harvested from the resulting embryo (leading to its destruction) with a view to then directing the stem cells down the pathway required by the nature of the somatic cell donor's illness. If the technique proved to be feasible, this use of cloning technology would move from research to clinical practice and be subject to the general regulation that pertains to clinical practice.

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63 The Social Responsibilities Committee of the Anglican Diocese of Melbourne, *Submissions*, p.S293

64 The Social Responsibilities Committee of the Anglican Diocese of Melbourne, *Submissions*, p.S296

65 Mrs Madge Fahy, *Submissions*, p.S354

66 Mr Garrick Small, *Submissions*, p.S355. See also Mr Patrick John Reidy, *Submissions*, pS360; and Renate Byrne, *Submissions*, p.S358

7.74 The greatest benefits of this technique may be expected in transplantation medicine where the risks of tissue rejection may be avoided by supplying a person with new cells or tissue of exactly their own genetic type.

7.75 As was noted in Chapter 3 there is still a great deal of research to be done before such a process would be feasible and safe. It may be many years before such a procedure could become a reality.[67]

7.76 As Professor Trounson noted, the extraction of embryonic stem cells from such embryos would be the same as extracting embryonic stem cells from embryos surplus to assisted reproductive technology programs but with the difference that the embryos would have been deliberately created using the somatic cell nuclear transfer technique.[68]

7.77 The Human Genetics Society of Australasia's policy on human cloning:

> …recognises that the technology used for human reproductive cloning will lead to the development of technologies that have important medical uses. In particular, the creation of totipotent or pluripotent stem cells from somatic cells would markedly simplify transplantation procedures. As transplantation is presently limited both by immune rejection and by availability of tissue, this is an important clinical outcome that could bring great benefit.
>
> The HGSA notes that at present the transformation of a somatic cell to a stem cell or totipotent cell may involve passage through a human embryo, which some think is unethical because it involves embryo destruction. There is a diversity of opinion within the HGSA, as within the community on this issue.[69]

7.78 As was noted earlier there are serious practical difficulties involved in creating embryos using somatic cell nuclear transfer. These include the requirement for egg donation by women and the expense and inefficiency of the somatic cell nuclear transfer process. To use embryos created using this method in the course of therapy leads to the prospect of a demand for women to undergo general anaesthesia and surgery to yield sufficient eggs to produce one healthy embryo. Embryonic stem cells would then need to be harvested from that embryo to treat someone, such as a relative, who may be suffering from an illness. This is likely to make using embryos created by somatic cell nuclear transfer to gain embryonic stem

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67 See paragraphs 3.35-3.38. Professor Trounson and Associate Professor Pera raised the same concerns, *Submissions*, p.S172

68 Professor Alan Trounson, *Transcript*, p.10

69 The HGSA represents the views of clinicians, counsellors, scientists and others professionally qualified in the area of human medical genetics. It includes most of those working in this field in Australia and New Zealand. The Human Genetics Society of Australasia, *Submissions*, p.S508

cells for therapy impractical. The probable expense and inefficiency of the process as well as the ethical sensitivities involved in using embryos are further factors rendering this method of gaining embryonic stem cells increasingly unlikely.

7.79 The Committee notes that adult stem cell therapies are likely to be developed in parallel with embryonic stem cell therapies. Where possible, research on adult stem cells should be fostered. The current scientific knowledge is inadequate to judge the interdependence of these two related lines of research.[70]

Similarity to cloning for reproductive purposes

7.80 Some people object to the use of somatic cell nuclear transfer for extracting embryonic stem cells because the procedure is identical to that involved in cloning for reproductive purposes except that the resulting embryo would be destroyed to obtain the embryonic stem cells rather than implanted in a woman's uterus. Their misgiving was evident in spite of the potential benefit to individuals and the possible relief of serious disease and suffering. Their opposition was centred on the view that such a procedure involved treating a potential human life (the embryo) as a commodity and as the means to an end desired by another.

7.81 The Catholic Archdiocese of Melbourne, for example, stated:

> …in both "therapeutic" and "reproductive" cloning what occurs is the generation of a human embryo by cloning: the only difference is in how long that embryo is allowed to develop. In the former case it is for hours, days or weeks until it is used for deriving cells or other materials and destroyed; in the latter it is allowed to develop to term. There is no difference in the kind of cloning, only in what the scientist later does to the cloned human being.[71]

7.82 The Queensland Bioethics Centre saw an incongruity in allowing cloning for one purpose and not another:

> If it is intended to allow the being to be nurtured and grow into an adult, then it is a human being and to be protected. If someone intends to use the organism for some other purpose then it is either not human or not protected.[72]

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70 See Chapter 3, paragraphs 3.62- 3.64

71 Catholic Archdiocese of Melbourne, *Submissions*, p.S512. See also Youth Concerned with Cloning, *Submissions*, pp.S545-546 and Catholic Women's League of South Australia, *Submissions*, p.S571

72 Queensland Bioethics Centre, *Submissions*, p.S706

Potential benefits do not outweigh ethical concerns

7.83 Those who object to the use of somatic cell nuclear transfer for this purpose are usually aware of the potential benefits such research may bring but believe the achievement of such aims does not justify the creation and then destruction of embryos. The Catholic Archdiocese of Melbourne, for example, stated:

> In common with people of all religions and none it [the Archdiocese] is attracted by some of the potential therapeutic applications of this science but concerned that the research, development and application of these technologies not involve offences to human dignity or the compromise of fundamental ethical norms.[73]

7.84 The Council for Marriage and the Family also:

> …reject any proposal to permit the "therapeutic" cloning of human life, for purposes such as the creation of replicate organs notwithstanding the benefits that may arise from this practice.[74]

7.85 NSW Right to Life is:

> …opposed to the proposal that new individuals could be cloned by nuclear transfer from a pre-existing person who required transplantation of a renewable tissue, because of a disease such as leukemia, and that the new individual could then provide a source of tissue.
>
> This is treating a new human as a commodity like a drug or some other curative process and as such offends against the inherent right to life of the new human, ignoring his/her own individual personality…[75]

7.86 The Social Responsibilities Committee of the Anglican Diocese of Melbourne argued that:

> …if we agree that it is wrong to create cloned people, how can it be ethical to create a cloned embryo, knowing full well it must be

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73 Catholic Archdiocese of Melbourne, *Submissions*, p.S513

74 Council for Marriage and the Family, *Submissions*, p.S494. A large number of submissions argued that cures for diseases would be excellent but not at the cost of the destruction of human embryos or the conduct of research involving them. See submission numbers 24, 30, 33, 34, 58, 88, 146, 147, 148, 149, 153, 154, 158, 160, 161, 162, 163, 164, 166, 167, 168, 170, 171, 172, 173, 175, 178, 179, 186, 188, 189, 192, 193, 198, 199, 201, 207, 208, 216, 224, 250, 263, 264, 271, 272, 400

75 NSW Right to Life, *Submissions*, p.S499. See also Right of Life Australia, *Submissions*, p.S167 and Australian Federation of Right to Life Associations, *Submissions*, p.S322

> destroyed to avoid ever growing to become a human being? This appears to be an ethical negation of the previous position. …[76]

The health imperative

7.87 The opposite view was put by Professor Julian Savulescu:

> Every day people die because there are insufficient tissues available for transplantation. The development of cloning and embryonic stem cell line technologies offer real hope for developing better sources of tissues for transplantation …We have a moral duty to engage in this research.[77]

7.88 Professor Savulescu considered 'both ES cell and cloning technology hold great promise for providing abundant sources of self-compatible tissue…'[78] He argues that recent developments in science and ethics should call into question the 'special respect given to the early human embryo by Australian legislation and guidelines'.[79] In his view human beings do not exist until the structures are present which would support consciousness. This means that the foetus would not attain moral status before 26 weeks gestation.[80] He considers that we, as a society, need 'to revise our views about embryos. If we do not, we risk engaging in fetishism about cells, while real people die'.[81]

What next?

7.89 Another element of the concern at this application of cloning technologies was that to allow it would be to take a large step on the road towards the introduction of cloning for reproductive purposes. The AHEC report mentioned this concern:

> …acceptance of such a process raises the ethical issues often referred to as "slippery slope" issues (that is, that in the acceptance of research on human embryos in order to produce desired tissues and organs an irreversible step may be taken that will lead to scientific advances that in turn will make the cloning of human beings more likely to be accepted).[82]

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76 Social Responsibilities Committee, Anglican Diocese of Melbourne, *Submissions*, p.S306.

77 Professor Julian Savulescu, *Submissions*, p.S648

78 Professor Julian Savulescu, *Submissions*, p.S650

79 Professor Julian Savulescu, *Submissions*, p.S652

80 Professor Julian Savulescu, *Submissions*, pp.S654-655

81 Professor Julian Savulescu, *Submissions*, p.S655

82 AHEC report, Chapter 3, paragraph 3.17

7.90 This notion of the 'slippery slope' was also supported by Drs Fleming and Pike of the Southern Cross Bioethics Institute:[83]

> Even if "therapeutic cloning" was permitted and "reproductive cloning" banned, it is hard to imagine that once our IVF clinics and research facilities are replete with cloned embryos, someone will not try implantation and full pregnancy cloning. For those who consider allowing the birth of a cloned individual to be acceptable or even in some cases ethically demanded, this would be a small and relatively easy step to take.[84]

Embryonic Stem Cells Imported From Overseas

7.91 A further source of the material for research and applications involving cloning technologies is through its importation from overseas.

7.92 Embryonic stem cells have already been imported into Australia.[85] Professor Norman's view was that '…this is all regulated and is quite appropriate'.[86]

7.93 However, the inquiry did not receive much evidence canvassing this issue. Those who did refer to it regarded it as raising the same ethical issues as research material derived from any other source. Those who opposed research that involves the destruction of embryos also opposed the importation into Australia of any material derived in that way. Professor Savulescu agreed that 'if creating embryonic stem cells is immoral, then importing them is immoral. I happen to believe that creating them is moral and so is importing them'.[87]

7.94 The Association of Catholic Families submitted that:

> …the continued importing and exporting of the products of human cloning involves our country in a moral contradiction whereby we are participants in a process where we have "outsourced" those aspects over which we have some moral repugnance.[88]

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83 See also the argument of Lord Alton set out in the submission of the Festival of Light (SA) *Submissions,* pp.S334-335. See also Ms Rhonda Taylor, *Submissions,* p.S131 and Geoff Taylor, *Submissions,* p.S132 and Mr Barrie Burrow, *Submissions,* p.S134

84 Dr John Fleming and Dr Gregory Pike, Southern Cross Bioethics Institute, *Submissions,* p.S562. See also Dr Eloise Piercy, *Submissions,* p.S582

85 Professor Alan Trounson of the Monash Institute of Reproduction and Development has imported embryonic stem cells into Australia, *Transcript,* pp.4, 12

86 Professor Robert Norman, *Transcript,* p.82

87 Professor Julian Savulescu, *Transcript,* pp.115-116

88 Association of Catholic Families, *Submissions,* p.S221

7.95 The Billings Family Life Centre wanted to close 'loopholes' that 'permit the importing and exporting of embryos, embryonic stem cells and other products of cloning'.[89]

Resource Priorities

7.96 There were other issues raised including the impact of directing resources into this research on funding priorities for research generally and the impact of this research on perceptions of people with disabilities. The Consumers Health Forum submitted:

> …in an environment of limited resources, it is not only the absolute merit of particular projects which needs to be considered, but also their relative potential for promoting improved health outcomes for all Australians. …
>
> Research into the use of therapeutic cloning procedures is very much "state of the art" medical research. While this research has the potential to extend and improve many lives, it is important that it is not undertaken at the expense of lower technology (and significantly cheaper) research, simply *because* it is cutting edge—it is certainly no panacea for all the ills of the world.[90]

7.97 The National Caucus of Disability Consumer Organisations argued:

> …if we are not careful then claims by scientists for experimentation based upon the notion of therapy could inflict serious harm and have negative consequences on those society regards as having disability.[91]

7.98 The Committee regards these as important issues. However, its inquiry has been focused on what research should be permitted or prohibited in this area. Decisions as to the funding to be given to this research in the light of other research priorities will still have to be made.

89 Billings Family Life Centre, *Submissions*, p.S553. See also Youth Concerned with Cloning, *Submissions*, p.S547 and Mr Klaus Clapinski, *Submissions*, p.S765

90 Consumers Health Forum, *Submissions*, pp.S762-763

91 National Caucus of Disability Consumer Organisations, *Submissions*, p.S774

COMMITTEE VIEWS ON THE ETHICAL ISSUES RELATING TO RESEARCH INVOLVING STEM CELLS

Potential Benefit To Be Gained From Stem Cell Research

7.99 At the beginning of this chapter the Committee noted the primary issue in assessing the ethical considerations relevant to research using cloning technologies. This is: is there any benefit to be gained from the research into and the application of cloning technologies to human beings? The evidence indicates there is potentially significant benefit in the form of treatments of serious disease and illness.

7.100 The Committee agrees that that there is potential in this research for the cure of serious disease. It sees clear and unarguable benefits to individuals and an obvious benefit to society in the relief of suffering. However, the Committee reiterates its comment concerning the time frames in which some of the results may come about and cautions against expectations being raised too high.

7.101 The Committee accepts there may be benefits in the outcomes of the research and notes the issues arising in respect of the sources of research material. The issue becomes whether or not to use and destroy embryos in the conduct of research that seeks those benefits.

7.102 Some research uses adult stem cells but other research relies on human embryos, whether created as part of assisted reproductive technology programs (including IVF), or specially created by means of embryo splitting or somatic cell nuclear transfer. Because much cloning research at present involves the use of human embryos, the specific issue then becomes whether it is permissible to use and/or destroy human embryos in order to conduct the research and gain the benefits.

Opposition To Cloning For Reproductive Purposes Reiterated

7.103 All members of the Committee oppose cloning for reproductive purposes. This was outlined in Chapter 6. Cloning research directed towards the production of a whole human being must be banned. It should also be unlawful to implant any embryo used or created in the course of cloning research into the uterus of a woman.

Adult Stem Cells

7.104 All members of the Committee endorse the use of adult stem cells in research. The Committee's unanimous view is that research using adult stem cells should be encouraged and pursued since this source of material

for research is accepted by all, even those who oppose the use of embryos in research. The Committee urges those who can fund this research to encourage and support it and urges researchers to devote more serious attention to this research.

7.105 The use of adult stem cells and other related research removes a major ethical objection to non-reproductive cloning procedures. Chapter 3 outlined alternative research holding significant promise that does not involve the use of embryos. Such research includes the use of adult stem cells,[92] techniques involving adult neuronal stem cells[93] and partial or full reversal of differentiation of adult cells.[94] The Peter MacCallum Cancer Institute also provided evidence detailing the well-established stem cell based therapies that are already in routine clinical practice based on tissue or somatic stem cells.[95]

7.106 All members of the Committee also endorse the use of placental stem cells in research subject to appropriate consent.

The Derivation Of Embryonic Stem Cells From Embryos Surplus To Assisted Reproductive Technology Requirements

7.107 It is not surprising that the diversity of opinion in the community over the use of embryos in cloning research for the derivation of embryonic stem cells or any other purpose, as evidenced in submissions to the inquiry, is reflected among Committee members.

7.108 All members of the Committee agree that given the number of surplus embryos resulting from assisted reproductive technology, the specific creation of new embryos for research purposes is unnecessary.

7.109 The majority of the Committee (Ms Roxon, Mr Billson, Ms Bishop, Mr Griffin, Mr Kerr and Mr St Clair) would accept non-reproductive cloning research involving embryonic stem cells because of its potential for the treatment of serious disease. They believe that the use of existing embryonic stem cell lines to conduct research or to develop banks of cell lines for future therapeutic use should be permitted.

7.110 They also believe that it is permissible to derive additional embryonic stem cell lines from embryos that are surplus to assisted reproductive technology requirements, but only within clear and stringent guidelines (set out in detail in Chapter 12, particularly paragraphs 12.4 and 12.43).

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92 See Chapter 3, paragraphs 3.46-3.61

93 See Chapter 3, paragraph 3.57-3.59

94 See Chapter 3, paragraphs 3.65-3.69

95 Peter MacCallum Cancer Institute, *Submissions*, p.S891

7.111 The following reasons are cited in support of this view:

- the quest to treat and cure serious illness places a duty on us to support, or at least not prohibit, research with such enormous long term potential to relieve suffering. While strong views are held by some that the moral status of embryos renders it unethical to destroy them, in our pluralist society there are many views on this matter. One view of the status of the embryo should not be imposed on society as a whole especially when to do so may be to the detriment of those with serious or debilitating illness or disease. There is also a broader duty to society to be taken into account;
- research on embryonic stem cells in conjunction with research on adult stem cells will speed the prospect of gaining results that can be used in therapy;
- many scientists asserted that the potential benefits of research using cloning technologies may be delayed and important knowledge may not be gained if research on adult stem cells is all that is to be permitted;
- in addition to the great benefits if this research leads to such cures, many thousands of 'surplus' embryos already exist as part of assisted reproductive technology programs. If these embryos are not used in research or donated to other couples they will be destroyed once statutory or other periods of storage are concluded. The current regime makes it difficult for couples to donate surplus embryos for this research. Provided that proper consent is obtained and safeguards are in place, it is much better that such surplus embryos be used in research or potential therapy for some greater good than simply be destroyed;
- the potential benefit to individuals and society from research involving the use of embryonic stem cell lines and stem cell banks is a significant imperative in permitting this research. Society owes responsibilities to people suffering from diabetes, Parkinson's disease, Alzheimer's disease and other debilitating illnesses which weigh against embryos (at the earliest stages of their development) being granted absolute protection from destruction, especially if surplus embryos are to be destroyed in any case;
- the argument that there are sufficient embryonic stem cell lines in existence was not fully tested and there remains some uncertainty over questions of intellectual property, control and the conditions of distribution of such existing lines. It is, therefore, likely that researchers may wish to derive further embryonic stem cell lines from embryos, but this is likely to involve only a very small number of embryos.

7.112 Some members (Mr Andrews, Mr Cadman, Mr Murphy and Mrs Vale) believe that research and therapy involving the destruction of human embryos should be prohibited.

7.113 They noted the evidence from Professor Trounson and Mr Klupacs that existing stem cell lines are sufficient for both research and the development of stem cell banks. Professor Trounson asserted there is no need to use any more embryos to create embryonic stem cells.[96] This was supported by Mr Robert Klupacs, the General Manager and CEO of ES Cell International Pte Ltd:

> We have now grown six cell lines within our research laboratories. The commercial reality is that it is very unlikely we will ever have to go back to another embryo source again to grow a new line… Our position is that we do not think we will ever have to go back to derive another embryonic stem cell line.[97]

These members note that this position was recently adopted by President Bush in the United States.[98]

> [The existing stem cell lines] were created from embryos that have already been destroyed, and they have the ability to regenerate themselves indefinitely, creating ongoing opportunities for research. …
>
> that could lead to breakthrough therapies and cures. This 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.
>
> I also believe that great scientific progress can be made through aggressive federal funding of research on umbilical cord placenta, adult and animal stem cells which do not involve the same moral dilemma.[99]

7.114 The following additional reasons are cited by these members:

- given the alternatives to the use of embryos in research outlined above especially the developments involving adult stem cells, it does not appear necessary to use embryos and the most appropriate ethical

96 Professor Alan Trounson, *Transcript*, p.4

97 Mr Robert Klupacs, *Transcript*, p.170

98 See Chapter 10, paragraph 10.72

99 Office of the Press Secretary, The White House, 'Remarks by the President on Stem Cell Research, 9 August 2001, http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html

conduct would be to focus research on those areas that do not involve the use of embryos;

- the potential benefits of the research must be balanced against the actual harm. As social philosopher Jean Bethke Elshtain of the University of Chicago told the US Congressional hearings:

  > The path down which we are headed unless we intervene now to stop human cloning is one that will deliver harm in abundance — and harm that can be stated clearly and decisively now—whereas any potential benefits are highly speculative and likely to be achievable through less drastic and damaging methods, in any case. The harms, in other words, are known—not a matter of speculation—whereas the hypothesised benefits are a matter of conjecture, in some cases rather far-fetched conjecture.[100]

- the potential benefits remain speculative. A decade ago, fetal tissue therapy was hailed as the future hope for overcoming disease, but progress has been as yet relatively unsuccessful. Cell transplantation faces considerable obstacles, not the least of which is the fact that the disease process of many conditions such as Alzheimer's disease remains unknown. By contrast, adult stem cells have the advantages of being compatible with the patient, involve the re-activation of existing cells in the body, and do not involve the destruction of embryos. Further, the acceptance of destructive embryo research opens the door to experimental testing of pharmaceutical products.

7.115 These members of the Committee also have concerns about the continued use of embryonic stem cells that have been derived from embryos, whether in Australia or overseas. (See paragraph 7.124 below).

The Use Of Embryos Specifically Created For Research Or Therapy

7.116 While the use of embryos that are surplus to assisted reproductive technology requirements may be seen to provide some public good, particularly when they would be destroyed in any case, the deliberate creation of embryos for research purposes is seen as unnecessary at the present time.

7.117 Additional questions arise if embryonic stem cell lines are derived from embryos created by somatic cell nuclear transfer. Although these embryos do not involve fertilisation of the egg by sperm, they are generally referred to as embryos by scientists and they are thought to be able to develop like other embryos.

100 19 June 2001 Legislative Hearing on 'Human Cloning'. http://genomics.phrma.org/cloning.html

7.118 Embryonic stem cell lines created via somatic cell nuclear transfer may be sought to be created in the future so as to provide compatible cell lines to treat disease or disability in a particular individual. This type of therapy is still some way off. In the meantime scientists may wish to create embryos through somatic cell nuclear transfer and then derive embryonic stem cell lines for a variety of research purposes. Such purposes could include to: improve the somatic cell nuclear transfer technique and render it safer; advance the use and understanding of adult stem cells; compare embryonic stem cell lines from embryos created by somatic cell nuclear transfer with those from naturally created or assisted reproductive technology embryos; or to research the use of such stem cell lines in individual therapy.

7.119 The Committee believes there should be a three year moratorium on the creation and use of embryos created by somatic cell nuclear transfer, after which the issue can be re-examined by the AHEC.[101] The reasons for this vary between members, but they include:

- to date, embryonic stem cells have been obtained from spare embryos. There is currently no need to undertake somatic cell nuclear transfer to obtain embryonic stem cells. Any use of the technique to treat individuals remains at best speculative. Moreover, the weight of scientific evidence suggests that this method of obtaining stem cells is likely to be impractical;
- both somatic cell nuclear transfer followed by implantation, gestation and birth (so-called 'reproductive cloning') and somatic cell nuclear transfer which does not proceed to implantation, gestation and birth (so-called 'therapeutic cloning') involve the creation of an embryo. In so-called 'therapeutic cloning' the resulting embryo is then destroyed in the process of deriving stem cells. For some, the prohibition of the former, and the permission of the latter is arbitrary; and
- human embryos created by somatic cell nuclear transfer for research purposes have no parents as such. They belong to no couple trying to have a child. At best they may have a tissue donor and possibly an egg donor and, as recent reports have shown, the latter might be an animal. The tissue donor might not even be identifiable and may even be long dead. There is an immediate problem in these circumstances because the ethical and legal requirements in relation to consent to the use of the embryos cannot be met. Questions then arise: do the cloned embryos belong to the laboratory or the scientist that makes them? They are property, rather than the subjects of guardianship.

101 See Chapter 12, paragraph 12.42

Importation Of Embryonic Stem Cells

7.120 Another source of embryonic stem cell lines would be through importation, either by importing the embryos from which to derive them or importing the stem cell lines.[102] All members of the Committee consider views on this matter must logically follow those outlined above. It would not be tenable to ban the use of embryos other than in accordance with strict guidelines in Australia and allow the evasion of the consequences of such a ban by importing such material from overseas.

7.121 Most members would allow the importation of embryonic stem cells so long as the derivation of the embryonic stem cell lines has complied with the Australian regulatory framework. The use of such embryonic stem cell lines in Australia should also be subject to the regulatory parameters outlined in Chapter 12.

Parameters For Research

7.122 The majority of the Committee considers non-reproductive cloning research involving the use of embryos and embryonic stem cells is acceptable because of its potential for the treatment of serious disease. However, these members believe that because any use of embryos for research purposes will be contentious, the public is entitled to know that clear parameters have been set for such research. An appropriate regulatory model is vital.

7.123 The Committee recognises that its report is advisory, and that regulatory decisions will be made finally by Commonwealth, State and Territory governments.[103] There are several possible outcomes of this process:

1. that it be permissible to produce human embryos by somatic cell nuclear transfer in order to obtain embryonic stem cells for research purposes provided they are destroyed before they pass the stage of the formation of a blastocyst;

2. that research involving embryonic stem cells be permitted and, in defined limited circumstances, research on embryos surplus to assisted reproductive technology programs, but otherwise the creation of human embryos for research be prohibited. (This position is supported by Ms Roxon, Mr Billson, Ms Bishop, Mr Griffin, Mr Kerr, and Mr St Clair);

3. that existing human embryonic stem cell lines be permitted to be used, but all further destructive experimentation on human embryos be

102 See Chapter 12, paragraph 12.4

103 Council of Australian Governments (COAG) Meeting, *Communique*, 8 June 2001

prohibited. (This is the position adopted by Mr Andrews, Mr Cadman, Mr Murphy and Mrs Vale, provided it is the case that human embryonic stem cell lines are not totipotent. If that proved to be so, then they would hold the following position);

4. that all destructive experimentation on human embryos and the use of stem cell lines be prohibited.

7.124 Consequently, if the Commonwealth, States and / or Territories permit some use of embryos and their destruction in order to obtain embryonic stem cells for research purposes, then all members of the Committee recommend that the research involving the use of embryos or embryonic stem cell lines should be carried out within the following parameters. This summary is dealt with in more detail in Chapter 12.

- there should be a complete ban on asexual reproduction and the creation of embryos specifically for the purposes of research;[104]
- there should be a three year moratorium on asexual reproduction involving an embryo;[105]
- the creation of new embryonic stem cell lines should be allowed within the parameters set out below, but only if the existing supply is inadequate, unsuitable or unavailable for such research;
- the use of embryos that are surplus to assisted reproductive technology programs in embryonic stem cell research should be permitted in limited circumstances, such as that:
  - ⇒ each such use follows full and informed consent of the parents of the embryo and / or the donors of the gametes;
  - ⇒ there should be no commercial incentive to the donor;
  - ⇒ the minimum number of embryos possible should be used;
  - ⇒ cross-species research must not be involved;
  - ⇒ an application be made on a case by case basis to a regulatory body;
  - ⇒ the criteria for approval include a requirement that the information sought through the research can not reasonably be achieved by means other than through the use of an embryo.[106]

7.125 This structure reflects the AHEC position, namely:

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104 The term ‘asexual reproduction’ in this context refers particularly to cloning for reproductive purposes. The Committee emphasises that this does not include reproduction by means of existing assisted reproductive technologies

105 This refers to the creation of embryos by means of, for example, somatic cell nuclear transfer

106 See Chapter 12, paragraph 12.43

- (a) that some procedures should be prohibited including the production of human embryos other than for use to treat infertility through an assisted reproductive technology procedure (section 11.1 of the National Health and Medical Research Council *Ethical Guidelines on Assisted Reproductive Technology* (1996)); and
- (b) that destructive research on spare embryos in assisted reproductive technology programs should be exceptional and severely constrained (guideline 6 of the National Health and Medical Research Council *Ethical Guidelines on Assisted Reproductive Technology* (1996)—and endorsed in the 1998 advice on human cloning to the Minister).