The Parliament of the Commonwealth of Australia

Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research

House of Representatives
Standing Committee on Legal and Constitutional Affairs

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Contents

Foreword

In February 1997, the world awoke to the news that seven months earlier scientists in Edinburgh, Scotland had created a sheep known as 'Dolly' by the technique of somatic cell nuclear transfer, commonly referred to as cloning. The news of Dolly's birth generated vast publicity, including suggestions that humans might also be replicated in a similar manner.

A year later, scientists in the US state of Wisconsin isolated stem cells from 14 embryos surplus to an IVF program. Grown in a special culture, these cells have demonstrated the capacity to develop into a wide range of specialised cell lines, raising the possibility that many diseases and disabilities might be cured in the future.

Elsewhere, scientists have discovered adult stem cells, and heralded the use of these cells for the repair of human disease.

In many nations, legislators and ethicists have been struggling for an appropriate response to these developments.

The Australian House of Representatives Legal and Constitutional Affairs Committee was asked in 1999 to review the report of the Australian Health Ethics Committee on Human Cloning. It has been examining the many complex issues surrounding human cloning and stem cell research for the past two years.

During this time the Committee has heard from many people. Scientists have shared their excitement about the discovery of techniques that could open future possibilities of cures for life threatening conditions. Families of people with disabilities have welcomed the prospect that some day relatives with Parkinson's or Alzheimer's disease might be restored to health. Yet researchers have cautioned also that such treatments remain speculative, and warned against raising hopes prematurely. In the case of Alzheimer's, the disease process has not even been identified.

At the same time many ethicists have gently, but firmly reminded us that where this research involves human embryos, the harvesting of embryonic stem cells for continued experimentation involves the destruction of the embryo.

Lawyers and regulators have indicated that three states (New South Wales, Queensland and Tasmania) and the territories have failed to properly regulate or legislate in this area, despite repeated urgings from the Australian Health Ethics Committee, and that the legislation elsewhere may not adequately cover new developments.

And many people have written urging a ban on human cloning.

CENTRAL QUESTIONS

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

These questions involve consideration of respect for human life, the appropriate limits of science, and the need for transparency and accountability in any system of regulation.

There is also a need for clear language in our public discussions. Expressions like 'therapeutic' and 'reproductive' cloning can be misleading and disguise the actual techniques involved. Even the expression 'cloning' includes a wide range of techniques that attract different ethical considerations. We have attempted in this report to clearly describe what is involved in the research.

CLONING FOR REPRODUCTIVE PURPOSES

Almost universal opposition was expressed to the Committee about the use of cloning techniques for the purpose of creating, implanting and bringing to birth a human being— a human 'Dolly'.

The clear evidence is that it would be unsafe, remembering that 'Dolly' was produced only after 276 attempts, many of which resulted in miscarriages, deformities, and still births. More importantly, the notion of 'photocopying' a human being is contrary to human dignity, confuses family and personal relationships and offends many of the deepest understandings of our unique identity and individuality.

The Committee concludes that there should be a national legislative ban on cloning for reproductive purposes.

THE USE OF ADULT STEM CELLS

Conversely, there was universal support for cloning techniques involving adult stem cells. Research in Australia and elsewhere has isolated stem cells in adult tissue. There is a growing appreciation that these cells may provide the key to future advances in medicine without the ethical problems associated with embryonic stem cells.

The Committee supports continued research involving adult and placental stem cells and encourages funding and resources for this work.

THE USE OF EMBRYONIC STEM CELLS

Great contention surrounds the use and destruction of embryos for the purposes of obtaining stem cells. Sincerely held arguments were presented to us both in favour of and against permitting these procedures.

A number of possible outcomes open to Australian governments were considered by the Committee:

- all destructive experimentation on human embryos and the use of embryonic stem cell lines could be prohibited;
- existing human embryonic stem cell lines could be permitted to be used, but all further destructive experimentation prohibited;
- research on embryos surplus to assisted reproductive technology programs, (which destroys these embryos) could be permitted in defined limited circumstances but otherwise the creation of human embryos for research be prohibited;
- human embryos produced by somatic cell nuclear transfer be permitted in order to obtain embryonic stem cells for research provided they are destroyed before they pass the stage of formation of a blastocyst;
- the creation of human embryos could be permitted for any destructive experimentation.

It is not surprising that the diversity of opinion in the community over the use of embryos in cloning research for the derivation of stem cells is reflected among Committee members.

All Committee members call for a ban on the deliberate creation of embryos for experimentation. They also support a moratorium on the creation of embryos by means of somatic cell nuclear transfer techniques for three years at which point the issue can be re-examined.

For reasons set out in the report, six members of the Committee support research, in defined limited circumstances, on embryos surplus to assisted reproductive technology programs. They also support research on existing stem cell lines and any stem cell lines newly created from surplus embryos within the defined parameters.

Four other members would restrict research to existing human embryonic stem cell lines, provided these stem cells cannot develop into an embryo. If these stem cells could develop into embryos, they would want a prohibition on all destructive experimentation on embryos, including the continued use of existing embryonic stem cell lines.

A SYSTEM OF REGULATION

All members recognise, however, that the final decision about cloning in Australia will be made by Commonwealth, State and Territory Parliaments. If Australian Governments and Parliaments decide to permit human cloning involving stem cells derived from embryos surplus to assisted reproductive technology programs, all Committee members agree upon a system of regulation outlined in the report.

This regulatory framework includes the following features:

- a national uniform legislative approach;
- a ban on cloning for producing children;
- one system of regulation for privately and publicly funded research;
- legislation regulating human cloning and stem cell research separate from that governing artificial reproductive technologies;
- any attempt to undertake reproductive cloning subject to criminal penalty and the withdrawal of a licence to undertake research in this area;
- research using cloning techniques subject to clear legislative parameters, including (subject to a moratorium on somatic cell nuclear transfer) a complete ban on the deliberate creation of embryos for research purposes;
- a national licensing body established to regulate human cloning and research using cloning techniques;
- individual researchers licensed for each research project that involves the use of an embryo;

- the import and export of embryonic stem cells permitted within the framework of principles outlined in the report, but a ban on the import and export of embryos; and
- a regulatory framework that is transparent, accountable and responsive.

The Committee proposes that the role of the Australian Health Ethics Committee be enhanced to consult and involve the public in consideration of ongoing issues raised by human cloning and stem cell research. We also propose an independent review of the Institutional Ethics Committee system in Australia.

CONCLUSION

These are not matters to be decided behind closed doors by scientists or lawyers, however expert and sincere, without widespread community consultation. Nor are they matters that can be resolved by doing nothing.

As a society we are confronted with profound issues that require ongoing attention and discussion.

We believe this report contributes to this end.

Kevin Andrews MP
Chair

Membership of the Committee

Chair	Mr Kevin Andrews MP	
Deputy Chair	Ms Nicola Roxon MP	
Members	Mr Bruce Billson MP (from 17/02/2000)	Hon Michael Ronaldson MP (until 17/02/2000)
	Ms Julie Bishop MP	
	Hon Alan Cadman MP	
	Hon Duncan Kerr MP	
	Mr Alan Griffin MP (from 31/08/2000)	Ms Kirsten Livermore MP (until 31/08/2000)
	Mr John Murphy MP (from 01/09/1999)	Mr Frank Mossfield MP (until 01/09/99)
	Mr Stuart St Clair MP	
	Mrs Danna Vale MP	

Committee Secretariat

Secretary	Claressa Surtees (until February 2000)
Acting Secretary	Catherine Cornish (from February 2000)
Inquiry Secretary	Deborah Nance (from July 2000) Marie Kawaja (until July 2000)
Research Officer	Deborah Nance (from January 2000) Dr Barbara Eckersley (from March 2001)
Scientific Adviser	Professor John Hearn
Administrative Officer	Frances Wilson

Terms of reference

On 10 August 1999, the Minister for Health, the Hon Dr Michael Wooldridge MP, asked the House of Representatives Standing Committee on Legal and Constitutional Affairs to review the report of the Australian Health Ethics Committee of the National Health and Medical Research Council, *Scientific, Ethical and Regulatory Considerations relevant to Cloning of Human Beings* (16 December 1998).

List of abbreviations

AAS	Australian Academy of Science
AHEC	Australian Health Ethics Committee
AQIS	Australian Quarantine and Inspection Service
ARC	Australian Research Council
CEO	Chief Executive Officer
COAG	Council of Australian Governments
ES Cells	Embryonic Stem Cells
FDA	Food and Drug Administration
GIFT	Gamete Intra-Fallopian Transfer
HFEA	Human Fertilisation and Embryology Authority
HGAC	Human Genetics Advisory Commission
IEC	Institutional Ethics Committee
IP	Intellectual property
IPP	Information Privacy Principles
IVF	*In vitro* fertilisation
NBAC	National Bioethics Advisory Commission

NHMRC	National Health and Medical Research Council
NIH	National Institutes of Health
NRC	National Regulatory Committee
RTAC	Reproductive Technology Accreditation Committee
UNESCO	United Nations Educational, Scientific and Cultural Organisation

List of recommendations

Proposed regulation of human cloning

Recommendation 1

The Committee recommends the enactment of legislation by the Commonwealth to regulate human cloning and stem cell research.

Recommendation 2

The Committee recommends that legislation regulating human cloning and stem cell research cover all research in this area, both publicly and privately funded.

Recommendation 3

The Committee recommends that the regulation of research involving the use of cloning technologies should be separate from that governing assisted reproductive technologies.

Recommendation 4

The Committee recommends that the legislation regulating human cloning and stem cell research contain a ban on cloning for reproductive purposes. Any attempt to undertake cloning for reproductive purposes should result in a criminal penalty and the withdrawal of a licence to undertake research in this area for the individual concerned.

Recommendation 5

The Committee recommends that the Commonwealth regulate human cloning and stem cell research within the strict parameters outlined in paragraphs 12.41-12.43.

Recommendation 6

The Committee recommends that a national licensing body be established to regulate any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 7

The Committee recommends that a licence issued by the national licensing body should be required to undertake any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 8

The Committee recommends that the national licensing body have the responsibilities listed in paragraph 12.55.

Recommendation 9

The Committee recommends that the Australian Health Ethics Committee (AHEC) be responsible for monitoring scientific developments in this area, analysing their potential impact and providing advice to Commonwealth, State and Territory governments on these matters.

Recommendation 10

The Committee recommends that individuals and organisations be licensed for each research activity involving the isolation, creation and use of embryonic stem cells they intend to undertake.

Recommendation 11

The Committee recommends that the matters listed in paragraph 12.63 be prohibited. Such a prohibition would mean that the licensing body would not have the authority to issue a licence for research involving any of the items listed in paragraph 12.63.

Recommendation 12

The Committee recommends that research using cloning technologies and involving the use of embryos may only be undertaken pursuant to a licence.

Recommendation 13

The Committee recommends that a licence for research using cloning technologies and involving the use of embryos only be granted if the licensing body is satisfied of the matters listed in paragraph 12.43 and that informed consent has been granted by all relevant persons.

Recommendation 14

The Committee recommends that the licensing body develop detailed guidelines specifying the requirements for informed consent and take into account the matters discussed in paragraphs 12.69-12.77 in developing these guidelines.

Recommendation 15

The Committee recommends that the Government establish an independent review of the institutional ethics committee system in Australia.

Recommendation 16

The Committee recommends that all Commonwealth Departments refer to the licensing body for guidance where a matter arises that involves the use of human reproductive material, embryonic stem cell research or cloning research.

Executive summary

INTRODUCTION

E1 The terms of reference for the inquiry were for the House of Representatives Standing Committee on Legal and Constitutional Affairs (the Committee) to review the report of the Australian Health Ethics Committee (AHEC) entitled *Scientific, Ethical and Regulatory Considerations Relevant to cloning of Human Beings.* The report was presented on 16 December 1998. The Committee considered the AHEC report and its recommendations carefully and found that it provided a thorough scientific review of developments prior to its completion and a useful summary of the ethical issues as they were perceived at the time.

E2 Since AHEC reported a great deal of scientific progress has been made. The Committee outlines this progress and has built on AHEC's report in developing its own recommendations. It hopes that this report will inform the public and contribute to development of the community debate on these issues. The Committee recommends a regulatory mechanism within which the research can progress in an appropriate way.

SCIENTIFIC ISSUES

E3 Chapters 2, 3 and 4 summarise the scientific principles, processes and issues related to cloning and stem cell technologies. Chapter 2 provides an outline of human reproductive processes and assisted reproductive technologies, and the research techniques relevant to the cloning of human tissues, organs or whole individuals. The AHEC report defines cloning as 'asexual propagation without altering the nuclear genome' and distinguishes between procedures for the cloning of a whole human being and the copying of the component parts of a human (such as DNA and cells). The Academy of Science developed the following definitions which recognise the different purposes for cloning and distinguish between the cloning of a whole human individual and cloning of cells and tissues:

- the production of a cell or organism with the same nuclear genome as another cell or organism;

- reproductive cloning: to produce a human foetus by nuclear replacement
- therapeutic cloning: to produce human stem cells, tissues and organs.

E4 The Committee acknowledges that the existing definitions of cloning are confusing and notes that cloning does not necessarily mean the replication of a whole individual. Many natural clones exist in the plant and animal kingdoms, including identical twins in humans. Cloning techniques may be used to duplicate DNA, cells, organs or whole individuals.

E5 The principal research techniques described are somatic cell nuclear transfer, the procedure that resulted in the birth of Dolly; the derivation of embryonic stem cells and embryonic germ cells; and current developments with adult stem cells. Somatic cell nuclear transfer involves the fusion (using an electric pulse) of a somatic cell from an 'adult' (foetal, juvenile or adult) animal with an unfertilised enucleated egg. The resulting 'embryo' is transferred to the uterus of a surrogate mother for development. The failure rate of this technique is currently very high.

E6 Embryonic stem cells are removed from the inner cell mass of a 6-7 day old embryo (blastocyst). They can replicate in culture indefinitely and can differentiate into a wide range of specialised cells.

E7 Adult stem cells, found in organs and tissues of the body throughout life, are difficult to identify, isolate and grow in culture. They are thought to be less flexible than embryonic stem cells, capable of differentiating into a more restricted range of specialised cells. An attraction of adult stem cells is that their isolation does not involve the destruction of an embryo.

E8 Brief reference is made to other technologies such as embryo splitting, cross species cell transfer and ooplasmic transfer. In considering the advantages and challenges of these procedures, the Committee noted the rapid pace of research in cell and developmental biology that will produce greater understanding and an appreciation of potential applications in the next few years. The Committee proposes that the field be monitored closely as new discoveries may have repercussions on the related ethical and regulatory dimensions.

Scientific conclusions by Australian Health Ethics Committee

E9 Chapter 3 presents the scientific conclusions from the AHEC report, and the recommendations of the Australian Academy of Science resulting from a review of the status and future directions of cloning and stem cell technologies. This chapter reports the evidence presented to the Committee on the scientific aspects of cloning for reproductive purposes and cloning for therapeutic purposes. The Committee notes that Australian scientists do not approve of the use of cloning

technologies to create a whole human being or wish to be involved in such work. The evidence presented raised concerns about the current high failure rate and risks of abnormalities caused by present reproductive cloning techniques.

E10 Scientists and members of the general public presenting evidence recognised the potential importance of 'therapeutic cloning' to medicine including the supply of tissue for transplantation, research into early human development and the discovery of factors which direct cell differentiation and tissue regeneration. However, a more cautious view expressed by some of the researchers in the field is that therapeutic cloning may prove too inefficient and expensive to become a routine clinical procedure. The potential applications of embryonic and adult stem cell research are considered, together with those of the cell signals that influence cell lineage development, currently the focus of much research.

E11 Evidence on the relative advantages and disadvantages of embryonic and adult stem cells is considered and it is noted that for the moment, embryos are required for the derivation of embryonic stem cells. Many scientists both in Australia and internationally dispute the assertion that adult stem cells will soon replace embryonic stem cells in their importance for basic or applied research, and believe that for the foreseeable future the study of embryonic stem cells derived from embryos is crucial to progress.

E12 Transdifferentiation or dedifferentiation of somatic cells is a fast emerging priority for research, as understanding cell flexibility may hold the potential for more specifically designed therapies for individual persons and diseases, while avoiding the need for embryos.

International and Australian scientific research

E13 Chapter 4 provides a few examples of the research being conducted in the United Kingdom, America and elsewhere. It notes the evidence from Australian scientists on Australia's international standing in the field and gives some examples of current Australian research. It looks briefly at funding of stem cell research in Australia and the predicted timeframes for results. Although it is difficult to predict, a 5–10 year projection for clinical trials of therapies was made by some of the scientists involved. The intellectual property and potential commercial applications from the field could hold significant advantage for Australia.

E14 The AHEC report suggested that existing non-human primate research facilities in Australia might be expanded, or a facility for developmental biology or embryology might be established. The Committee considered evidence presented on the need for basic research, including that on primates. While the Committee supports the need for more basic research including that in animals, it does not

support the establishment of a separate primate facility in Australia for cloning and stem cell research. Current priorities are to focus on human cell differentiation.

E15 In supporting the need for research towards new cell therapies, the Committee also notes the concern expressed in some submissions that 'state of the art' research such as therapeutic cloning should not diminish the importance of less expensive, lower technology research that may also deliver results.

ETHICAL ISSUES

E16 Chapters 5, 6 and 7 discuss the ethical issues raised by human cloning and related research. Chapter 5 provides an introduction by outlining, and commenting on, the discussion of ethical issues in the AHEC report.

E17 Chapter 6 considers the issue of 'reproductive cloning', that is, the use of cloning techniques for reproductive purposes in order to produce a whole human being. There has been almost total condemnation of the proposition that a whole human being might be replicated. The Committee agrees and totally rejects the use of cloning techniques for reproductive purposes, that is, to produce a child. The Committee believes that cloning for reproductive purposes is unacceptable. While the Committee holds this view unanimously, individual members reached this conclusion for a variety of reasons encompassing ethical, medical, legal and/or social considerations. The Committee emphasises that its conclusions are equally applicable to the use of any future technologies for the purpose of the artificial creation of whole human beings.

E18 The use of cloning technology for the purpose of the implantation, gestation and birth of a whole human being is not the only aspect of cloning related research that aroused passionate interest and comment during the inquiry. Ethical issues have also arisen in relation to more general research involving cloning techniques and the possible application of these techniques to treat illness. Chapter 7 considers the ethical issues in relation to the use of stem cells (including embryonic stem cells) and embryos in research. 'Embryos' in this context may include embryos that are surplus to assisted reproductive technology programs and embryos created by somatic cell nuclear transfer techniques.

E19 Chapter 7 considers the key issue of whether there are benefits to be obtained from applying cloning techniques to human beings. Having concluded that there are potential benefits to be gained, the Committee considers whether research involving the use of stem cells, embryos and cloning technologies should be permitted in order to realise those potential benefits and, if so, within what parameters. Members of the Committee hold different views on some of these matters but agreed on the parameters within which research involving the use of

embryonic stem cells and embryos surplus to assisted reproductive technology programs should be permitted.

REGULATORY ISSUES

E20 Regulatory issues relevant to human cloning and its related research are discussed in Chapters 8-12. Chapters 8 and 9 provide an outline of the legislative and non-legislative framework that currently regulates human cloning and research involving embryos in Australia. As a result of its review of this framework the Committee considers the current regulatory framework governing these matters is unsatisfactory and outdated. In addition to legislative regulation in three States there is a system of self-regulation coupled with non-legislative national guidelines applied by individual institutional ethics committees. The system is complicated, confused, inconsistent and ad hoc. It is difficult for the public to understand and lacking in transparency and accountability. One of the greatest inadequacies of the current regulatory framework is its differing application to the public and private sectors in many States and Territories. This does not assist researchers, businesses, investors or citizens who must try to navigate their way through this intricate array of regulatory arrangements. It is also unfair that such different regulations apply to citizens living in different States and Territories.

E21 The Committee asserts that consistent regulation must be applied to both publicly and privately funded research and that the current regulatory framework should not continue. The questions raised by human cloning and research involving the use of embryos are social questions and should not be left to ethics committees to decide. Nor should the answer to such fundamental questions depend on geography or source of funding. It is vital to ensure public knowledge of, and confidence in, the regulatory processes in place.

E22 A number of inquiries and consultation exercises have been conducted in various countries addressing the potential benefits and difficulties posed by human cloning and its related research and assessing the potential ethical and regulatory implications of the research. Some recent initiatives in the regulation of human cloning and research involving the use of embryos in the international sphere are outlined in Chapter 10. It has not been possible to outline comprehensively all international developments. Multilateral instruments developed by the Council of Europe and the United Nations Educational, Scientific and Cultural Organisation (UNESCO) are canvassed as well as recent significant regulatory developments in the United States of America and the United Kingdom. Several factors emerged relevant to Australia's consideration of the issues arising from human cloning and related research emerged as a result of this overview. These included the consistent condemnation of cloning for

reproductive purposes, the attempts to balance the harnessing of the potential of stem cell research with the protection of the human embryo, and the problems created by distinguishing between publicly and privately funded research for the purposes of regulation.

E23 In Chapter 11 the Committee responds to the recommendations made by AHEC and considers options for the regulation of human cloning and its related research. Chapter 12 outlines the Committee's proposed framework to regulate human cloning and related research in Australia. This report is advisory; if Australian governments and parliaments decide to regulate human cloning involving stem cells derived from embryos surplus to assisted reproductive technology programs, all Committee members agree on the proposed system of regulation outlined in Chapter 12 of the report. Those members who believe the use of embryos in research is unethical agree that if such research is permitted that it be undertaken within clear parameters. In summary, the Committee's proposed regulatory framework would have the following features:

- a national uniform legislative approach;
- a ban on cloning for reproductive purposes;
- one system of regulation for privately and publicly funded research**;**
- legislation regulating human cloning and stem cell research to be separate from that governing artificial reproductive technologies (ART);
- any attempt to undertake cloning for reproductive purposes to be subject to criminal penalty and the withdrawal of a licence to undertake research in this area;
- research using cloning techniques be subject to clear legislative parameters, including (subject to the moratorium referred to in paragraph 12.42) a complete ban on the deliberate creation of embryos for research purposes;
- a national licensing body be established to regulate human cloning and research using cloning techniques;
- individual researchers to be licensed for each research project that involves the use of an embryo;
- the import and export of embryonic stem cells should be permitted within the framework of principles outlined in this report, that is, it should be permissible to import or export embryonic stem cell lines that are already in existence or have been created using embryos that are surplus to the requirements of assisted reproductive technology programs. The import or export of embryos for the purposes of cloning related research need not

occur. As there is no evidence to suggest that this is required, the Committee is not convinced that it is appropriate or necessary; and

- the regulatory framework must be transparent, accountable and responsive.

E24 The legislation should permit the licensing body to issue a licence for a person to use a surplus embryo from an assisted reproductive technology program for research or therapy that damages or destroys the embryo where that project has the approval of both an institutional ethics committee (IEC) established, composed and conducted in accordance with NHMRC guidelines and the national licensing body proposed in this report, and that the approval is given on the 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 IEC and the national licensing body (as is the case with animal research);
- all tissue and gamete providers involved and their spouses or domestic partners, if any, have consented to the specific form of research for each embryo used;
- no animal tissue or animal gametes are used to form a human-animal hybrid embryo;
- no embryo that has been the subject of cloning technology, or produced other than by fertilisation of a human ovum by a human sperm is ever transferred to the body of a woman or otherwise allowed to survive beyond the stage at which a blastocyst forms or the age by which a blastocyst would normally have formed;
- no human embryo is ever allowed to be transferred to the body of an animal or to be artificially gestated;
- no attempt is made to form embryos using stem cells or stem cell cultures; and
- a licence has been granted for the use of the embryo.

SUMMARY OF RECOMMENDATIONS

If Australian governments and parliaments decide to regulate human cloning involving existing stem cell lines derived from embryos surplus to assisted reproductive technology programs, all Committee members agree on the

proposed system of regulation outlined in Chapter 12. Those members of the Committee who believe the use of embryos in research is unethical agree, however, that if such research is permitted it should be undertaken within clear parameters.

Recommendation 1: the enactment of legislation by the Commonwealth to regulate human cloning and stem cell research.

Recommendation 2: that legislation regulating human cloning and stem cell research cover all research in this area, both publicly and privately funded.

Recommendation 3: that the regulation of research involving the use of cloning technology should be separate from that governing assisted reproductive technologies.

Recommendation 4: that the legislation regulating human cloning and stem cell research contain a ban on cloning for reproductive purposes. Any attempt to undertake cloning for reproductive purposes should result in a criminal penalty and the withdrawal of a licence to undertake research in this area for the individual concerned.

Recommendation 5: that the Commonwealth regulate human cloning and stem cell research within the strict parameters outlined in paragraphs 12.41-12.43.

Recommendation 6: that a national licensing body be established to regulate any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 7: that a licence issued by the national licensing body should be required to undertake any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 8: that the national licensing body have the responsibilities listed in paragraph 12.55.

Recommendation 9: that AHEC be responsible for monitoring scientific developments in this area, analysing their potential impact and providing advice to Commonwealth, State and Territory governments on these matters.

Recommendation 10: that individuals and organisations be licensed for each research activity involving the isolation, creation and use of embryonic stem cells they intend to undertake.

Recommendation 11: that the matters listed in paragraph 12.63 be prohibited. Such a prohibition would mean that the licensing body would not have the authority to issue a licence for research involving any of the items listed in paragraph 12.63.

Recommendation 12: that research using cloning technologies and involving the use of embryos may only be undertaken pursuant to a licence.

Recommendation 13: that a licence for research using cloning technologies and involving the use of embryos only be granted if the licensing body is satisfied of the matters listed in paragraph 12.43 and that informed consent has been granted by all relevant persons.

Recommendation 14: that the licensing body develop detailed guidelines specifying the requirements for informed consent and take into account the matters discussed in paragraphs 12.69-12.77 in developing these guidelines.

Recommendation 15: that the government establish an independent review of the institutional ethics committee system in Australia.

Recommendation 16: that all Commonwealth departments refer to the licensing body for guidance where a matter arises that involves the use of human reproductive material, embryonic stem cell research or cloning research.

1

Introduction

BACKGROUND TO THE INQUIRY

1.1 In the past few years two developments in science have placed the issue of human cloning firmly on the public agenda. The first of these was the birth of Dolly the sheep in 1996 and the second was the isolation of human embryonic stem cells in 1998. Since then there have been other developments in the field. The scientific, ethical and legal aspects of these developments are the subject of this report.

1.2 The Committee finds the term 'clone' unhelpful because it means different things to different people. Several scientific processes are associated with 'cloning'; they involve different techniques and serve different purposes.[1] To 'clone' is understood popularly to mean to replicate a whole, living being, for example, Dolly the sheep.

1.3 Dolly was the first mammal to be cloned from a cell of an adult animal[2] and her initial media appearance generated huge public interest and concern because of the implications it raised for humans.[3] The Committee

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1 In Appendix E, the glossary produced by the Australian Health Ethics Committee (AHEC) in its report, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*, is included, together with some definitions produced by the Australian Academy of Science, and other definitions that the Committee has found useful

2 The means by which Dolly was produced, somatic cell nuclear transfer, is discussed further in Chapters 2 and 3

3 Dolly was born on 5 July 1996. Her birth was announced formally in a paper by Dr Ian Wilmut, leader of the team that produced her, in *Nature* on 27 February 1997, but the *Observer* newspaper broke the story on 23 February 1997. See the Roslin Institute website: http://www.ri.bbsrc.ac.uk/library/research/cloning

notes there is almost universal condemnation of the proposition that a whole human being might be replicated.[4]

1.4 The term 'cloning' also may be used to describe processes that involve the replication of cells (including the clonal replication of embryonic and adult stem cells) and tissues, and may be associated with research directed towards the treatment of disease. These other processes, including 'therapeutic cloning' will be discussed further, beginning in Chapter 2.

The Committee's Approach

1.5 Dolly's birth raised the real possibility that humans might be cloned, and it was followed by a number of inquiries and consultation exercises around the world. These inquiries addressed not only the benefits of scientific advances related to cloning, but also the ethical and regulatory implications they raised. Implicit in these inquiries was the issue of whether there are benefits to be obtained from applying cloning techniques to human beings. This has also been a significant issue in this inquiry.

1.6 The Committee is conscious that cloning techniques may offer astounding alternatives to the treatment of human diseases. However, this area of science is in its early stages of development. If there are benefits—and risks—attached to the techniques, they should be identified and weighed, so that informed decisions can be made as to the uses that may be made of them. So that regulation in this area is appropriate to these benefits and risks, the debate and consultation over the issues arising from the scientific advances in science should be as informed as possible. During its inquiry and in this report the Committee has aimed to contribute to the debate and its outcomes.

1.7 Throughout the report, as the Committee describes the various processes or techniques (beginning in Chapter 2) and their purposes, it specifies the meaning it attaches to the scientific terms. The Committee canvasses the opinions that have come to its notice, and then draws its own conclusions about the issues involved in the processes and the oversight that may be appropriate to their use. In the final chapter the Committee proposes a regulatory model for Australia.

International Background

1.8 In the United Kingdom in February 1997 the House of Commons Science and Technology Select Committee inquired into experiments at the Roslin

4 Later in this chapter the Committee notes AHEC's early acknowledgment of this view. Further detail is also provided in later chapters, particularly Chapter 6

Institute, where Dolly was produced. The inquiry was concerned with the benefits that might flow from the work, the scientific challenge it represented, and the adequacy of the law regarding cloning.[5] The government's response to that report affirmed that the cloning of human individuals is ethically unacceptable and would not be permitted in the United Kingdom.[6]

1.9 In 1998 the United Kingdom Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority undertook a joint public consultation exercise on human cloning. They presented their findings in a report *Cloning Issues in Reproduction, Science and Medicine*, together with comment on the current legal and administrative arrangements on treatment using human embryos. The report recommended that the regulatory regime then in place be recognised as adequate to forbid human reproductive cloning in the United Kingdom.[7]

1.10 In 2000 an Expert Group established by the government and chaired by the Chief Medical Officer undertook an assessment of the benefits and risks of new areas of research using human embryos and was asked to advise whether the new areas of research should be permitted. The report, *Stem Cell Research: Medical Progress with Responsibility*, was released in August 2000. The report concluded that research across a range of sources of stem cells was warranted. The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 were passed by both Houses of the United Kingdom Parliament and implemented the Group's major recommendation: that research using embryos (created by assisted reproductive technologies or cell nuclear replacement) be permitted so as to increase understanding about human disease and cell-based treatments.[8]

1.11 In March 2001 the House of Lords appointed a Select Committee to consider and report on issues connected with human cloning and stem cell research arising from the Human Fertilisation and Embryology (Research

5 *The Cloning of Animals from Adult Cells*, Fifth Report from the Science and Technology Committee, Session 1996-97, HC 373-I

6 *The Cloning of Animals from Adult Cells*, Government Response to the Fifth Report of the House of Commons Select Committee on Science and Technology, 1996-97, Cm 3815. Recent developments in the United Kingdom are discussed in detail in Chapter 10

7 Human Genetics Advisory Commission and Human Fertilisation and Embryology Authority, *Cloning Issues in Reproduction, Science and Medicine*, December 1998, section 9.2

8 16 August 2000. See Chapter 10 of this report for further detail; see also: http://www.doh.gov.uk/cegc/stemcellreport.pdf

Purposes) Regulations 2001. These issues include the ethical, legal, scientific, medical and commercial issues surrounding the Regulations.[9]

1.12 In February 1997, President Clinton asked the United States National Bioethics Advisory Commission to report on the ethical and legal issues surrounding the cloning of human beings. The Commission sought evidence from interested parties including scientists, scientific societies, ethicists, theologians and legal experts. It focused on the particular technique that produced Dolly and the ethical, religious, legal and regulatory implications of cloning human beings in this way. The Commission reported in June 1997 and concluded, among other things, that 'at this time it is morally unacceptable for anyone in the public or private sector … to attempt to create a child using somatic cell nuclear transfer cloning'.[10] President Bush's statement of 9 August 2001 in which he approved federal funding for research on certain stem cell lines that already had been taken from human embryos received world-wide attention. In that address the President confirmed his opposition to human/reproductive cloning. When he discussed the issue of embryonic stem cell research he articulated concerns that were raised by many of those who gave evidence to this inquiry:

> Research on embryonic stem cells raises profound ethical questions, because extracting the stem cell destroys the embryo, and thus destroys its potential for life. …
>
> At its core, this issue forces us to confront fundamental questions about the beginnings of life and the ends of science. It lives at a difficult moral intersection, juxtaposing the need to protect life in all its phases with the prospect of saving and improving life in all its stages.
>
> As the discoveries of modern science create tremendous hope, they also lay vast ethical mine fields.[11]

The Australian Health Ethics Committee Report

1.13 In Australia, after the birth of Dolly, the Minister for Health and Aged Care, the Hon Dr Michael Wooldridge, MP, (the Minister), sought advice

9 House of Lords, *Current Inquiries and Invitations to Submit Evidence*, Session 2000-01, http://www.publications.parliament.uk/pa/ld199697/ldselect/ldscenqs.htm The Committee has been asked to report by the end of 2001

10 See the Bioethics Advisory Commission's site: http://bioethics.gov/pubs/cloning1/executive.htm. Recent international developments are discussed in Chapter 4, in which this Committee provides an overview of developments in research and Chapter 10, which canvasses the international regulatory framework

11 ABCNews.com, http://abcnews.go.com/sections/politics/DailyN…/stemcells_Bush_transcript010809.htm

from the Australian Health Ethics Committee (AHEC) on the 'potential and need for further pronouncement or possible legislation regarding cloning of human beings'.[12] AHEC set up a Working Group to consider the issues; the Group conducted limited consultation and sought comment from a number of individuals and organisations on its draft report. The final report was approved by the full membership of AHEC.[13]

1.14 The report by AHEC, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings* (the AHEC report), was presented in December 1998, and contained four recommendations and two resolutions. The AHEC report and recommendations are discussed in detail throughout this report but it is useful to begin with an outline of the findings.[14]

1.15 An initial finding by AHEC was that there was 'an international consensus that a distinction should be drawn between two categories of cloning: cloning of a human being and copying (cloning) of human *parts* (such as DNA and cells)'.[15] AHEC also considered there was consensus that it is 'unacceptable to undertake any procedure with the aim of cloning a human being'.[16] Cloning of individual human beings is prohibited by State legislation in Victoria, South Australia and Western Australia, as well as by the NHMRC *Ethical guidelines on assisted reproductive technology* (NHMRC *Ethical guidelines*), AHEC noted.[17]

1.16 In summary, AHEC recommended:

- the government reaffirm support for the UNESCO *Declaration on the Human Genome and Human Rights*, particularly Article 11 that states:

12 Australian Health Ethics Committee of the National Health and Medical Research Council (NHMRC), *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*, 16 December 1998, (referred to throughout this report as the 'AHEC report'), p.iv. The terms of reference, executive summary, recommendations and resolutions are contained at Appendix D of this report. An overview of the role of the NHMRC (as set out in section 7 of the *National Health and Medical Research Council Act 1992*) is contained in Chapter 9. The NHMRC is a statutory authority charged, among other things, with inquiring into and advising government on matters relating to health, public health and medical research, ethical issues relating to health, and making recommendations to the Commonwealth on expenditure on public health research and training and medical research and training. AHEC is a principal committee of the NHMRC and among other things it develops guidelines for the conduct of medical research involving humans. See also the NHMRC site: http://www.nhmrc.health.gov.au/ethics/clone.pdf

13 AHEC report, pp.47-49. Appendix 2 of the AHEC report lists the individuals and organisations which commented on the draft report. These include academics, ethicists, religious, scientific and medical organisations

14 AHEC's terms of reference, executive summary and recommendations are at Appendix D

15 AHEC report, Chapter 1, paragraph 1.1

16 AHEC report, Chapter 1, paragraph 1.1

17 AHEC report, E3, p.iv. The Committee notes that there is some uncertainty regarding the interpretation of the statutory prohibitions: see Chapter 8 of this report

'Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted...' (Recommendation 1);

- as Victoria, South Australia and Western Australia already have legislation regulating embryo research and prohibiting the cloning of human beings, the Minister should urge the other States and Territories to legislate to limit research on human embryos according to the principles set out in the NHMRC *Ethical guidelines* (Recommendation 2);
- as Victoria, South Australia and Western Australia have statutory authorities that consider and may approve human embryo research under strict conditions, the Minister should urge the other States and Territories to establish similar statutory authorities to regulate research on human embryos according to the principles set out in the NHMRC *Ethical guidelines* (Recommendation 3). AHEC was critical of the States that had not introduced regulation despite earlier urging;
- the Minister should encourage and promote informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques (Recommendation 4).

1.17 The Resolutions stated that pending State and Territory legislation, AHEC should collect information from institutional ethics committees (IECs) (in the jurisdictions without legislation) on IEC research approvals involving the application of current cloning techniques to human embryos. Also the NHMRC should consider establishing an expert advisory committee to assist IECs that seek advice on scientific aspects of research projects involving the application of current cloning techniques to human embryos.[18]

THE COMMITTEE'S INQUIRY AND REPORT

Referral Of The Inquiry

1.18 In August 1999 the Minister for Health and Aged Care, the Hon Dr Michael Wooldridge, MP, asked the House of Representatives Standing Committee on Legal and Constitutional Affairs (the Committee) to review the AHEC report. The following report is the result of the Committee's investigations into the issues raised by the AHEC report.

18 AHEC report, Chapter 6, Resolutions 1 and 2, p.44

Conduct Of The Inquiry

1.19 An advertisement inviting submissions to the inquiry appeared in major metropolitan newspapers on 21 August 1999 and was posted on the Committee's website.[19] Letters seeking submissions were sent to Commonwealth Government agencies, State Premiers, Territory Chief Ministers, church leaders, medical organisations and scientific research institutions as well as community groups, ethicists and individuals who were known or likely to have an interest in the subject of the inquiry.

1.20 The Committee received a total of 347 written submissions and 50 exhibits.[20] In addition, many members of the public (approximately 316) wrote simply to urge a ban on human cloning.[21]

1.21 The Committee collected most of its oral evidence at two public forums. These were held in Melbourne on 1 March 2000 and in Canberra on 29 March 2000. The Committee was keen to hold public forums so as to bring together as many members of the scientific community, church and community groups, ethicists and legal professionals as possible to explain and contest the array of views that were presented. Members of the public were able to participate directly in the collection of oral evidence at the forums by way of comment and questions to the witnesses.[22] The Chairman also met with representatives from relevant authorities and scientists in the United States and the United Kingdom. A list of these people is at Appendix G.

1.22 The transcripts of evidence taken at the public forums and hearings and electronic copies of this report, as well as written submissions provided to the Committee in electronic form, can be found on the Committee's website.[23]

The Report

1.23 As this report is a review of the findings of the AHEC report, the broad structure relates to the main themes canvassed by AHEC: the scientific, ethical and regulatory aspects of human cloning.

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19 The advertisement indicated that form letters received by the Committee would not be treated as individual submissions

20 Appendix A comprises a list of submissions and Appendix B comprises a list of exhibits. Witnesses who appeared before the Committee are listed at Appendix C

21 Appendix H contains a list of people who wrote to the Committee to urge a ban on human cloning

22 At intervals during the forums members of the public were invited to put questions and comments—through the Committee Chairman

23 www.aph.gov.au/house/committee/laca

Scientific issues

1.24 Chapter 2 provides an introduction to the science, as well as the scientific terms and techniques relevant to discussion of cloning.

1.25 In Chapter 3 the Committee discusses the scientific conclusions from the AHEC report and presents an overview of the scientific evidence to the inquiry. In Chapter 4 the Committee outlines the status of international scientific research, current Australian research, and timeframes for results.

Ethical issues

1.26 Chapter 5 introduces the general ethical issues surrounding cloning of human beings. It discusses the approach of the AHEC report to these issues, the views expressed to this Committee about AHEC's discussion of the ethical issues, and the approach the Committee has taken in this regard.

1.27 In Chapter 6 the Committee examines cloning for reproductive purposes. The initial question raised is, what does 'cloning for reproductive purposes', also called 'reproductive cloning', mean? The Committee considers what reproductive cloning technology may be used for and canvasses the opinions expressed about it. It is worth noting that almost all who presented evidence to the inquiry expressed opposition to cloning for reproductive purposes.

1.28 The focus of Chapter 7 is on ethical issues associated with research that involves cloning techniques and the possible application of these techniques to treat illness. The ethical issues relate to the way the research is to be conducted and the source material necessary to conduct it. The Committee considered the issues relating to material from the following sources: adult stem cells, stem cells from embryos surplus to assisted reproductive technology; from embryos created for research; from embryos created by somatic cell nuclear transfer using a patient's own tissue for therapy for the individual patient; and cells such as embryonic stem cells imported from overseas.

Regulatory issues

1.29 Chapter 8 introduces the issues involved in regulation of cloning. It begins with the approach taken by AHEC in its report and then considers the regulatory framework that applies to human cloning and related research in the Australian States and Territories. Relevant Commonwealth legislation is also considered. Non-legislative regulation in Australia is discussed in Chapter 9.

1.30 International developments in regulating human cloning are canvassed in Chapter 10, together with the implications they present for Australia.

1.31 In Chapter 11 the Committee responds to the recommendations of the AHEC report and in Chapter 12 the Committee provides its own model for the regulation of human cloning and related research in Australia.

2

Introduction to the science

INTRODUCTION

2.1 Chapters 2, 3 and 4 cover the scientific processes and related issues underlying cloning and stem cell technologies. This chapter gives a background to the field of reproductive and developmental biology and the technologies relevant to the cloning of human tissues, organs or whole individuals. It provides a basis for the scientific developments, ethical issues and regulatory options discussed in the rest of the report.

2.2 A glossary of scientific terms is provided at the end of this report [Appendix E]. The glossary is based on that used by AHEC.[1] Where new terminology has arisen from research over the past three years, the glossary developed by the Australian Academy of Science[2] is used. A few definitions of basic terms are from Collins Dictionary of Biology.[3] Many definitions are changing as new research revises understanding of reproduction and development. The key issues and terminology are presented in the diagrams at the end of this chapter.

2.3 Research in molecular, cellular and developmental biology is progressing at extraordinary speed and challenging previous understanding of cell, tissue and embryo development. The future directions of this research, the potential for revolutionising aspects of medicine and health care, and the role of Australian scientists in these developments is the subject of Chapters 3 and 4.

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1 AHEC report, Appendix 3, p.50

2 *Human Stem Cell Research*, Australian Academy of Science, 18 April 2001

3 Hale, WG, and Margham, JP, *Dictionary of Biology*, Collins, Glasgow, 1988

REPRODUCTIVE BIOLOGY—BACKGROUND

2.4 Knowledge of human reproduction and the molecular, cellular, hormonal and other factors that regulate the development of sperm and egg (gametes), fertilisation, pregnancy, embryo and foetal development, has accumulated over the past seventy years. Current developments in research, including those covered in this report, depend fundamentally on this background of knowledge. Traditionally, such knowledge has been gained first by studying reproductive processes in apparently simple systems such as those of amphibians (including frogs and toads), fish and a range of mammals including the rodents (mice, rats), agricultural livestock (sheep, cattle, pigs) and primates (marmoset, rhesus monkey, baboon) with validation in the human as appropriate. The developmental mechanisms that regulate reproduction in primates and humans are similar, whereas in other species some mechanisms may have significant differences.

2.5 The development of this and any scientific field depends on experiments that are carried out with laborious precision. The process includes a careful review of the background knowledge, definition of a question, formulation of an hypothesis and design of an experiment to test this hypothesis. The results are published after critical review by peers in the field.

2.6 Much of scientific debate concerns the validity of experiments and the interpretation of results. This rigorous approach is essential if robust results are to be obtained. The scientific approach has tended to be tested first on animal model systems before being extended to the human, to reduce the risk of unpredictable side effects. Results from such studies over the past fifty years have provided new treatments for infertility, the regulation of fertility, assisted reproductive technologies and now cloning technologies.

2.7 The field of human reproduction and assisted reproductive technologies is an area where scientific method needs special care for a variety of moral, legal and social reasons. However, at some point a leap has to be made to the human from the earlier, animal work. This leap was made in the development of *in vitro* fertilisation (IVF), resulting in the birth of Louise Brown[4] in 1978, and of about 350,000 IVF babies born since then.[5] Because of the worldwide focus of research in this area in the past twenty years, in which Australian scientists have played a prominent role, there is now

4 Joint Report of Human Fertility and Embryology Authority and Human Genetics Advisory Commission, UK, in *Cloning Issues in Reproductive Science and Medicine*, 1978, paragraph 3.1

5 Some press estimates are as high as 1 million.

more information about human gametes and embryos than about other primates.

2.8 Consequently there is a strategic point when deciding if research is best pursued in a rodent or primate model system, or if it is better pursued directly in the human. This is now the case with some assisted reproductive technologies where carrying out research in animal models would be a reversion to a less understood system. In practice, research is normally carried out in parallel in humans and animals.

Outline of Human Reproductive Processes

2.9 The female human reproductive tract includes the ovary, oviduct (fallopian tube) and uterus (Figure 1).[6] Eggs grow in the ovary, regulated by circulating hormones. Usually, one egg is released each menstrual cycle in the human female (ovulation). This egg passes into the oviduct. Fertilisation can occur approximately twenty four hours later if sperm are present. The sperm and egg fuse in the process of fertilisation.

2.10 The male human reproductive tract includes the testis, epididymis and vas deferens, with the prostate, seminal vesicles and Cowper's glands. Sperm are produced in the testis, matured and stored in the epididymis and tens of millions are released at ejaculation.

2.11 The process of fertilisation includes the attachment of sperm to the membrane surrounding the egg (zona pellucida); the penetration of the egg by the sperm; the migration of the sperm head across the cell and fusion of the sperm and egg nuclei. Fusion occurs when the chromosomes from the sperm and egg align to form the new embryo (syngamy). During this process, from the penetration of the zona pellucida by sperm to syngamy, the cell is called a zygote.[7] Once syngamy is completed the cell is referred to as an embryo.

2.12 The embryo divides (2, 4, 8, 16 cells etc) as it passes through the oviduct, arriving in the uterus about day 4 as a 'morula', a ball of 32-64 cells (Figure 2). Once in the uterus the morula develops into a 'blastocyst' (by day 5-6) which consists of an outer casing of cells that will become the placenta, and an inner cell mass that will become the foetus.

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6 The terms used in this section are explained in the glossary at the end of this report

7 The Infertility Treatment Act (Vic), section 3 defines an 'embryo' as 'any stage of human embryonic development at and from syngamy'. Syngamy is defined as 'that stage of development of a fertilised oocyte where the chromosomes derived from the male and female pronuclei align on the mitotic spindle'. The term zygote means 'the stages of human development from the commencement of penetration of an oocyte by sperm up to but not including syngamy'

2.13 Consequently, the first week of pregnancy is a dynamic period when the embryo develops from a single cell, resulting from the fusion of sperm and egg, to a blastocyst of 100-200 cells (Figure 3). At about day 6-7, the blastocyst 'hatches' from the zona pellucida and becomes attached to the inner lining of the uterus. At this point of early implantation the placenta starts to form and to invade the blood supply of the mother in order to gain nourishment. At about 14 days the primitive streak is formed (see below). Implantation of the embryo continues until the pregnancy becomes fully established (Figure 3).

2.14 Although precise data is difficult to obtain, it is estimated that up to half of all naturally formed embryos fail before the full establishment of pregnancy.[8] 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.

2.15 It is at this early stage, during the first two weeks of pregnancy, that twins can be formed. Non-identical twins are the result of two eggs being fertilised and both of these implanting. Identical twins (natural human clones) are the result of a splitting of the single embryo at some stage during the first 2 weeks of its development.

2.16 Fourteen days is the approximate time when the primitive streak, the first confirmation of the organised embryo and its orientation, is formed. This is when 'identical' (monozygotic) twin embryos derived from a single egg first become evident and also when implantation and pregnancy are becoming more established. This was one reason that 14 days was adopted by the Warnock Committee and by the legislature in the United Kingdom as the limit for the period when research on embryos is permitted.[9] In Australia, 14 days is also the limit for research on embryos in Western Australia, South Australia and in the guidelines of the National Health and Medical Research Council (NHMRC).

Assisted Reproductive Technologies

2.17 During the last thirty years a significant field of medicine has developed, aiming to help infertile couples achieve successful birth. In general, the techniques have resulted from the close study of the normal process,

8 Wood, J.W., 1989, Fecundity and actual fertility in humans, *Oxford Reviews of Reproductive Biology*. 11, pp.61-109; Wilcox, A. J. *et al*, 1988; Incidence of early loss of pregnancy. *New Engl. J. Med.* 319, pp.189-194

9 *Report of the Committee of Inquiry into human Fertilisation and Embryology* (1984), known as the Warnock Report, www.doh.gov.uk/bus guide/hfea/page1.htm

outlined above, and then a series of interventions to enhance or replace the factors that are inhibiting fertility in the male or the female.

2.18 The causes of infertility in men and women can be obscure, but many factors are known. These can be physical, such as blockage or damage in the male or female tract, genetic, hormonal, biochemical or metabolic, resulting in inadequate growth and maturation of the sperm or egg or failure of embryo development and the establishment of pregnancy.

2.19 About 350,000 successful births around the world have been achieved by a wide range of assisted reproductive techniques. The overall success rate of these assisted procedures is still low, with babies born averaging fewer than 20% of attempts made**,** although some clinics claim to achieve over 30% success. One should remember that the overall success of natural fertilisation and implantation is estimated as little more than 50%.[10]

2.20 As a result of all this work it is now routine to collect eggs from the ovary of women and sperm from men. The process of egg collection in humans requires a course of hormone treatment during the first two weeks of the menstrual cycle to stimulate multiple egg development. Egg development is monitored by ultrasound scanning and blood samples are taken for hormone measurement. Eggs are collected in one of two ways: using a needle guided by ultrasound (under a general anaesthetic or a mild sedative), or by laparoscopic surgery. During this latter procedure which normally requires a general anaesthetic, a small incision is made in the abdomen through which the laparoscope is inserted. This enables the surgeon to see into the abdomen and locate the mature eggs in the ovary. A fine, hollow needle is inserted at another site and the eggs are collected by suction. There may be minor side effects, discomfort or complications during this process.[11]

2.21 Sperm and eggs can be maintained in appropriate culture conditions, frozen and stored, used to carry out fertilisation *in vitro* (outside the body); or for transfer of sperm, eggs, or embryos back into the female reproductive tract for pregnancy to be established.

2.22 One result of the success of these procedures is that more embryos may be produced than are required for replacement into the woman's uterus. These embryos are frequently stored frozen for possible later use by the parents. However, many thousands of these surplus embryos are not

10 Wood, J. W., 1989, Fecundity and actual fertility in humans, *Oxford Reviews of Reproductive Biology*. 11, pp.61-109; Wilcox, A. J. *et al*, 1988, Incidence of early loss of pregnancy, *New Engl. J. Med.* 319, pp.189-194

11 The egg donation procedure is outlined in a leaflet—'Egg Donation'—produced by the Human Fertilisation and Embryology Authority in the United Kingdom http://www.hfea.gov.uk/egg/eggdon.htm

required.[12] A few of these embryos have been used to isolate embryonic stem cells from the inner cell mass, giving rise to the current explosion of interest in the field. The nature and use of embryonic stem cells is discussed further below.

2.23 Another assisted reproductive technique, pre-implantation genetic diagnosis or cell biopsy**,** involves the removal of a single cell from a multi-celled embryo after *in vitro* fertilisation. This cell may be analysed to diagnose some genetic abnormalities or physiological deficiencies, without damaging the whole embryo. The technique can be applied when there is a family history of a genetic disorder that is expressed in a proportion of the embryos and allows the identification of normal embryos for transfer to the mother. Similar techniques could be used to screen stem cells for some defects.

The Structure and Life Cycle of a Cell

2.24 Cells are the building blocks of the body, usually specialised for their role in particular tissues and organs (for example, nerve cell, muscle cell etc). Cells have limited life spans and are replaced throughout life by new cells, generated within the tissue or organ. Cells are made up of the nucleus, which contains the chromosomes carrying genetic information, and the cytoplasm. The cytoplasm contains mitochondria which contain a few genes and are responsible principally for energy and cell regulation. (Figure 4)

2.25 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.

2.26 Until relatively recently, once cells embarked on the various pathways towards specialisation, such as muscle, nerve, liver etc, they were thought to be 'committed' and irreversibly locked into that particular cell type. Although each somatic cell contains a full set of chromosomes and genes (genome) of the individual, only the genes that are required for that cell's particular function are expressed (selectively activated).

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12 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

2.27 Recent research shows that, under certain conditions, cells are much more flexible than was thought. For example, a muscle cell can be 'deprogrammed' and turned into a nerve cell when transplanted into nerve tissue. This process is known as 'transdifferentiation' and scientists are only now starting to understand how it is achieved since it implies the reprogramming of the cell and activation of other parts of the genome to form a different cell type. Embryonic stem cells or adult stem cells can develop more easily down different pathways, since they have yet to become fully specialised and committed to a single pathway.

2.28 Most of the cellular triggers and signals that determine the choice of pathway, that is, towards muscle, nerve etc are not known and this is where a lot of the international effort in cloning technologies and stem cell research is now focused.

2.29 This flexibility introduces the concept of cell 'potency' or potential (Figure 5). There are 'totipotent' cells, which can develop into a whole individual, such as a fertilised egg or the individual cells of the embryo up to the 16-32 cell stage. There are also 'pluripotent' cells, such as embryonic stem cells (ES cells) and embryonic germ cells (EG cells) which can develop into many or all of the cells or tissues of the body but not into a whole individual. There are also 'multipotent' cells, such as adult stem cells that can develop into a more restricted range of tissues or organs. The terms pluripotent and multipotent are often used as synonyms.

Somatic cells and germ cells

2.30 The human has two fundamentally different cell types:

- germ cells, located in the gonads (ovary and testis). These are the cells from which sperm and eggs arise; and
- somatic cells, which are all other cell types of the body.

The genome in germ cells is transmitted, after fertilisation of the egg by the sperm, to future generations. Therefore genetic manipulation of germ cells results in the modified genome being transmitted to future generations. In contrast, the genome in somatic cells is not transmitted to future generations and genetic manipulation of a somatic cell only affects the genome of that cell.

CLONING

The Definition Of Cloning

2.31 There are many definitions of cloning in plants and animals. 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. Cloning techniques in plants have been in widespread use for centuries in gardening and crop development. Lower vertebrates such as earthworms or flat worms, when cut in half, will regenerate two genetically identical individuals.

2.32 Cloning can also be achieved through artificial technologies. It is possible to clone DNA, cells, tissues, organs and whole individuals. The method of nuclear transplantation, (now known as somatic cell nuclear transfer) which was developed first about 40 years ago in frogs, has now been adapted successfully to make clones of mice, sheep, goats, pigs and cattle. Rhesus monkeys have been cloned by embryo splitting techniques.

2.33 **Therefore, it is important to note that cloning does not necessarily mean the replication of an entire individual. This, however, is often the public perception, reflected in the Australian and international media.**

2.34 The AHEC report defines cloning as 'asexual propagation without altering the nuclear genome'.[13] There is little distinction in the AHEC report between the different purposes for cloning, for example, cloning for reproductive purposes or cloning for the purposes of therapy. The isolation of human embryonic stem cells, which opened the possibility of such cell therapy, was achieved just before the AHEC report was published in December 1998.

2.35 However, the AHEC report does distinguish between procedures for the cloning of a whole human individual and the copying of the component parts of a human (such as DNA and cells).[14]

2.36 An alternative definition of 'cloning' to that in the AHEC report was developed by the Australian Academy of Science. The Academy published a position statement *On Human Cloning* in February 1999[15] and held an international symposium *Therapeutic Cloning for Tissue Repair* in

13 AHEC report, Glossary

14 AHEC report, E3 p.iv

15 *On Human Cloning*. A Position Statement, 4 February 1999, Australian Academy of Science

September 1999.[16] The Academy published a statement *Human Stem Cell Research*[17] in April 2001. The following working definitions were used:[18]

- cloning: the production of a cell or organism with the same nuclear genome as another cell or organism;
- reproductive cloning: to produce a human fetus by nuclear replacement; and
- therapeutic cloning: to produce human stem cells, tissues and organs.

These definitions recognise the different purposes for cloning and distinguish between the cloning of a whole human individual and cloning of cells and tissues.

2.37 Therefore, cloning can mean different things to different people. Moreover, there is overlap between the definitions for reproductive cloning and for therapeutic cloning, since in both an embryo may be formed or used for research. The Committee acknowledges that existing definitions are confusing.[19]

Cloning Technologies

2.38 Two major scientific breakthroughs have shaped the recent developments in cloning technologies. The first, somatic cell nuclear transfer, is represented by the 'Dolly' experiment reported in 1997.[20] The second, the isolation and characterisation of human embryonic stem cells was reported in 1998.[21]

Somatic cell nuclear transfer

2.39 For many years attempts to clone mammals by nuclear transplantation were unsuccessful, possibly because the nuclei were usually placed in fertilised rather than unfertilised eggs.[22] In 1996 Dr Ian Wilmut and his colleagues cloned the first mammal produced from a sheep foetal skin cell fused with an oocyte.[23] Their subsequent experiments resulting in Dolly produced the first mammal cloned from a fully differentiated adult somatic cell.

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16 *Therapeutic Cloning for Tissue Repair,* Report from a Forum held on 16 September 1999, Australian Academy of Science

17 *Human Stem Cell Research,* 18 April, 2001, Australian Academy of Science

18 *On Human Cloning*, A Position Statement, 4 February 1999, Australian Academy of Science, pp.7-8

19 See Chapters 6 and 7 for further discussion of reproductive and therapeutic cloning

20 Wilmut, I. *et al, Nature*, Volume 385, 1997, pp.810-13

21 Thomson, James A. *et al, Science*, Volume 282, 6 November 1998, pp.1145-1147

22 Gurdon J.B. and Colman A., *Nature*: Volume 402, 16 December 1999, p.744

23 Campbell *et al, Nature*, Volume 380, 7 March 1996, pp.64-66

2.40 In the Dolly experiment, a cell from the mammary gland of an adult sheep was fused, by means of an electric pulse, with an unfertilised, enucleated (nucleus removed) egg from a second sheep. The resulting fused cells developed into an embryo which, after transfer into the uterus of a third sheep, developed into a whole individual (Figure 6). This new sheep known as Dolly, born after a normal pregnancy, has lived an apparently normal life and produced lambs. Dolly was the only lamb born from 277 attempts. The cloning procedure, where the nucleus of a somatic cell is transferred into an unfertilised enucleated egg, is now known as 'somatic cell nuclear transfer'.[24]

2.41 This experiment proved that an adult cell could, under certain circumstances become totipotent, form an embryo and develop into a whole individual—a result that could not have been predicted from earlier understanding of mammalian embryonic cell specialisation and commitment.

2.42 The Dolly experiment raised the possibility that human reproductive cloning is feasible. However, many of the 277 attempts to clone Dolly resulted in abnormal placentas and foetuses and other complications during pregnancy or at birth. Similar failure rates and abnormalities have resulted from attempts at cloning other animals.

Embryonic stem cells

2.43 The second major scientific breakthrough to shape recent developments in cloning technologies has been in the isolation and characterisation of human embryonic stem (ES) cells. These pluripotent cells can be grown to produce cell lines and tissues with the aim of treating disease or perhaps growing organs for transplantation, an application referred to as 'therapeutic' cloning.

2.44 During the early development of an embryo, the morula develops into a blastocyst (Figure 3). The cells of the blastocyst are specialised into an outer casing of cells that will become the placenta, and an 'inner cell mass' that will eventually become the foetus. The outer cells are now 'committed' to become placental tissue and have lost the ability to develop into other tissues and organs. However, the inner cell mass is composed of embryonic stem cells, which retain the ability to become many specialised cells or tissues.

2.45 Embryonic stem cells can be removed from the blastocyst with a thin glass needle (pipette), or by a biochemical dissociation of the cells (Figure 7). They can then be placed into culture medium, and can replicate, retaining

24 Wilmut, I. *et al, Nature*, Volume 385, 27 February 1997, p.810

their pluripotent capacity indefinitely. They may be frozen and stored. Stem cells can be grown in culture, differentiating into a wide range of specialised cell lines.

2.46 The first embryonic stem cells from mammals were isolated from mice in 1981.[25] It took 14 years more before embryonic stem cells were isolated from non-human primates, this delay being due largely to the difficulties associated with obtaining monkey embryos in sufficient numbers for experimental research. The breakthrough came with the rhesus monkey in 1995,[26] followed by the marmoset monkey in 1996.[27] The same techniques were then applied in the USA to 14 human blastocysts produced by IVF, donated with informed consent, resulting in the isolation of five human embryonic stem cell lines in 1998.[28] Concurrently, the isolation of pluripotent human embryonic germ cells was reported in 1998.[29]

2.47 Research in human embryonic stem cell biology has spread rapidly in Australia, Europe and the USA, with significant research teams also in Israel and Singapore. There was an immediate global debate initiated about the science and ethics of reproductive and therapeutic cloning. The ethical and regulatory dimensions of this debate are addressed in Chapters 5-12 of this report.

Adult stem cells

2.48 Just as the embryo contains stem cells that may take different paths to build tissues and organs, stem cells remain present in the body throughout life and are responsible for normal repair and replacement in the different tissues and organs. These 'adult' stem cells are thought to have less flexibility. For example, blood stem cells in the bone marrow have the ability to develop into all of the various blood cells. The identification of such stem cells in muscle, brain, liver, pancreas and other tissues is in its early stages but research is progressing rapidly.

2.49 To date, it has proved difficult to routinely identify adult stem cells from the majority of organs. It has not proved easy to grow such cells or to maintain them 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.

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25 Martin, G., 1981, *Proc. Nat.. Acad. Sci. USA* 78, pp.7634-7638

26 Thomson, J. A. *et al*., 1995, *Proc. Nat. Acad. Sci. USA*. 92, pp. 7844-7848

27 Thomson, J. A. *et al*., 1996, *Biology of Reproduction* 55, pp.254–259

28 Thomson, J. A. *et al*. *Science*, Volume 282, 6 November 1998, pp.1145-1147

29 Shamblott, M. J. *et al*., 1998, Derivation of pluripotent stem cells from cultured human primordial germ cells, *Proc. Nat. Acad. Sci. USA* 95, pp.13726-13731

2.50 Figure 8 shows an idealised adult stem cell therapy. An adult cell from a patient is reprogrammed, and perhaps genetically manipulated, before being cultured to the required cell type and transplanted back to the patient. At present these procedures may require a somatic cell nuclear transfer stage, passing through an embryo phase. In future it may be possible to reprogram the cell without an embryo phase.

2.51 In the past two years there has been a major expansion in research on adult stem cells. There is a new understanding of their flexibility and potential but current knowledge suggests it is unlikely that these will be as broad as in embryonic stem cells. A summary of the procedures employed for somatic cell nuclear transfer, embryonic stem cell and adult stem cell research is provided in Figure 9.

Subsequent developments

2.52 The cloning procedures that resulted in Dolly have been extended to other mammals but not to humans. There is a low success rate and many embryos transferred to surrogate mothers die during pregnancy, others at birth, many with serious abnormalities. In general terms, 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 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 before it becomes a viable technique, either for animal husbandry or for cell manipulation.

2.53 An example of the application of somatic cell nuclear transfer technique is provided here. Whilst it illustrates the developments it was not an area on which the Committee received evidence. In 1997, Dr Wilmut's group cloned a sheep, Polly, from a foetal skin cell into which a human gene for a valuable pharmaceutical protein, the human clotting factor IX had been inserted. Factor IX could subsequently be extracted from Polly's milk and concentrated for potential use in treating human haemophiliacs.[30] This new source of factor IX avoids the risk of human blood products transmitting viruses such as AIDS or hepatitis C.

2.54 Applications of somatic cell nuclear transfer and other cloning technologies in the near future may include, for example, the production of animals that generate valuable pharmaceuticals in their milk or urine, or produce milk or meat with enhanced nutritional value.

30 McLaren, A., *Science*, Volume 288, 9 June 2000, 1779

Potential benefits of stem cell therapy

2.55 A great deal of research is focusing on how undifferentiated embryonic or adult stem cells can be induced to develop into one or other tissue and organ cell lineage. This 'cell lineage choice' will determine whether they become brain, muscle, gut, liver, pancreatic cells or so on. 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 prospects include banks of cells that are tailored for specific diseases in specific people. The intellectual property associated with the factors that determine cell choices will be valuable. Consequently, there is intense competition in laboratories around the world to elucidate the process and to patent this new knowledge.

2.56 The scientific competition to understand the factors regulating cell differentiation emphasises the urgency of this research. 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. These applications may derive from the use of embryonic stem cells, adult stem cells or the factors that regulate their differentiation.

2.57 A hypothetical example of embryonic stem cell therapy is 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 (except for mitochondrial genes in the cytoplasm of the donor egg) 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.

2.58 Adult stem cells could provide an ideal cell therapy if it were possible to identify and isolate them from a specific tissue or organ type, multiply and grow them in culture, manipulate them to repair any genetic or metabolic deficiency and store them until required. When using these cells to repair damaged organs, including the brain (Parkinson's or Alzheimer's), they could be transplanted back into the same person following manipulation. The cells would be fully matched and compatible since they would have been specifically designed or enhanced for the person and that disease.

2.59 However, a great deal of research is required before applications of stem cell biology to diabetes and other diseases will become available. Diabetes may also prove intractable to such treatments; and in this and other

diseases the replacement of cells may not necessarily cure the disease. Indeed, the new cells may be vulnerable to the original disease process, but they may provide a temporary solution.

2.60 While stem cell therapies are unlikely to be widely available for 5–10 years, the potential cost savings of therapies arising from stem cell research, including the use of newly discovered cell signals and triggers that regulate differentiation, is enormous. The health care implications are considerable.

Other Related Technologies

2.61 Applications arising from research in somatic cell nuclear transfer, embryonic stem cells and adult stem cell will become a major field of biomedical science. In addition, there are other methods and variants that may lead to new cloning technologies. These include embryo splitting, cross species cell transfer and mitochondrial transfer. These are not the focus of this report and are summarised only briefly below because of recent press references.

Embryo splitting

2.62 During the first few days after fertilisation, the morula, a ball of 32-64 cells, enters the uterus and develops into a blastocyst. All of the individual cells (blastomeres) up to the morula stage are thought to be totipotent. They can be separated singly or in multiple cell groups each of which can develop to form a whole new individual. This procedure has now been achieved routinely in rodents, sheep and cattle and was demonstrated recently in the rhesus monkey.

2.63 In addition, the morula and the blastocyst may be bisected, the latter requiring the presence of some inner cell mass cells, and each half may develop into a separate individual. This procedure has been performed but is not routine. Natural embryo splitting is known to occur in the formation of identical twins (natural clones) in humans.

Cross species cell transfer

2.64 The transfer of DNA, cells, tissues or organs between species is known as xenotransplantation. Examples of this research include somatic cell nuclear transfer of an adult cell from one species into an egg of another. Some of these attempts have resulted in the formation of embryo-like structures, used as a potential source of embryonic stem cells.

2.65 A further example is in organ transplantation, where an animal heart, liver, or kidney is used as a short-term transplant until a human organ

becomes available. This may require genetic manipulation to facilitate acceptance of the organ. A risk of these procedures is the inadvertent transfer of known and unknown viruses or other infectious agents. The Committee's recommendation on cross species research is in Chapter 12, at Recommendation 11.

Ooplasmic transfer

2.66 Recently, about 30 births were reported in the press[31] and in *Human Reproduction*[32] after the eggs of the mothers had been injected with additional cytoplasm from a donor egg. The objective was to overcome infertility in the mothers. The donated cytoplasm included mitochondria, small cellular organelles that contain a few genes that are responsible for energy regulation in the cell. There is no direct evidence that this treatment overcomes infertility. Many in the scientific community have questioned the approach, which had not been fully tested in animals. Subsequent reports have revealed that 2 of the 17 foetuses formed by the technique at one medical centre had Turner's syndrome, a serious chromosomal abnormality.[33]

SUMMARY

2.67 Any review of the scientific literature, or indeed the popular press, over the past two years will confirm the extraordinary pace of research in this area. The methods for isolating embryonic, adult and other cells are being refined. The chance of success, one in 277 in the case of Dolly, is being improved. However, the field is still young and many procedures are proving difficult to repeat. Undoubtedly, progress in the next five years will accelerate with further breakthroughs. These developments will need to be monitored as they will have repercussions on the related ethical and regulatory dimensions of cloning and stem cell technologies.

31 BBC News, 4 May 2001

32 Mitochondria in human offspring derived from ooplasmic transplantation: Brief communication, J.A. Barritt *et al, Human Reproduction*, Volume 16, No.3, pp.513-516, March 2001

33 *Sydney Morning Herald*, 21 May 2001, p.5

Figure 1. The human female reproductive tract

Eggs grow in the ovary, stimulated by circulating hormones. Usually, one egg is released each cycle in the human female (ovulation). This egg passes into the oviduct where fertilisation may take place. The fertilised egg starts to divide as it passes through the oviduct, arriving in the uterus as a 'morula' of about 30-60 cells as shown in Figure 2. Once in the uterus the morula develops into a 'blastocyst' which consists of an outer casing of cells that will become the placenta, and an inner cell mass that will become the foetus.

Figure 2. Development of the human embryo in the reproductive tract, from fertilisation to implantation

Figure 3. Early embryo development

In the uterus, the blastocyst 'hatches' from its surrounding membrane called the zona pellucida on about day 6-7. The hatched blastocyst then attaches to the inner lining of the uterus. Immediately, cells project out to invade the uterus and connect with the maternal blood supply so that nutrients will flow to sustain the embryo. This process of attachment and invasion is called implantation.

Figure 4. The cell

Figure 5. Cell potency

Figure 6. Somatic cell nuclear transfer

An adult cell (eg. mammary cell, in the case of 'Dolly') is fused, using an electric pulse, with an egg from which the nucleus has been removed. The resulting 'embryo' is then transferred to the uterus. In the case of Dolly, only one lamb was born from 277 attempts. The cell treated this way has been 'reprogrammed' by as yet unknown factors in the egg cytoplasm to becomes totipotent (capable of developing into a whole individual).

Figure 7. Embryonic stem cells

Embryonic stem cells (ES) cells are isolated from the inner cell mass of the blastocyst. They can be grown and multiplied indefinitely in culture without differentiating, but can be made to differentiate into a range of cell types. The factors determining 'cell lineage choice' ie. whether cells grow into brain, liver, muscle, gut etc. are not yet understood and are the focus of much current research. At present, embryonic stem cells can only be derived from the inner cell mass of the blastocyst and the procedure destroys the blastocyst. Embryonic stem cells are multipotent / pluripotent (they can form many of the cells or tissues of the body) but not totipotent (they cannot form a whole individual).

Figure 8. Adult stem cells

Stem cells are present in the foetus, child and adult. These 'adult' stem cells have a limited ability to differentiate into various cell types. They are responsible for normal cell replacement and wound healing. An example is the blood stem cell, present in the bone marrow, which replaces blood cells throughout life. Currently there is no routine way to identify adult stem cells in tissues and organs and this is the focus of much research. Successful identification and multiplication of adult stem cells would allow the development of stem cell therapies that do not require the use of embryos.

Figure 9. Summary of procedures

The three main lines of research are summarised in this diagram. On the left, embryonic stem cells are recovered from the inner cell mass of surplus embryos from IVF programs, for research including cell therapies. In the centre, embryos are cloned by the somatic cell nuclear transfer technique to provide ‘designer’ stem cells for research aimed at specific patients and diseases. On the right, adult stem cells may be isolated, programmed to grow into particular cell or tissue types, and used in cell therapies.

3

Scientific evidence

INTRODUCTION

3.1 This chapter presents the scientific conclusions from the AHEC report, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings;*[1] the recommendations of the Australian Academy of Science resulting from a review of the status and future directions of cloning and stem cell technologies;[2] the evidence presented to the Committee and the Committee's consideration of the scientific aspects of the inquiry.

The AHEC Report: Scientific Considerations

3.2 The Executive Summary and Recommendations of the AHEC report are at Appendix D. Inevitably new discoveries have resulted in the AHEC report being overtaken to some extent, although it remains a useful background document.[3]

3.3 The AHEC report was published in December 1998. The AHEC working party considered the request from the Commonwealth Minister for Health and Aged Care for advice as to the need for further pronouncement or legislation regarding human cloning. After consultation, there was no support for the application of any technique aimed to intentionally clone whole individual human beings.[4]

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1 Australian Health Ethics Committee of the NHMRC, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings, (*referred to as the AHEC report), 16 December 1998

2 *Human Stem Cell Research*, Australian Academy of Science, 18 April 2001

3 AHEC report, Chapter 1, paragraphs 1.1–1.25; AHEC report, Executive Summary, E1–E9 and Recommendations p.v

4 AHEC report, Executive Summary E2, p.iv

3.4 The AHEC report discussed the support for basic research related to cloning technology in Australia. The report outlined relevant scientific considerations and various techniques for cloning human embryos. It sketched background embryology, technical applicability and feasibility. An outline of the projected benefits of cloning techniques which have the potential for supporting transplantation, tissue and organ repair was given, together with the possible risks of these techniques.[5]

3.5 Ethical issues associated mainly with cloning techniques involving human embryos were identified.[6] These ethical and policy issues form the basis of Chapter 7 in this report. The relevant international and national regulatory frameworks were reviewed, as was the NHMRC *Ethical guidelines on assisted reproductive technology*. The international consensus at that time was that the intentional cloning of humans is unacceptable.[7] This matter is discussed in Chapters 6 and 10 of this report.

The Australian Academy of Science

3.6 The Academy published a position statement *On Human Cloning* in February 1999 and hosted an international forum on *Therapeutic Cloning for Tissue Repair* in September 1999. A statement on *Human Stem Cell Research* was published in April 2001. In the first and third of these documents and in its submission to this inquiry the Academy recommended:

- Reproductive cloning to produce human fetuses is unethical and unsafe and should be prohibited. However, human cells, whether derived from cloning techniques, from embryonic stem cell lines or from primordial germ cells should not be precluded from use in approved research activities in cellular and developmental biology.[8]
- The Minister for Health and Aged Care should encourage informed community debate on therapeutic benefits and risks of development of cloning technologies.[9]
- If Australia is to capitalise on its undoubted strength in medical research, it is important that research in therapeutic cloning should not

5 AHEC report, Chapter 2, paragraphs 2.1- 2.49

6 AHEC report, Chapter 3 paragraphs 3.1-3.33

7 AHEC report, Chapter 4 paragraphs 4.1-4.34, Chapter 5 paragraphs 5.1-5.19

8 *On Human Cloning. A position statement*. February 1999, p.6, *Human Stem Cell Research,* 18 April 2001, p.4, *Therapeutic Cloning for Tissue Repair,* Report from a forum held on 16 September 1999, Australian Academy of Science, *Submissions,* p.S245

9 *On Human Cloning. A position statement*. 4 February 1999, p.6, *Human Stem Cell Research,* 18 April 2001, p.4, *Therapeutic Cloning for Tissue Repair,* Report from a forum held on 16 September 1999, Australian Academy of Science, *Submissions,* p.S245

be inhibited by withholding federal funds or prevented by unduly restrictive legislation.[10]

- It is essential to maintain peer and public scrutiny of all research involving human embryos and human embryonic stem (ES) cells undertaken in Australia. The Academy recommends that a national regulatory two-tier approval process be adopted for research on human embryos and human ES cells. Approval to undertake any research involving human embryos and human ES cell lines would need to be obtained from a duly-constituted institutional ethics committee prior to further assessment by a national panel of experts, established by the National Health and Medical Research Council. Approval would be based on the scientific merits, safety issues and ethical acceptability of the work.[11]

3.7 In its conclusions to *Human Stem Cell Research* the Academy stated:

> The Academy of Science continues to promote public discussion on human stem cell research. Scientists are using terms that are not yet understood by the public; community discussion forces clear definition of terminology but can also find new words that are more broadly understood. Social issues should be canvassed during the debate, such as the potential impact on our view of human-kind as medical technology becomes more manipulative, and on attitudes to and by women as potential donors of eggs and embryos for use in tissue repair.[12]

3.8 Both the AHEC report and the Academy agreed that reproductive cloning of an individual should not be permitted; that research in stem cell biology should be facilitated under agreed guidelines; and that public discussion should be encouraged.

CLONING FOR REPRODUCTIVE PURPOSES

3.9 Scientists from whom the Committee received evidence agreed that there is no medical reason for cloning for reproductive purposes to be attempted in humans. There is no evidence that any Australian scientist approves of the use of cloning technologies to create and bring to birth a live human being, or wishes to be engaged in such work.

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10 *On Human Cloning. A position statement*, Australian Academy of Science, 4 February 1999, p.6, *Human Stem Cell Research*, 18 April 2001, p.4, *Therapeutic Cloning for Tissue Repair*. Report from a Forum held on 16 September 1999; Australian Academy of Science, *Submissions*, p.S245

11 *On Human Cloning. A position statement*, 4 February 1999, p.6; *Human Stem Cell Research*, 18 April 2001, p.4; *Therapeutic Cloning for Tissue Repair*, Report from a Forum held on 16 September 1999; Australian Academy of Science, *Submissions*, p.S245

12 Australian Academy of Science, *Human Stem Cell Research*, 18 April 2001, p.26

3.10 While opinion presented to the Committee was overwhelmingly opposed to cloning for reproductive purposes there were two submissions which argued that a ban on cloning for reproductive purposes is not appropriate because views may change with time.[13] These opinions are noted in Chapter 6.

3.11 Despite statements by scientists such as Dr Arthur Caplan[14] that human cloning is not imminent**,** overseas there appears in some quarters to be a race to clone the first human. Dr Severino Antinori (Italy) and Dr Panayiotis Zavos (USA) state they plan to clone a human within a year or two,[15] and in America a religious group, the Raelians, has announced plans to clone a 10 month old child who died in a hospital accident.[16] These claims have been challenged by many scientists around the world who doubt the ability or capacity of these scientists to produce a human clone with current technology, even if it was ethically acceptable.[17]

3.12 In a recent paper, Dr Jaenisch and Dr Wilmut (who produced Dolly) argue strongly against the cloning of whole human beings. Their arguments are based on the high potential risks of chromosomal damage due to rapid reprogramming[18] of the nucleus over a few hours in nuclear transfer techniques, compared to the months or years taken in natural programming during the development of the sperm or the egg. These risks are becoming evident in many studies of animal cloning. These investigators say:

> We believe attempts to clone human beings at a time when the scientific issues of nuclear cloning have not been clarified are dangerous and irresponsible.[19]

3.13 In the USA, the National Bioethics Advisory Commission reached the same conclusion in 1997:

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13 Professor Felix Beck, *Submissions*, p. S684. Dr Loblay was of the view that at some future time there may be pressure from certain groups to use this technology for reproductive purposes but that 'current community values are such as to make this unacceptable.' Dr Loblay, *Exhibit* 8

14 The Committee on Energy and Commerce: Hearing on Issues Raised by Human Cloning Research (USA) March 2001, http://www.house.gov/commerce/hearings/03282001-141/Caplan211.htm

15 http://news.bbc.co.uk/hi/english/sci/tech/newsid_1209000/1209716.stm, 9 March 2001

16 http://www.washingtonpost.com/wp-dyn/articles/A39671-2000Oct9.html, 10 October 2000

17 http://www.Sunday-times.co.uk/news/pages/sti/2001/03/11stifocnws01003.html 11 March 2001

18 Jaenisch, R., and Wilmut, I., 'Don't Clone Humans!' *Science*, Volume 291, 30 March 2001, p.2552

19 Jaenisch, R., and Wilmut, I., 'Don't Clone Humans!' *Science*, Volume 291, 30 March 2001, p.2552

> At present, the use of this technique to create a child would be a premature experiment that would expose the fetus and the developing child to unacceptable risks.[20]

3.14 The scientific evidence accumulated over the past 5 years only reinforces this position. The reasons for genetic or epigenetic (non genetic, environmental conditions etc) damage to cloned animals are not understood.

Safety— Cloning for Reproductive Purposes

3.15 Almost all submissions to the Committee expressed opposition to cloning for reproductive purposes. Many raised concerns about the associated safety and the serious medical risks. In cloned animals these risks are evident in the many abnormal foetuses formed, with a high proportion of miscarriages and deaths soon after birth. Since there is currently very little support anywhere in the world for cloning for reproductive purposes in human beings, the evidence is presented briefly below with references provided to other relevant submissions and publications.

3.16 In a USA government investigation into Issues Raised by Human Cloning Research, Dr Rudolf Jaenisch explained:

> Most new born clones (animals) are overweight and have an increased and dysfunctional placenta. Those that survive the immediate perinatal period may die within days or weeks of birth with defects such as kidney or brain abnormalities, or with a defective immune system.
>
> The most likely cause of abnormal clone development is faulty reprogramming of the genome. This may lead to abnormal gene expression of any of the 30,000 genes residing in the animal.
>
> The experience with animal cloning allows us to predict with a high degree of confidence that few cloned humans will survive to birth, and of those, the majority will be abnormal.[21]

3.17 Many submissions to this inquiry raised concerns about the high failure rate of cloning attempts and the considerable risks of abnormal development, congenital abnormalities and the effects of somatic cell

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20 National Bioethics Advisory Commission, Executive Summary, *Cloning Human Beings*, http://bioethics.gov/pubs.html p.ii, June 1997

21 The Committee on Energy and Commerce: Hearing on Issues Raised by Human Cloning Research, (USA) 28 March 2001, http://www.house.gov/commerce/hearings/03282001-141/Jaenisch202.htm. See also Gurdon, J.B. and Colman, A., *Nature* Volume 402, 16 December 1999, p.744

mutations and aging DNA on the resulting individual.[22] Some of these fears now appear unlikely, for example, the issue of premature ageing.[23]

3.18 Mr Bill Muehlenberg for the Australian Family Association sums up many of these concerns:

> Any attempts at human cloning (which will be much more complex and difficult than sheep cloning) will undoubtedly involve many failed attempts as well. How many embryos will be lost, how much fetal wastage will occur before we arrive at an acceptable success rate for human cloning.[24]

3.19 In summary, the assessment of all those submitting scientific evidence to the Committee and of international scientific sources is that any attempt to clone a whole human individual is premature and should not be permitted. This concurs with lay opinion presented to the Committee. Ethical issues are considered further in Chapters 5, 6 and 7.

CLONING FOR THERAPEUTIC PURPOSES

3.20 The Committee considered the various forms of cell therapy being derived from research. Inherent in these approaches are those that currently require the formation or use of an embryo and derivation of embryonic stem cells; and those, including aspects of adult stem cell research, that do not require embryos. At present there is not a clear definition of these approaches, or of the full capacities of embryonic and adult stem cells.

3.21 The term 'therapeutic cloning' is used generally to describe three distinct approaches:

- somatic cell nuclear transfer, with stem cells being derived from the blastocyst formed by this procedure;
- embryonic stem cell therapies, resulting from cells derived from an embryo, for example, a surplus embryo from IVF procedures; and

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22 Professor Felix Beck, *Submissions*, p.S683. See also AHEC report Chapter 2, paragraph 2.47; Dr Eloise Piercy, *Submissions*, pp.S582-3; Professor Bob Williamson, *Submissions*, p.S347; Social Responsibility Committee of the Anglican Diocese of Melbourne, *Submissions*, p.S304; Ridley College, *Submissions*, p.S32; Australian Academy of Science *On Human Cloning. A Position Statement*, 4 February 1999, p.9; Dr David Gawler, *Submissions*, p.S626; Natalie Ross-Lapointe, *Submissions*, p.S229; Women's Action Alliance (Victoria) Inc. *Submissions*, p.S782; Neil Ryan, *Submissions*, p.S56

23 Roslin Institute Annual Report 1998-99, p.12. Dolly does not appear to be ageing abnormally

24 The Australian Family Association, *Submissions*, p.S695. See also: Ridley College, *Submissions*, p.S32; Natalie Ross-Lapointe, *Submissions*, p.S229

- adult stem cell therapies where an embryo stage is not involved.

3.22 As set out in Chapter 9 in this report, the reference to 'therapeutic cloning' by AHEC is a reference to limited procedures undertaken on an embryo for the benefit of the embryo. This is distinct from procedures undertaken on an embryo for purposes which may benefit other embryos or persons but which destroy the embryo on which the experiment is undertaken. AHEC refers to these procedures as 'non therapeutic cloning'. Although the expressions 'therapeutic' and 'reproductive' cloning are used commonly, the Committee notes that the term 'therapeutic cloning' can be misleading.[25] For this reason the Committee refers to specific procedures rather than using terminology that is ambiguous.

The Potential Importance To Medicine

3.23 In contrast to the wide consensus against cloning for reproductive purposes expressed by international and national organisations and scientists, there was strong support in the scientific community and elsewhere for cloning for purposes of advancing scientific knowledge, with its potential benefits in many areas of human medicine.

3.24 The 1998 AHEC report commented that 'somatic cell nuclear transfer to a mammalian oocyte is still at an early stage of development'.[26] Notwithstanding the major advances made since then, there is much research to be done before the procedures are either understood or safe for clinical application.

3.25 Many submissions to the Committee recognised the potential value and importance of cloning technologies for clinical medicine, particularly for transplantation medicine and pharmaceutical production. A number of submissions, from scientists and others, hailed the breakthroughs in this field as the most significant and exciting of recent times.

3.26 Professor Marilyn Monk said that:

> 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.[27]

3.27 This sense of excitement about the new technologies was shared by Dr Karen Milne:

> The scientific advances that have paved the way for new technologies in IVF, cloning, genetic manipulation and transplant

25 See paragraphs 9-11-9.12 of this report

26 AHEC report, Chapter 2, paragraph 2.23

27 Professor Marilyn Monk, *Submissions*, p.S806

> therapies are scientifically exciting and appear to offer life to those who might otherwise not have survived (or existed).[28]

3.28 Similarly, Professor Alan Trounson, speaking of embryonic stem cells, said that 'the derivation of these cells is one of the biggest breakthroughs in human medicine.'[29]

3.29 Professor Robert (Bob) Williamson of the University of Melbourne stated that while recognising that (reproductive) cloning will be medically unsafe,

> … we recognise that 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.[30]
>
> …stem cell research is extremely important clinically.[31]

3.30 Dr David Gawler saw as laudable:

> The benefits suggested from the production of human ES cells, including studies of normal and abnormal embryogenesis, aging and cancer, gene discovery, drug testing, a source of transplantable tissue and so on…[32]

3.31 In its submission, St Vincent's Hospital also recognised that these techniques 'seem to hold out great benefits both for our understanding of human biology and our capacity to develop therapies for cancer and other pathologies'.[33]

3.32 The Australian Research Council also recognised the clinical and scientific importance of the cloning procedures:

> There are clinically important reasons for carrying out such procedures, for example, tissue and organ replacement, and therapies involving genetically modified but otherwise genetically identical cells. Scientifically, too, study involving such cells and tissues is important. Specifically, an understanding of mechanisms of cell determination and differentiation, genomic imprinting, and somatic cell aging can all be approached using such procedures.

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28 Dr Karen Milne, *Submissions*, p.S68

29 Professor Alan Trounson, *Transcript*, p.5. See also Professor Julian Savulescu, *Submissions*, p.S650

30 Professor (Robert) Bob Williamson, *Submissions*, p.S347

31 Professor Robert Williamson, *Transcript*, p.8

32 Dr David Gawler, *Submissions*, p.S624. See also Caroline Chisholm Centre for Health Ethics Inc., *Submissions*, p.S491

33 St Vincent's Hospital, *Submissions*, p.S152. See also Dr Paul Jewell, *Submissions*, p.S9; Drs Fleming and Pike, *Submissions*, p.S560

> At present, the use of embryonic stem (ES) cells is the most likely source of such material.[34]

3.33 The Human Genetics Society of Australasia recognised 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 currently limited by both immune rejection and by availability of tissue this is an important clinical outcome that could bring great benefit.[35]

3.34 The Law Society of NSW submitted:

> …this new technology will have important medical applications. The cloning of human DNA into other species is likely to be of increasing importance for the production of human proteins with pharmaceutical uses such as insulin.[36]

Some Words Of Caution

3.35 Scientific and public submissions agreed on the substantial potential benefits of these technologies. The greatest benefits may be expected in the field of 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. However, the initial enthusiasm for therapeutic cloning is being replaced in recent months by a more cautious view, illustrated by an article in *Nature:*

> So to the casual observer, it may come as a surprise that many experts do not expect therapeutic cloning to have a large clinical impact. Aside from problems with the supply of human egg cells, and ethical objections to any therapy that requires the destruction of human embryos, many researchers have now come to doubt whether therapeutic cloning will ever be efficient enough to be commercially viable. "It would be astronomically expensive," says James Thomson… who led the team that first isolated ES cells from human blastocysts.[37]

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34 Australian Research Council, *Submissions*, p.S225. See also Dr Julian Savulescu, *Submissions*, p.S655

35 Human Genetics Society of Australasia, *Submissions*, p.S508. See also Richard Dewis, *Submissions*, p.S13

36 Law Society of NSW, *Submissions*, pp.S279-80. See also Richard Dewis, *Submissions*, p.S13; Dr Robert Loblay, Central Sydney Area Health Service (RPAH Zone), *Submissions*, p.S677

37 *Nature*, Volume 410, 5 April 2001, p.622

3.36 Mr Robert Klupacs,[38] stated:

> We do, however, support therapeutic cloning under carefully regulated conditions and then only for research purposes, rather than for ongoing clinical therapies.[39]
>
> We do not envisage that it will ever be feasible, or indeed necessary to incorporate therapeutic cloning, which is a very labour intensive and inefficient process, into a routine clinical treatment.[40]

3.37 There are concerns in the recent scientific literature about the possible use of abnormal embryos[41] for the derivation of cell lines, and about inadequate reprogramming of the nucleus during somatic cell nuclear transfer.[42] There are risks that transplanted cells might develop in an uncontrolled way to form the wrong tissue type or cancers in the transplantation sites.[43] Other issues raised included the questionable integration and normal function of transplanted cells in their new site and the possibility that the original disease process would neutralise the transplanted cells.[44] Basic research is necessary before these issues are understood.

3.38 The evidence emphasised the dilemma between the need for painstaking basic and strategic research when the potential medical and health benefits are being assumed as reality and magnified by the press and public. In the race to compete and develop new therapeutic approaches to major medical problems, several scientists and others underlined the need to proceed with rigorous scientific method and clinical trial procedures.[45] Further pressure for immediate results comes from industry, especially in the USA, where there is no restriction on investment and research in the

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38 Mr Robert Klupacs is General Manager and Chief Executive Officer, ES Cell International Pte Ltd

39 Mr Robert Klupacs, *Submissions*, p.S892

40 Mr Robert Klupacs, *Submissions,* p.S893

41 Professor Robert Norman emphasised that in his opinion, the majority of embryos derived from IVF are genetically normal. Professor Robert Norman, *Transcript*, p.104, Dr John Smeaton, *Transcript*, pp.160- 161

42 Jaenisch, R., and Wilmut, I., 'Don't Clone Humans!' *Science*, Volume 291, 30 March 2001, p.2552

43 Dr Eloise Piercy, *Submissions,* p.S582. See also World Federation of Doctors Who Respect Human Life, *Submissions,* p.S800; David Elder, *Submissions*, p.S199

44 World Federation of Doctors Who Respect Human Life, *Submissions*, S.801; Ms Maryke Vaartjes, *Submissions,* p.S128; Dr Peter McCullagh, *Submissions*, p.S315. AHEC report; Chapter 2, paragraphs 2.46-2.47

45 Dr Peter McCullagh, *Submissions*, p.S313; Professor Robert Norman, *Transcript*, p.73; Ethics Committee, Royal Australasian College of Surgeons, *Submissions*, p.S568

private sector. Federal funding, which supports public sector research, cannot be used for research on embryos.

Embryonic Stem Cell Research

3.39 Research is now being focused on mouse, monkey and human pluripotential stem cells, in order to guide differentiation to specific cell types in culture with the ultimate aim of providing cells and tissue for the repair of damaged and diseased organs. There have been several successes in animal models: embryonic stem cell-derived cardiac muscle cells were incorporated successfully into damaged rat hearts, and neural cells into the brain of a mouse model of multiple sclerosis.[46] Immature nerve cells derived from mouse embryonic stem cells and transplanted into the damaged spinal cords of rats partially restored spinal cord function.[47]

3.40 Embryonic stem cell research also offers insights into developmental events that cannot be studied directly in the intact human embryo. They can be used to identify targets for new drugs, elucidate mechanisms that facilitate the efficient differentiation of embryonic stem cells to specific cell types, and provide an unlimited source of cells for drug discovery and transplantation therapies.

3.41 Professor Peter Rathjen pointed out that:

> …using embryonic stem cells potentially gives us the ability to produce any kind of cell in any number with any genetic modification, and that potentially opens the opportunity to treat diseases which are currently inaccessible to us.[48]

3.42 Associate Professor Martin Pera spoke of the application of embryonic stem cell technology as he sees it in four areas:

> …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…[49]

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46 *Science*, Volume 288, 9 June 2000, p.778

47 *Science*, Volume 286, 3 December 1999, p.1826

48 Professor Peter Rathjen, *Transcript*, p.65

49 Associate Professor Martin Pera, *Transcript*, pp.5-6. See also Professor Julian Savulescu, *Submissions*, p.S649

3.43 The AHEC report identified the benefits to be anticipated from the production of human ES cells 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.[50]

3.44 Associate Professor Pera predicted that embryonic stem cell technology is

> …going to have a major impact on biotechnology and on the pharmaceutical industry. It is likely through transplantation medicine to have a major role in what is now called regenerative medicine. …there will be likely spin-offs in agriculture and agricultural biotechnology as discoveries in human ES cell biology are applied to other species. [51]

3.45 Much of the evidence and discussion of embryonic stem cells recognised the value and the significant potential benefits of basic and strategic research on pluripotency of cells and the regulatory steps in cell lineage development. Research to find the cell signals and triggers that govern differentiation may provide alternatives to therapies using the cells, but the stem cell research has to be completed in order to find and characterise these factors. As this inquiry concludes, the pace of the research continues to increase.

Adult Stem Cell Research

3.46 There is growing evidence that many adult organs contain stem cells which retain their ability to divide and transform into a range of different cell types as and when the need arises. This process occurs under the influence of biochemical signals that are not yet understood. The hope is that adult stem cells, like embryonic stem cells, may also be exploited to generate cells for transplantation which are not rejected.[52] Ideally they could be harvested from a patient, grown and multiplied into the desired

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50 AHEC report, Chapter 2, paragraph 2.27

51 Associate Professor Martin Pera, *Transcipt*, p.6

52 Dr Peter McCullagh supports as an alternative approach to solving the tissue transplantation problem the use of adult stem cells. He notes that *Science* identified the production of stem cells for particular tissues as being 'the breakthrough of the year'. Dr Peter McCullagh, *Transcript*, p.67

cell types and used to repair diseased or damaged cells or tissues. The avoidance of an embryo stage would be a major added benefit.

3.47 Research in the areas of identification of adult stem cells is advancing rapidly. Professor Rathjen noted however:

> Even where adult stem cells have been defined rigorously and can be identified *in vivo* and *in vitro*, there have generally been considerable difficulties in maintaining these cells in an undifferentiated state *in vitro*, and in achieving long term and efficient proliferation. It is therefore difficult to grow sufficient cells for therapeutic transplantation. …In the absence of proliferation, effective genetic manipulation of adult stem cells cannot be achieved.[53]

3.48 There is a growing understanding that adult stem cells may be more flexible than previously thought. Recent research has shown that adult stem cells can differentiate into developmentally unrelated cell types such as nerve cells into blood cells.[54] According to Drs Fleming and Pike of the Southern Cross Bioethics Institute:

> Lineage defined progenitor cells [stem cells] in adult tissues may be more plastic than hitherto thought. They might have the capacity to de-differentiate, or be reprogrammed, becoming totipotent stem cells.[55]

3.49 Preliminary research indicates that bone marrow stem cells appear to be very versatile forming brain and muscle cells and liver cell precursors.[56] Brain stem cells in mice have been shown to be surprisingly flexible, becoming nearly every tissue in the body.[57] Adult neural (brain) stem cells previously thought to be committed to becoming various types of nerve cells can de-differentiate and become blood cell precursors.[58] Liver cells have been derived from human blood stem cells.[59]

3.50 According to a House of Commons Research paper, umbilical cord blood which has the advantage of being readily available, is rich in stem cells but these appear to have limited ability to differentiate, that is, they may only

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53 Professor Peter Rathjen, *Submissions*, p.S766. See also Associate Professor Martin Pera, *Transcript*, p.6

54 'Adult stem cells may be redefinable', *British Medical Journal*, Volume 318, 30 January 1999, p.282

55 Drs Fleming and Pike, *Submissions*, p.S563

56 *Science*, Volume 287, 25 February 2000, pp.1419-1419

57 'Generalized Potential of Adult Neural Stem Cells', D.L.Clarke et al., *Science*, Volume 288, 2 June 2000, pp.1660-1663

58 *Science* , Volume 283, 22 June 1999, pp.534-537

59 *Nature*, Volume 406, 20 July 2000, p.257

produce blood cells or bone marrow cells. Some foetal tissues are also rich in stem cells.[60]

3.51 The paper went on to say that stem cells from cord blood and foetal tissue

> … are already partially committed in development, and it is as yet uncertain what potential exists for differentiation of foetal and umbilical cord blood stem cells into different tissue cells other than those from which they were derived. In the future it may be possible to change the programming of these stem cells so that they mature into other types of tissue.
>
> Stem cells from primitive sex cells of foetuses up to about 6 weeks of development (that are destined to develop into eggs and sperm) have a greater potential to differentiate. They have a similar capacity to develop into other kinds of tissues as embryonic stem cells—they could be termed pluripotent.[61]

3.52 The Royal Society urged that 'the potential of umbilical cord stem cells should be explored vigorously as a high priority' but pointed out the disadvantages of adult stem cells:

> …they are small in number and often hard to access. By the time they have been multiplied up in culture to a therapeutically useful stock of cells their proliferative lifespan may have become dangerously short.[62]

3.53 The AHEC report considered:

> A possible advantage, for transplantation, of stem cell lines with a restricted capacity to differentiate only into the cells normally occurring in a single organ system is that it might reduce the risk of development of mature cell types, inappropriate for the location in which the stem cells were implanted.[63]

3.54 While embryonic stem cells tend to differentiate spontaneously into all kinds of tissue, adult stem cells do not spontaneously differentiate but can be induced to do so by applying appropriate growth factors or other external cues. However, one drawback of adult stem cells is that some seem to lose their ability to divide and differentiate after a time in culture. This short life span might make them unsuitable for some medical applications.[64]

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60 House of Commons Research Paper 00/93, (United Kingdom) 13 December 2000, p.22

61 House of Commons Research Paper 00/93, (United Kingdom.) 13 December 2000, pp.22-23

62 *Stem Cell Research- second update*, Policy document 9/01, June 2001, p.2, www.royalsoc.ac.uk

63 AHEC report, Chapter 2, paragraph 2.38. See also Dr David Gawler, *Submissions*, p.S625

64 *Science*, Volume 287, 25 February, 2000, p.1419

3.55 There were concerns expressed in evidence to the Committee that stem cells, including embryonic stem cells, which have an inherent capacity for proliferation are aberrant. The World Federation of Doctors Who Respect Human Life considered:

> Before the full potential of neural stem cells can be realized, we need to learn what controls their proliferation, as well as the various pathways of differentiation available to their daughter cells.
>
> The definition of a cell with a capacity for prolonged proliferation with retention of its undifferentiated form, could be that of a cancer cell.[65]

3.56 Examples of adult stem cell research include the isolation and growth of human mesenchymal stem cells that have been made to develop into fat, tendons, muscle and bone marrow cells,[66] and stem cells isolated from fat removed by liposuction have been grown into muscle, cartilage and bone cells.[67] Neural stem cells have recently been extracted from the brains of mice and, under specific conditions in the laboratory, been made to differentiate into muscle cells. According to the scientists involved this is the first 'unequivocal' evidence that adult stem cells, like embryonic stem cells, could develop into different tissue types.[68]

3.57 The Spinal Cord Society, a consumer based organisation with members in over 37 countries around the world, has developed a technique for growing human adult neuronal stem cells for treatment of Parkinson's disease. It has received approval from the US Food and Drug Administration (FDA) to proceed to a Phase II clinical trial. The Society is also attempting to derive neuronal (nerve) cells from bone marrow cells and hopes to derive stem cells from even more convenient sites, such as skin, and is also stimulating stem cells *in situ* by altering the local micro-environment of cells, leading to differentiation and repair *in situ*.[69]

3.58 Biochemical cues for transformation and control of adult stem cells are poorly understood. Better understanding of how to control adult stem cells is crucial for their prospects in regenerative medicine or tissue

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65 World Federation of Doctors Who Respect Human Life, *Submissions*, S.800. See also David Elder, *Submissions*, p.S199

66 Dr Mark Pettinger and colleagues at Osiris Pharmaceuticals and the Johns Hopkins School of Medicine. *Science*, Volume 284, No. 5411, 2 April 1999, pp.143-146

67 Patricia A. Zuk *et al*, 'Multilineage cells from Human Adipose Tissue: Implications for Cell-Based Therapies'. *Tissue Engineering*, Volume 7, No.2, pp.211-228

68 *Nature*, Volume 412, pp736-739 (2001); *Sydney Morning Herald*, 16 August 2001, p.1, referring to Dr Perry Bartlett of the Walter and Eliza Hall Institute of Medical Research, Melbourne. Earlier work demonstrated that mouse neural stem cells could change into blood cells

69 Spinal Cord Society, *Submissions*, pp.S853-54, *Exhibit* 32

replacements and this understanding may depend on embryonic stem cell research. The AHEC report comments that the state of knowledge in relation to the control of development of most specialised tissues is still confined to interpreting the events that occur in normal development rather than attempting to mimic this *in vitro*. It suggested that:

> It is likely "organiser" molecules secreted by one cell type with the ability to influence the development of adjacent cells are of major importance in development of specialised tissues.[70]

3.59 This appears to be supported by recent research. An Italian group led by Drs Vescovi and Cossu reported in *Nature Neuroscience:*

> …that nerve stem cells from an adult were more flexible than thought and could give rise to skeletal muscle. When placed in contact with other neural stem cells, they give rise to neurons and glia. … But neural stem cells in contact with muscle gave rise to muscle.[71]

3.60 Dr Vescovi, co-director of the Institute for Stem Cell Research in Milan, stated:

> "…we are far from showing that adult stem cells equal embryonic stem cells with respect to their growth potential and plasticity". … It was not possible to say whether any adult stem cell could turn into any tissue, depending on where it was in the body. … I hope, though, that this is the case. "The implications for therapy of human diseases would be astounding…"[72]

3.61 Adult stem cells may offer advantages over embryonic stem cells in that ideally they could be harvested relatively simply (compared to somatic nuclear transfer to form an embryo) from patients, transformed in the laboratory and transferred back to patients. Such auto-transplants would avoid both graft rejection problems and risks of graft to host viral infection.

3.62 Although there are many advocates for the adult stem cell approach and recent reports in the media suggest that this research is advancing rapidly, many scientists agree that embryonic stem cell research is, for the time being, crucial to further understanding and progress. They dispute the assertion that adult stem cells will replace embryonic stem cells in their importance for either basic or applied studies in the near future. The American Academy for the Advancement of Science wrote to President Bush:

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70 AHEC report, Chapter 2, paragraph 2.41

71 House of Commons Research Paper 00/93, p.24. (United Kingdom)

72 House of Commons Research Paper 00/93, p.24. (United Kingdom)

> One of the misconceptions held by some is that study of adult stem cells will be sufficient to realize the medical promise of this line of research. But the prevailing view of expert scientific opinion is that it is far too early to know if adult stem cells have the same potential as embryonic stem cells. It is important to convey to the public the limitations of the research on adult stem cells. It is likely to take years to discover whether adult stem cells will be effective in treating many diseases that may be treatable sooner with embryonic or fetal stem cells.[73]

3.63 A similar view is expressed by Irving L.Weissman and Nobel Laureate David Baltimore:

> Although HSCs (Haematopoietic Stem Cells) capable of regenerating the blood can be isolated from adults or fetuses, so far brain stem cells capable of robust growth and transplantability have come only from fetal or ESC (Embryonic Stem Cell) sources. This is likely to be true for a number of tissues; fetal stem cells are much more active than postneonatal cells. A moratorium on research and / or transplantation of fetal stem cells could thus be devastating. As for the search for pluripotent adult stem cells, it is always possible, perhaps even likely, that further research might reveal a source. But that is simply a hope, and it would be foolish to abandon the surer path for the unproven one.[74]

3.64 The Royal Society also believes that:

> …adult stem cell research and embryonic stem cell research **are not alternatives** and **both** (emphasis in original) must be pursued. In all likelihood each will yield distinctive therapeutic benefits but (i) we cannot predict which will be first or better and (ii) work on one system may help work on the other.[75]

Transdifferentiation Or Dedifferentiation

3.65 Somatic cell nuclear transfer and the derivation of embryonic stem cells provide one method for obtaining tissue for repair and transplantation. Adult stem cell technologies may provide another. Alternative technologies suggested by the Australian Academy of Science included full or partial reversal of differentiation of adult cells.[76]

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73 http: / / www.aaas.org / spp / dspp / sfrl / projects / stem / bushltr.htm, 6 March 2001.

74 Weissman, I. L., and Baltimore, D., *Science* ,Volume 292, 27 April 2001, p.601

75 *Stem Cell Research- second update*, Policy document 9 / 01, June 2001, www.royalsoc.ac.uk

76 Australian Academy of Science *On Human Cloning. A position statement*, 4 February 1999, p.15

3.66 Transdifferentiation or dedifferentiation, (full or partial reversal of differentiation) is the process of taking an adult cell of one tissue type and, through a cellular process yet to be understood, reprogramming it to form a different type of tissue for transplantation. Associate Professor Pera said of this possibility:

> There are some very exciting recent advances in that area and it has some potential, but I have to point out to you that the mechanism, and even a basic phenomenology of what is going on in these experiments, is very poorly understood at present and it may be a long time before we know how to control that process.[77]

3.67 Professor Rathjen stated:

> There is therefore some reason to believe that pluripotent cells might ultimately be attained by direct dedifferentiation of somatic cells. This would provide a route to generation of ES cells in the absence of embryonic intervention. [78]

3.68 Professor Rathjen referred in his submission to worldwide interest in cell 'deprogramming':

> Publications already show "dedifferentiation" of adult CNS stem cells into neural lineages in rat neonates, differentiation of bone marrow to hepatic lineages and skeletal muscle following transplantation, and differentiation of cells derived from skeletal muscle to haemopoietic cells *in vivo*. The initial results therefore support the contention that microenvironments within the mammal retain signals that can direct the fate of transplanted cells to a locally appropriate outcome.[79]

3.69 The submissions and evidence show the growing worldwide research effort that is being directed towards the understanding of differentiation and transdifferentiation of many cell types. It may be some time, however, before scientists know how to control the process.

RESEARCH INVOLVING HUMAN EMBRYOS

3.70 Although a great deal of effort is being invested in new technologies to avoid the use of embryos, it is not possible yet to study early differentiation, cell lineage choice and multipotency without embryo-derived stem cells. Consequently, the derivation of embryonic stem cell

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

78 Professor Peter Rathjen, *Submissions*, p.S767

79 Professor Peter Rathjen, *Submissions*, p.S767

lines will involve the use of embryos until adequate alternatives are developed.

3.71 Professor Trounson noted:

> There is no way in which anybody can derive the base cell lines that are of interest through any other way than making embryonic stem cells.[80]

However, the needs may be limited:

> If we want to derive four new lines of embryonic stem cells we would theoretically use eight embryos and we would not really want to use any more ever again. We would have enough cells there to supply all the research institutes in Australia, and probably world-wide…[81]

3.72 Mr Robert Klupacs submitted that the use of embryos beyond the derivation of initial cell lines would be limited. The patient could be treated with new anti-rejection drugs or immunised with their own antigens to overcome the immunological incompatibility between donor and recipient.[82]

> Our aim is to produce stem cells which can be used as "Universal Donors". That is, they can be derived from couples who have donated excess embryos after the completion of IVF treatment for the purpose of creating stem cells which can then multiply into large numbers and be used for transplantation into anyone requiring treatment…
>
> The "Universal Donor" approach means that the cell lines which we currently have which have been derived from only 12 embryos, will most likely be sufficient to provide cell therapies for Australia and other countries. It is unlikely that any further embryos will ever be required.[83]

3.73 The Committee queried claims that a limited number of stem cell lines can supply all demands and therefore no new research on embryos will be required. These claims ignore the related issues of a potential monopoly position[84] of cell lines and the associated intellectual property. Before

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80 Professor Alan Trounson, *Transcript*, p.5

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

82 Mr Robert Klupacs, *Transcript*, p.187

83 Mr Robert Klupacs, *Submissions*, pp.S892-893

84 http://theage.com.au/news/state/2001/08/28/FFXIZRRBVQC.html There is already resentment amongst US scientists over the control that Geron Corporation, the biotechnology company that claims it has "worldwide exclusive commercial rights" to stem cells, seeks over their work

clinical applications could be developed for specific individuals and specific diseases, it is likely that more embryos will be necessary unless new research obviates the need for embryos as a source of cells.

3.74 Stem cells derived from embryos are essential for research aimed at understanding early human developmental processes and disorders thereof and potential new contraceptive approaches. According to Associate Professor Pera:

> These early embryonic cells may be the only way to identify new factors that are active on early, very primitive, progenitor cell populations… Finally and most importantly, basic research on embryonic stem cells will teach us what pluropotentiality is. What is a primitive undifferentiated cell? What gives it the ability to turn into all those types of adult tissues? It is really this basic research, perhaps the identification of key genes that control that feature of embryonic stem cells, that may eventually teach us how to eliminate the need for embryos and how to reprogram adult cells.[85]

3.75 Currently, somatic nuclear transfer resulting in an embryo stage is the only way to derive deprogrammed cells. New techniques are being researched and developed, for example, *New Scientist* reports that a type of mouse white blood cell was deprogrammed following fusion with a mouse embryonic germ cell.[86] Professor Rathjen alluded to research in this direction:

> …many scientists are hopeful that it will prove possible to revert a somatic nucleus to a more primitive, pluripotent state by intercellular nuclear transfer. This would occur in the absence of oocyte injection and creation of a viable embryo.[87]

3.76 In summary, alternative sources for the derivation of pluripotent or multipotent cells may become available. It is unclear when this will happen, or if such availability will remove or reduce the need for embryos in stem cell research.

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

86 *New Scientist*, 29 January 2000, p.4

87 Professor Peter Rathjen, *Submissions*, pp.S767-768

SUMMARY

3.77 The Committee considered the AHEC report and recognised the thoroughness of its review. It noted that a great deal of progress and new discovery has been made in the science since the report was published.

3.78 The Committee noted the recent scientific breakthroughs that have shaped this field, the very rapid pace of current scientific development and the prospect for further new discovery and applications. In particular, the Committee agreed that current knowledge and definitions may change further as a greater understanding of the fundamental principles in cell and developmental biology is achieved.

3.79 Although the scientific basis of this new field is becoming established, many other facets of cell regulation and transdifferentiation may be found. New approaches may remove the need to use embryos and embryonic stem cells, while identification of cell signals and triggers of differentiation may form the basis of new therapies. Consequently, the monitoring and further review of the field, by a delegated authority at appropriate intervals, will be necessary.

4

The focus of international and Australian scientific research

INTRODUCTION

4.1 The scientific advances with the birth of Dolly (1996)[1] and the isolation of human embryonic stem cells (1998)[2] focused immediate international attention on the scientific, medical, intellectual property and industrial opportunities now available. In the few years since, the field has expanded exponentially as demonstrated in the previous two chapters. This chapter summarises the status of the field at the time the report was written and indicates the balance required between basic and applied dimensions of the research. The examples provided below are a small selection illustrating work in progress.

United Kingdom

4.2 Cloning research in Britain is likely to increase dramatically since Parliament extended the purposes for which a licence to derive embryonic stem cells and to form embryos for cloning research and therapeutic technologies can be obtained.[3]

4.3 Some examples of work being carried out in the United Kingdom are given below:

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1 Wilmut, I, *et al, Nature*, Volume 385, 27 February 1997, p.810

2 Thomson, J.A. et al, *Science*, Volume 282, 6 November 1998, pp.1145-1147

3 For more detail on the system of regulation in the UK see Chapter 10, from paragraph 10.73

- At the Roslin Institute in Scotland, Geron Bio-Med, a British subsidiary of Geron Inc (USA) was established to exploit research using cloning technology to create replacement tissues and organs for diseases such as Alzheimer's and Parkinson's.[4]
- PPL Therapeutics, has been given a licence to use the Roslin Institute's patented technology to create pharmaceuticals in the milk of animals. PPL announced in February 2001 that it has been able to demonstrate the possibility of producing multipotential stem cells without the need to go through an embryo stage. PPL's initial commercial target for its stem cell research is the production of insulin producing pancreatic islet cells.[5]
- At London's Imperial College School of Medicine researchers have recently shown that liver cells can be derived from human blood cells.[6]
- In other initiatives reported recently, British scientists are planning to inject stem cells into the brains of stroke patients. If this approach is successful, the technique will be used to treat Parkinson's disease and Alzheimer's. It is predicted there will be new therapies and drugs on the market within six years.[7]

United States of America

4.4 Funding and regulation of human embryo and embryonic stem cell research in the USA is discussed in Chapter 10.[8] There are many privately and publicly funded laboratories working in stem cell biology in the USA. Examples of current work include:

- Dr James Thompson at the University of Wisconsin, the first investigator to isolate human embryonic stem cells, is focusing on the factors that promote ES cell renewal as well as the differentiation of primate ES cells to haematopoietic and neural cells. Human embryonic stem cells developed in Wisconsin have now been distributed to over 30 institutions in the USA and elsewhere.[9]

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4 Roslin Institute, Annual Report 1998-99, p.15

5 PPL claims that they reverted fully differentiated bovine skin cells to stem cells first and then transformed these into a distinct population of heart cells. Their next challenge is to repeat the findings using human cells. Press release, 23 February 2001

6 *Nature*, Volume 406, 20 July 2000**,** p.257

7 House of Commons Research Paper 00/93, (UK) p.48

8 See paragraphs 10.44-10.71

9 Thomson, J.A. *et al.*, 1998, Neural differentiation of rhesus embryonic stem cells, *AMPHIS*, 106: 149-157; Kaufman *et al*, (2000) Transplantation therapies from human embryonic stem cells-circumventing immune rejection, *Regen. Med.* 1: 1-5; Odorico *et al.* (2001) Multilineage differentiation from human embryonic stem cell lines, *Stem Cells* 19: 193-204; Kaufman, D.S. *et*

- Dr Thomas B. Okarma, President and CEO of Geron Corporation, said that Geron uses cloning technology for purposes including regenerative medicine, predictive toxicology and drug discovery.[10]
- At the Johns Hopkins School of Medicine in Baltimore, Dr Gearhart has isolated human embryonic germ (EG) cells and demonstrated that they are pluritipotent.[11]
- David Anderson and his colleagues at the Californian Institute of Technology claim to have identified many environmental triggers that stimulate the nervous system's stem cells to turn into neurons or supporting glial cells. According to a report in *Time* they have also isolated the genes responsible for the transformation.[12]
- At the University of California in San Francisco Dr Roger Pedersen has directed the differentiation of embryonic stem cells into cardiac muscle.[13] He has announced recently that he will move to Cambridge University in the UK due to restrictions on embryonic stem cell research in the USA.
- Researchers in New Jersey claim they can produce an almost unlimited supply of nerve cells to repair patients' own bone marrow stem cells.[14]
- Massachusetts General Hospital reports a new technique for isolating human adult stem cells[15] and has identified a key protein that appears to control the development and proliferation of haemopoietic stem cells.[16]
- The Jones Institute of Reproductive Medicine (private sector) in Norfolk, Virginia, announced that it has bought eggs from women volunteers and created human embryos for the sole purpose of harvesting ES cells.[17]

4.5 The size of the American science base, both public and private, together with its adaptability and speed allows hundreds of laboratories to work

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al. Hematopoietic colony forming cells derived from human embryonic stem cells, *Proc. Natl. Acad. Sci.U.S.A.*, in press

10 The Committee on Energy and Commerce: Hearing on Issues Raised by Human Cloning Research (USA) March 2001, http://www.house.gov/commerce/hearings/03282001-141/Okarma200.htm

11 *Time*, 1 May 2000, p.55, http://www.jhu.edu/gazette/2001/jan0801/08stem.html

12 *Time*, 1 May 2000, p.55; Stemple, D. L. and Anderson, D. J., 1992, 'Isolation of a stem cell for neurons and glia from the mammalian neural crest', *Cell* 71, 973-985

13 *Time*, 1 May 2000, p.54

14 *Journal of Neuroscience Research*, 15 August 2000

15 *New Scientist*, 19 August 2000, p.5 and p.16

16 *Science*, Volume 287, 10 March 2000, pp.1804-1808

17 *Nature*, Volume 412, 19 July 2001, p.255

on basic and clinical aspects of cloning and stem cell biology. The leading weekly journal, *Science*, seldom appears without new reports in this field.

Elsewhere

4.6 Other laboratories in many countries around the world are active in the field and are contributing significant new knowledge and approaches. For example:

- The Institute for Stem Cell research in Milan focuses its research program on adult stem cell differentiation.[18]
- Hadassa University in Israel and the National University of Singapore have both derived embryonic stem cells from surplus IVF embryos and are building active research programs, including links with the Monash Institute for Reproduction and Development.[19]
- At the Netherlands Institute of Developmental Biology in Utrecht researchers are working on aspects of embryonic stem cell differentiation particularly into cardiomyocytes (heart muscle cells).[20]
- In Japan, Amgen Ltd is carrying out research aimed at understanding self renewal and differentiation mechanisms of stem cells including haematopoietic stem cells, neural stem cells and embryonic stem cells. It is also developing methods to regulate functions of stem cells.[21]
- A group of researchers at the Karolinska Institute in Stockholm, Sweden, including Jonas Frisen, is working with adult stem cells. Research demonstrated that adult mouse brain stem cells injected into early chick and mouse embryos gave rise to cells of various types and contributed to the generation of tissues and organs of all germ layers including heart, liver, intestine and nervous system.[22]

4.7 However, the culture and maintenance of human embryonic and adult stem cells is still a difficult art, performed well in relatively few laboratories.

18 *House of Commons Research Paper* 00/93, p.24 (UK)

19 Pera, M.F (2001) *Human stem and precursor cells*, Cold Spring Harbor Laboratory Symposium

20 Mr Robert Klupacs, *Transcript*, p.179

21 http://www.ims.u-tokyo.ac.jp/stem/

22 *Science*, Volume 288, 2 June 2000, pp.1660-3

CURRENT AUSTRALIAN RESEARCH, ITS INTERNATIONAL STANDING AND FUTURE DIRECTIONS

4.8 Australian science has held a leading international role in assisted reproductive technologies from which the new fields of cloning and stem cell technologies have developed. Many scientists involved in cloning research consider that Australia has a leading role to play in these new technologies and that Australia stands to benefit from the ultimate commercial applications of new therapies arising from this research.[23] According to Associate Professor Pera:

> Australia, as a whole, has a longstanding track record in reproductive biology, growth factor and stem cell research. Although the developmental biology community here is small, it is of very high quality and makes very significant contributions on the international scale.[24]

4.9 Dr Tolstoshev[25] submitted:

> There is a real chance that Australian organisations could take a leadership position in this field. It is also important to appreciate that the ultimate commercial impact of such new therapies could be very large.[26]

4.10 Some examples of research in Australia include:

- At the University of Adelaide, Professor Peter Rathjen's group is studying embryonic stem cell differentiation in mouse and human stem cell model systems with a view to defining cell signals.[27]
- At Monash University, Professor Alan Trounson's group has a comprehensive research program in stem cell biology including human and animal research. The Monash group has established four human embryonic stem cell lines, from cells extracted by colleagues in Singapore and derived in compliance with NIH guidelines.[28]
- An Australian biotechnology company, BresaGen Ltd, is supporting and financing a program at the University of Adelaide whose main focus is to develop more effective cell-based treatments for Parkinson's

23 Professor Peter Rathjen, *Transcript*, p.65; Professor Alan Trounson, *Submissions*, p.S170. Similar views expressed by Dr Paul Tolstoshev, General Manager, Cell Reprogramming Division, BresaGen, *Submissions* p S822; Professor Peter Rathjen, *Submissions*, p. S767

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

25 Dr Paul Tolstoshev, General Manager, Cell Reprogramming Division, BresaGen Ltd

26 BresaGen Ltd, *Submissions*, pp. S822-823

27 Professor Peter Rathjen, *Transcript*, p.65

28 Professor Alan Trounson, *Transcript*, pp.4, 5

disease and other neurological disorders. Another area of interest is bone marrow replacement in cancer. BresaGen has combined with CytoGenesis Inc (USA), bringing together two researchers in cell therapeutics, Dr Steve Stice of the University of Georgia and Professor Peter Rathjen of the University of Adelaide and Scientific Director of BresaGen's Cell Therapy Program.[29]

- A Melbourne-based company, Stem Cell Sciences is reported as having inserted human DNA into pig eggs to investigate whether a human nucleus will divide in a foreign cell. Dr Peter Mountford[30] is quoted as saying that embryos made this way developed to the 32 cell stage.[31]
- The Peter MacCallum Cancer Institute in Melbourne is focusing research on adult or somatic stem cells aimed at developing clinical applications.[32]
- ES Cell International Pte Ltd, a joint venture company registered in Singapore but with management operations based in Melbourne, is funding research in a number of centres around the world. The focus of their research is embryonic stem cells for use in transplantation medicine and for discovery of genes and factors controlling the differentiation of embryonic stem cells.[33]
- At the Walter and Eliza Hall Institute of Medical Research in Melbourne scientists have isolated adult neural stem cells from the brains of mice and directed their differentiation into muscle cells.[34]

Funding Of Stem Cell Research In Australia

4.11 Major laboratories in Australia have a mixture of public and private sector support. Sources of funding include the host university, program and project grants from the National Health and Medical Research Council (NHMRC) and Australian Research Council (ARC), private funding from industry, venture capital and medical charities and overseas sources. In addition several laboratories have established close links with commercial companies, based in Australia and abroad.

4.12 At the centre of the funding issue is the protection of discovery through patenting strategies. Patented intellectual property gives value to the discovery and can be marketed to national or international companies

29 Press Release, 7 September 2000, BresaGen, *Submissions,* p.S822 and *Exhibi*t 21

30 Dr Peter Mountford, Chief Executive Officer, Stem Cell Sciences

31 *The Weekend Australian*, 17-18 March 2001, p.26

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

33 Mr Robert Klupacs, *Transcript*, p.169

34 *Nature*, Volume 412, pp.736-739, *Sydney Morning Herald*, 16 August 2001, p.1

through licensing agreements. Although it is likely that much of the commercialisation of cloning and stem cell technologies will be developed abroad, a strong patent position for Australian 'inventors'will ensure the eventual return of some of the proceeds to Australia.

4.13 In Australia, as for elsewhere in the world, the pace of research is such that future directions and results are impossible to specify. This pace, and the acquisition of intellectual property attached to new discoveries will depend on the continuing competitiveness of Australian research groups and their participation and collaboration with the global research enterprise.

Timeframe For Results

4.14 New avenues for improving the efficiency of cloning procedures, together with new discoveries of the underlying cell regulatory processes, suggest that progress will be rapid. It is difficult to predict time frames to results and clinical application other than in broad terms. Associate Professor Pera submitted that, subject to regulatory approvals:

> …the first set of objectives, basic research on human development, is already happening. We are already using the cell lines to identify new genes expressed in early human development. I think within the next one to 10 years we will see the identification of factors active in tissue regeneration and repair. The *in vitro* models for drug discovery and toxicology will come on line perhaps in two to three years time, and I think transplantation is really the longest goal in terms of time frame and we will see that happening within perhaps five to 10 years before the beginning of clinical applications.[35]

4.15 Dr John Smeaton indicated that treatment of patients with their own (genetically compatible) cells is still a long way off but some therapies using donor cells may begin clinical trials in 2-3 years.[36]

4.16 Dr Robert Loblay of Central Sydney Area Health Service (RPAH Zone) made a five to ten year projection for results, assuming rapid progress in overcoming technical hurdles.

> Consequently, I believe there will be an explosion of knowledge in cellular and molecular biology over the next few years. … I expect that *in vitro* cloning of human cells and tissues will become rapidly

35 Associate Professor Martin Pera, *Transcript*, pp.5-6. See also Professor Roger Short, *Transcript*, p.7

36 Dr John Smeaton, *Transcript*, p.157. Dr Smeaton is Chief Executive Officer and President, BresaGen Ltd and BresaGen Inc.

> feasible. My guess is that organs will be more difficult to produce in culture.[37]

4.17 The Royal Society, in *Stem Cell Research—second update*[38] predicts:

> …that time-scales for the use of stem cells may well be shorter than those anticipated ….[39] However, two points should be emphasised: (i) the occurrence of unexpected adverse reactions to stem cell transfer (eg tumour formation or the loss of cell function or control) would seriously delay the exploitation of these therapies; and (ii) that time-scales for realising medical advantages of stem cell therapy are likely to be different for different organs (eg brain repair therapies are likely to take longer to develop than islet cell replacement in the pancreas). Time-scales are always difficult to predict. Adult stem cells are already in routine use, in the form of bone marrow transplants and it is likely that the first clinical trials (probably in the USA) of both adult and embryonic stem cells will take place within the next 5, certainly 10 years.

Scientific Method And Animal Research

4.18 The AHEC report recommended the support of research in animals, including the establishment of a primate research facility for cloning and stem cell research in Australia.[40] The Committee noted the views of witnesses in oral evidence and in the submissions, arguing both sides of this issue.

4.19 The views ranged from support for a primate facility in order that normal scientific inquiry could be pursued with non-human primate embryos, to opposition to a facility, because adequate animal research has been completed and the research can now be done on humans.

4.20 Most of the scientists who made submissions to the inquiry considered that there is no benefit in the use of non-human primates in this research and that the establishment of a non-human primate facility is not the best way of using limited resources. Associate Professor Pera stated:

> The proposed initiative for non-human primate ES cell and cloning research is not justified: funds should be committed to research on human cells. …there is no benefit to the use of non-

37 Central Sydney Area Health Service (RPAH Zone), *Exhibit* 8

38 *Stem Cell Research - second update*, Policy document 9/01, June 2001, www.royalsoc.ac.uk

39 In *Therapeutic Cloning* and *Stem Cell Research and Therapeutic Cloning: an update*. Both documents are available at www.royalsoc.ac.uk. In *Stem Cell Research and Therapeutic Cloning: an update,* the Royal Society stated 'it might be several decades before we achieve a full understanding of how the specialised state of cells is achieved and maintained'

40 AHEC report, Chapter 1, paragraphs 1.23 and 1.24

> human primates for such research. Many potential benefits of human ES research will stem from *in vitro* studies which carry no risks whatsoever to patients. The safety of human ES cells in transplantation applications will be addressed chiefly by *in vivo* studies in immunocompromised hosts such as SCID or nude mice, where for instance the potential for tumour formation, and the ability to engraft correctly, may be evaluated. Only very limited preclinical study in primates will be necessary or desirable. The highest priority for commitment of funds for research in this area should be for studies based on human cells: non-human primate ES cell research should be at best a minor adjunct to such a program.[41]

4.21 Professor Julian Savulescu considered 'This proposal would set back research in this field by years',[42] and Professor Roger Short stated:

> To set up a primate colony and try and do embryonic stem cell research would be ducking the issue and diverting scarce resources from the real core of the question, which is to study human embryonic stem cells, particularly those produced by cloning.[43]

4.22 Professor Marilyn Monk said that 'a limited amount of direct analysis on human embryos is essential. Research on animals other than the human is not sufficient and maybe misleading' and it is 'essential to work on human material that is as normal as possible'.[44]

4.23 Professor Robert Norman was inclined to support research in non-human primates:

> I think, in terms of embryonic stem cell technology, it would be wise to have primate research going on, but there should be the potential to move through into human work once adequate, safe experimental work has occurred in subhuman primates.[45]

4.24 Dr Peter McCullagh argued for the establishment of an Australian primate facility for cloning and stem cell biology. He emphasised rigorous

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41 Associate Professor Martin Pera, *Submissions*, p.S172. The establishment of a primate research facility also opposed by Dr Eloise Piercy, *Submissions*, p.S584. The view that the establishment of a non-human primate facility is not the best way of using limited resources was also expressed by Professor Robert Williamson, *Transcript*, p.26 and *Submissions*, p.S347; Primates for Primates, *Submissions*, p.S831; and Dr Oliver Mayo, *Transcript*, p.73

42 Professor Julian Savulescu, *Submissions*, p.S650. Similar views were expressed by Dr David Gawler, *Submissions*, p.S625

43 Professor Roger Short, *Transcript*, p.8

44 Professor Marilyn Monk, *Submissions*, p.S806

45 Professor Robert Norman, *Transcript*, p.73

scientific method together with the need for animal research including that on primates, to provide the basis for human applications.

> It is axiomatic that, when assessing any research proposal involving human participants, as much information as possible should be derived from previous studies using animals. There are some types of human research for which animal analogues may not be attainable or appropriate (eg research on psychiatric conditions). However, in relation to cloning several mammalian species have been found to be suitable for research…. Certainly, non-human primate species are likely to be highly relevant to studies with human embryonic stem cells.[46]

4.25 Concerns have been raised in relation to the introduction of embryonic stem cell technology into human trials without adequate testing in suitable animal models. Dr Bernadette Tobin summarised the reasons given by scientists for rejecting the recommendation of the AHEC report that research be done in non-human primates first as:

> …even if we do research on non-human tissue or organs, we will have to revalidate that research in humans. A second reason was the resource allocation problem: there are better ways to spend the limited dollar that goes on medical research. A third reason is that it would be silly or unwise not to capitalise on the information that has been generated by the human genome project. A fourth reason was that we ought to use the primate facilities in neighbouring countries and not reduplicate what already exists. A very interesting one was the fifth reason: that was an unease about conducting research on primates.[47]

4.26 Mr Peter Eddington extended the emphasis on rigorous scientific method to include a model that incorporates scientific and societal consultation.[48]

4.27 The arguments put to the Committee for direct research on human material were both scientific, concerning the appropriateness and availability of model systems; and related to the scarce research resources available in Australia compared to many of our international scientific and industrial competitors. Australian scientists argued that collaborative arrangements could be made with established primate research centres in the USA, Indonesia and elsewhere.[49] In the USA research on cloning and

46 Dr Peter McCullagh, *Submissions*, p.S313. The Executive Council of Australian Jewry also called for increased budget allocation to establish a primate research facility for approved research relating to cloning technologies, *Submissions*, p.S728

47 Dr Bernadette Tobin, *Transcript*, p.29

48 Mr Peter Eddington, *Submissions*, p.S96

49 Professor Robert Williamson, Transcript, p.27; Professor Alan Trounson, Transcript, p.26; Dr Oliver Mayo, *Transcript*, p.73

stem cell biology in animal model systems is being promoted and supported strongly by the NIH.[50]

4.28 While the Committee supports the need for more basic research including that in animals, current priorities are to focus on human cell differentiation. The Committee was not presented with sufficient evidence supporting the need for the establishment of primate facility for cloning and stem cell research in Australia.

Alternative Technologies And Limited Health Resources

4.29 Concerns were expressed in a number of submissions that therapeutic cloning technologies may have significant potential for medicine, but other more cost-effective approaches may deliver benefits for a greater number of people. Some submissions also suggested that alternative cloning and transplantation technologies such as xenotransplantation, the use of foetal tissue and organs derived from transgenic animals might provide new options. The Committee notes these concerns but in this inquiry is not involved in determining priorities for research funding.

4.30 The Consumers Health Forum (CHF) submitted that:

> … 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.[51]

4.31 CHF also expressed concern

> …about poor utilisation of medical research findings and that too little weight is given to "low-tech" research which can significantly improve quality of life. CHF concluded that more work should be done to ensure positive research findings actually result in positive health outcomes through the development and implementation of best practice guidelines.
>
> …research into the use of therapeutic cloning procedures is very much "state of the art" medical research. Whilst this research may have significant potential, it is important it is not undertaken at the expense of lower technology (and significantly cheaper) research,

50 http://www.nih.gov/grants/guide/pa-files/PA-99-086html

51 Consumers Health Forum, *Submissions*, p.S793. See also Dr Eloise Piercy, *Submissions*, p.S583; Drs Chris Ireland and Sally Pittman, *Submissions*, p.S181; Ms Maryke Vaartjes, *Submissions*, p.S129; Frances Murrell, *Submissions*, pp.S42-43

> simply *because* it is cutting edge—it is certainly no panacea for all the ills of the world.[52]

4.32 Drs Fleming and Pike of the Southern Cross Bioethics Institute commented:

> Perhaps the seemingly obvious outcomes of ES cell research could be supplanted by more effective and morally acceptable research using adult stem cells. In the serendipitous world of scientific research, it would not be the first time that less conspicuous research turns out to be the most fruitful approach for medical therapeutic application.[53]

SUMMARY

4.33 The Committee noted the current contribution of Australian science and scientists in cloning and stem cell biology, and the opportunities presented for Australian intellectual property in biosciences, biomedicine and biotechnology. The longer term applications in agriculture and food, medicine and health and perhaps in environment and conservation could be revolutionary.

4.34 The recommendation in the AHEC report that a primate research facility be established for cloning and stem cell research in Australia was not thought to be the best use of limited resources by the majority of scientists who submitted evidence.

4.35 In considering initiatives in cloning and stem cell technologies, the Committee noted the views of those supporting other research approaches. The emphasis on basic and strategic research, rather than on clinical applications at this time, was a feature of much of the evidence.

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52 Consumers Health Forum, *Submissions*, pp.S794. The National Caucus of Disability Consumer Organisations submitted that 'Even a small proportion of the budgets devoted to genetic and cloning research could produce important outcomes for people already condemned by our society to live low quality lives because disability care is not the 'sexy' issue that cloning and genetics is', S*ubmissions*, p.S775

53 Drs Fleming and Pike, *Submissions*, p.S563. A similar view was expressed by Dr Peter McCullagh and the suggestion that xenotransplantation is another alternative, *Submissions*, p.S315

5

Overview of AHEC's discussion of ethical issues

INTRODUCTION

5.1 The following three chapters discuss the ethical issues raised by human cloning and its related research. This chapter will provide an overview of the issues and outline the approach taken in the AHEC report to the ethical issues associated with cloning. Chapter 6 will consider the ethical issues raised by cloning for reproductive purposes and outline the Committee's reasons for rejecting the use of cloning technologies for such purposes. Chapter 7 will discuss the ethical issues associated with cloning technologies and stem cell research that involve the use of embryos and will outline the Committee's views on these matters.

5.2 The Committee considers it would be difficult to treat the ethical considerations that may emerge from, for example**,** the replication of a skin cell in the same way as the ethical considerations that may emerge from the replication of a human being. Therefore the Committee has decided to differentiate between:

- use of cloning technology to create whole human beings; and
- use of cloning technology for other purposes such as the extraction of embryonic stem cells or the creation of embryos by means such as asexual reproduction.

5.3 The ethical issues touch on the most sensitive of matters and inevitably give rise to strong views that have been reflected in the submissions and oral evidence received.

5.4 While the majority of members of the public appear to have connected the term 'human cloning' with the replication of whole human beings, the use

of somatic cell nuclear transfer technology to create an embryo followed by its implantation, gestation and the birth of a human being has not occurred. Nevertheless this has been seriously proposed. The possibility has aroused passionate interest and comment. Underlying many of the concerns expressed has been a sense that the cloning of whole human beings is something that is 'bound' to happen.

5.5 However, this is not the only area of research related to the use of cloning technology where strong views have been expressed. Equally passionate interest and comment has resulted from practices not related to the cloning of whole human beings. These include the creation of embryos by means of somatic cell nuclear transfer and the use of embryos derived from assisted reproductive technologies for research purposes such as the derivation of embryonic stem cells.

5.6 The key ethical issues raised in the inquiry were i) the potential replication of a whole human being; and ii) the creation and / or use of embryos in research or therapy. The fundamental question is: is it ethical to proceed with the research and development of this technology and, if so, to what extent?

THE AHEC REPORT'S DISCUSSION OF ETHICAL ISSUES

Terminology

5.7 The AHEC report distinguished between '… two categories of cloning: cloning of a human being and copying (cloning) of human component *parts* (such as DNA and cells).'[1]

5.8 This distinction was expanded on in Chapter 3 of the AHEC report in which the ethical issues raised by cloning were discussed. The report states:

> … a distinction was drawn between (a) applications of cloning techniques to generate new human subjects and (b) applications of cloning techniques to generate human genes or cell lines. Another, more general, way of expressing the same difference is to distinguish between (a) the (re)production of human *wholes* or (b) the (re)production of the component *parts* of a human.[2]

5.9 The AHEC report then goes on:

1 AHEC report, Chapter 1, paragraph 1.1

2 AHEC report, Chapter 3, paragraph 3.4

> This discussion of the ethics of cloning focuses in the main on the ethical issues associated with the use of cloning techniques involving whole human entities, in particular embryos.[3]

5.10 A number of different terms and descriptions are used by AHEC. Its report refers variously to 'cloning of a human being', 'generat[ing] new human subjects', '(re)production of human wholes' and 'whole human entities'.[4] This raises the issue of what AHEC is referring to when it uses these terms.

5.11 'New human subjects' are elsewhere referred to in the AHEC report as the production of a 'child, a fetus or an embryo'. For example, AHEC states the report deals principally with:

> [p]roposals for the application of cloning techniques to generate new human subjects (embryonic, fetal or post-natal) not with cloning of human genes or cell lines…. Nevertheless, there may be situations in which development of a cell line necessitates the production of a new human subject as a preliminary step.[5]

Elsewhere in its report AHEC refers to the production of 'new human individuals with a post-natal existence.'[6]

5.12 In expanding on the distinction it has drawn, the AHEC report states:

> Recognising a fundamental distinction between the cloning of a "whole" human entity and the cloning of a component "part" of a human being does not commit one to the idea that all the members of the first category are "human beings" in an ethical or moral sense. It merely follows from the fundamental biological difference between copying a new individual of the human species identical to some other individual and copying component parts of an individual.[7]

5.13 In its submission to this inquiry AHEC stated (in relation to its report):

> After pointing out the fundamental ethical difference between proposals to clone whole human entities (embryos, foetuses, etc) and existing practices of cloning parts of human entities (cells, etc) AHEC concentrated on the acceptability of proposals to clone whole human entities.[8]

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3 AHEC report, Chapter 3, paragraph 3.4

4 AHEC report, Chapters 1, 2 and 3. See paragraphs 1.1, 2.7 and 3.4 respectively

5 AHEC report, Chapter 2, paragraph 2.7

6 AHEC report, Chapter 2, paragraph 2.1

7 AHEC report, Chapter 3, paragraph 3.5

8 AHEC, *Submissions*, p. S350. This distinction was reiterated in correspondence from Dr Kerry Breen, the Chairperson of AHEC, on 15 December 2000. AHEC, *Position on Cloning and Related*

5.14 The use of such a variety of terms to describe similar things creates ambiguity and is liable to lead to some confusion. However, the Committee understands the discussion of ethical issues in the AHEC report to be focused primarily on the use of cloning technologies that may lead to the creation of embryos, foetuses and whole human beings.

AHEC's Approach To Ethical Issues

5.15 The AHEC report discussed the ethical issues relevant to human cloning by reference to the four factors it considered should be taken into account when considering ethical issues raised by proposals to engage in human cloning:

- the ethical significance of a variety of objectives or goals for which cloning might be pursued as a means. Such goals or objectives might include—the use of cloning technologies as a way of increasing the number of embryos available for implantation in reproductive technologies, as a way of investigating human biology and pathology or as a way of producing transplantable human organs and tissues;
- the ethical significance of the circumstances in which cloning might take place, such as whether cloning techniques have been tested on animals prior to being tested on humans, whether it would require destructive research on human embryos or how safe the techniques for cloning are judged to be;
- the ethical significance of cloning in itself; and
- the ethical significance of a social policy which permits cloning in some circumstances but not in others or of a policy which prohibits it altogether.[9]

5.16 The rest of Chapter 3 of the AHEC report discusses each of these factors in more detail and states, in summary, 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.'[10]

Technologies, Exhibit 45. This correspondence was intended as clarification of the NHMRC position on the use of cloning and stem cell technologies which Dr Breen's correspondence states was inadvertently mis-stated in background material issued to State and Territory health officials

9 AHEC report, Chapter 3. These factors are discussed in paragraphs 3.8-3.32 of the AHEC report

10 AHEC report, Chapter 3, paragraph 3.33

5.17 In evidence to this inquiry, Professor Chalmers, Chairman of AHEC when the AHEC report was completed, emphasised that the primary focus of that report was on the use or creation of human embryos. He stated:

> … most importantly, the [AHEC] committee looked at the source of the material to be involved in cloning. … It was the assumption throughout the terms of the report that the legislation in the various states and the principles embodied in a number of national reports suggested and led to no other conclusion than the fact that this country has a view about the integrity and dignity of the human embryo and that research should not be conducted on the human embryo, except according to prescribed regulation.[11]

Comments On The AHEC approach

5.18 While some submissions to the inquiry praised the AHEC report for providing a good overview of the ethical issues, a number suggested that AHEC's approach was only a preliminary step towards forming conclusions about the ethical issues surrounding cloning and that more rigorous analysis and detailed deliberation was required. In Chapters 6 and 7 of this report the Committee seeks to provide further analysis and reach conclusions about the ethical issues arising from engaging in human cloning and stem cell research.

5.19 The AMA praised Chapter 3 of the AHEC report saying it 'comprehensively addresses the major ethical issues associated with cloning techniques applied to humans'.[12] Likewise St Vincent's Hospital Sydney submitted that the framework used by AHEC is:

> … a good one in which to think about the ethics of cloning. However, each of the main ethical theories in current use has some contribution to make in considering the ethics of cloning.[13]

5.20 The Hospital went on to argue:

> Much of the discussion in this chapter is so brief as to be of very little use … If this chapter is to be genuinely instructive and thought provoking, it needs further development.[14]

5.21 St Vincent's Hospital Sydney suggested, for example, that it would have been useful if the main ethical theories in current use:

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11 Professor Donald Chalmers, *Transcript*, p.3

12 AMA, *Submissions*, p.S25

13 St Vincent's Hospital Sydney, *Submissions*, p.S153

14 St Vincent's Hospital Sydney, *Submissions*, p.S154

> … or "frameworks for reasoning about ethical issues" had been identified, rather than alluded to, and distinguished from each other … By clearly setting these theories out, at the beginning of the chapter, providing some illustrations of the ways in which these approaches might be applied to the ethics of cloning and illuminating the strengths and weaknesses of each of these approaches, in particular as each is applied to the ethics of cloning, it would have been possible to present the ethical considerations with a greater richness and depth through accessing the contribution that each theory has to offer.[15]

5.22 The Queensland Bioethics Centre argued that AHEC did not really detail in its report why it considers the cloning of humans to be wrong and why it should be prohibited by legislation.[16]

5.23 St Vincent's Hospital Sydney submitted that a serious failure in Chapter 3 of the AHEC report is the:

> …failure … to distinguish the considerations relevant to an assessment of the intrinsic ethics of cloning from considerations relevant to the social regulation of cloning.[17]

5.24 The Plunkett Centre for Ethics in Health Care, argued that it is:

> … one thing to consider the ethics of an individual case of cloning. It is another to consider the ethics of a social policy which permits or prohibits cloning. … From the fact that something is reasonably judged to be unethical, it does not follow that it ought to be subject to legal prohibition.[18]

5.25 The Plunkett Centre for Ethics in Health Care agreed with AHEC that the ethics:

> … of a particular proposal is never solely a matter of the intentions of those who engage in it (and never solely a matter of its likely consequences): there is always also a question of the rightness or wrongness of the proposal in itself. That is why the question of whether cloning research and technologies would involve destructive research on embryos matters.[19]

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15 St Vincent's Hospital Sydney, *Submissions*, p.S154

16 Queensland Bioethics Centre, *Submissions*, p.S708

17 St Vincent's Hospital Sydney, *Submissions*, p.S154

18 Plunkett Centre for Ethics in Health Care, *Submissions*, p.S178. Dr Tobin, the Director of the Plunkett Centre, was a member of AHEC during the time the AHEC report was developed and is currently a member of AHEC

19 Plunkett Centre for Ethics in Health Care, *Submissions*, p.S178

5.26 The Social Responsibilities Committee of the Anglican Diocese of Melbourne also criticised the AHEC report for its lack of 'ethical reflection and analysis'.[20]

5.27 These concerns were also reflected in comments from some members of the public such as Dr Russell Blackford, for example, who criticised the discussion of ethical issues in Chapter 3 of the AHEC report as lacking in rigour[21] and Dr David Swanton, who argued that AHEC's methodology indicates 'that it assumes that human cloning is ethically unacceptable before its study has begun'.[22]

5.28 Mr Peter Eddington, while not expressing any views on the ethics of cloning, submitted a detailed critique of the AHEC report. He argued that although it provided a great deal of information about cloning techniques, it 'failed to provide any guidance about how our society might deal with the complex issues that must inevitably follow genetic research'.[23] It:

> … fails to take the process forward. It fails to provide a social context, and it fails to provide any meaningful framework for dealing with these issues.[24]

Mr Eddington stated Chapter 3 of the AHEC report 'does not set out the choices that we face, or the decisions that we must make'.[25]

THE COMMITTEE'S OBSERVATIONS ON AHEC'S APPROACH

5.29 In the Committee's view, the discussion of ethical issues in Chapter 3 of the AHEC report provides a useful summary of the ethical considerations relevant to human cloning as they were perceived at the time of the report. It is worth reiterating that there have been many developments in this area of research since the AHEC report was completed.

5.30 However one of the principal functions of AHEC is to advise the National Health and Medical Research Council on ethical matters relating to health.[26] AHEC represents a broad spectrum of views.[27] In this context it is

20 Social Responsibilities Committee, Anglican Diocese of Melbourne, *Submissions*, p.S293

21 Dr Russell Blackford, *Submissions*, p.S1

22 Dr David Swanton, *Submissions*, p.S114

23 Mr Peter Eddington, *Submissions*, p.S81

24 Mr Peter Eddington, *Submissions*, p.S98

25 Mr Peter Eddington, *Submissions*, p.S84

26 *National Health and Medical Research Council Act 1992* (Cth), section 35 (3) (a)

27 *National Health and Medical Research Council Act 1992* (Cth), section 36 (1). Section 36 (1) of the Act establishes the composition of AHEC

unfortunate that the summary of the ethical issues in Chapter 3 of the AHEC report did not canvass in more detail the reasoning underpinning AHEC's discussion of the key ethical factors or its conclusions on these matters. The Committee would have found Chapter 3 of the AHEC report more useful in informing its own consideration of the ethical issues had that been the case.

6

The ethics of cloning for reproductive purposes

INTRODUCTION

6.1 This chapter discusses the issue of cloning for reproductive purposes. The process of cloning for reproductive purposes as it is currently envisaged was outlined in Chapter 2, (paragraph 2.40). However, in the future, the artificial reproduction of a human embryo for implantation, gestation and the birth of a human being may take place using a range of techniques deriving from existing cloning technologies.[1] The current focus of attention (and the discussion in this chapter) is on the use of the somatic cell nuclear transfer technique to achieve this result. The Committee's rejection of the use of cloning techniques for reproductive purposes extends to future developments of such technologies that also aim to reproduce a whole human being unless other social and ethical issues are resolved, and this seems most unlikely for the foreseeable future. The following discussion outlines the evidence the Committee received on cloning for reproductive purposes and sets out its reasons for rejecting the use of cloning technologies for such purposes.

6.2 AHEC's first recommendation to the Commonwealth Minister for Health and Aged Care was that the Commonwealth Government should

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1 Some may argue that this description could apply equally to existing assisted reproductive technologies by means of, for example, *in vitro* fertilisation. The Committee emphasises that its rejection of cloning for reproductive purposes involves the use of somatic cell nuclear transfer techniques or further developments of it

> …reaffirm its support for the UNESCO Declaration on the Human Genome and Human Rights, in particular Article 11 …[2]

6.3 Article 11 states, in part, that

> Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.[3]

6.4 The Attorney-General's Department submitted that Article 11 refers to 'the replication of a whole human being with an identical gene set with a viable post-natal existence'.[4] This interpretation was strongly disputed by Dr Nicholas Tonti-Filippini who submitted that the term 'reproductive cloning' in Article 11 also includes cloning human embryos for research purposes.[5] The interpretation of Article 11 is discussed in detail in Chapter 10. The use of embryos in other cloning research is also a crucial issue and it forms the focus of Chapter 7.

6.5 In its Glossary of Terms at Appendix 3 to the AHEC report, AHEC defines 'cloning' as 'asexual propagation without altering the nuclear genome'.[6] The same Glossary contains the following definition of 'human reproductive cloning'—the 'creation of human beings genetically identical to one another or to any other human being'.[7]

6.6 Except in relation to recommendation 1 and the UNESCO Declaration upon which it is based, or when quoting the views or findings of others, the body of the AHEC report does not use the term 'reproductive cloning'.[8] Nor does the report discuss its meaning.

6.7 Given the discussion in Chapter 5 of this report of the ambiguity inherent in some of the terminology in the AHEC report, it is unclear what precisely, AHEC means by the term 'reproductive cloning' in the context of its discussion of the ethical issues. It could refer to:

- the use of somatic cell nuclear transfer with the intent of producing a whole human being; or

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2 AHEC report, Executive Summary, p.v and Recommendations and Resolutions, p.43. The AHEC recommendations are reproduced at Appendix D of this report

3 AHEC report, Recommendations and Resolutions, p.43. Article 11 is set out in full on p.43 of the AHEC report. See also Chapter 10, paragraph 10.12

4 Attorney-General's Department, *Transcript*, p.136. Professor Chalmers also stated that that was his understanding of Article 11, *Transcript*, p.2. The interpretation of Article 11 of the UNESCO Declaration is discussed at paragraphs 10.14– 10.26 of Chapter 10

5 Dr Nicholas Tonti-Filippini, *Submissions*, p.S591

6 AHEC report, Appendix 3, p.50. The Glossary is reproduced at Appendix E of this report. See also Chapter 2 of this report at paragraphs 2.30-2.36 for a discussion of the definition of 'cloning'

7 AHEC report, Appendix 3, p.52. See Appendix E of this report

8 See for example AHEC report at paragraphs 2.29, 5.11 and 5.12

- the use of somatic cell nuclear transfer with the intent of producing an embryo with no intention of implanting that embryo into a woman's uterus or seeking the production of a whole human being; or
- both of the above.

6.8 The Committee received much evidence that suggested many people had varying ideas about what conduct the term 'reproductive cloning' described and all three of the above possibilities were present in the evidence.

6.9 It was clear that many submissions expressed views based on an understanding that 'reproductive cloning' means the use of cloning techniques with the intent of producing a whole human being—or as more commonly understood—the copying of human beings. Both the AMA and the Coalition for the Defence of Human Life, for example, understood this to be the meaning AHEC intended.[9]

6.10 The scientists who gave evidence expressed a similar understanding of the term 'reproductive cloning' although the way in which this was expressed varied. Professor Short stated that it meant 'reproducing another adult individual'.[10] Professor Williamson said that by reproductive cloning he meant 'the creation of a living foetus or individual'.[11] Professor Serjeantson of the Australian Academy of Science stated that reproductive cloning 'represents the manipulation of the embryo or germ line tissues in order to produce a new individual'.[12] The Human Genetics Society of Australasia defined 'cloning' as:

> to produce a liveborn individual who shares a full genetic complement with a pre-existing child or adult donor of a somatic cell nuclear genome.[13]

6.11 Professor Trounson said:

> You can clone a gene and that is gene cloning; you can clone a cell and that is cell cloning or you can clone an embryo and that is

9 AMA, *Submissions*, pp.S25, 26 and Coalition for the Defence of Human Life, *Submissions*, p.S268. Dr John Palmer of the Royal College of Obstetricians and Gynaecologists indicated that the College supported the statement of the Federation of International Gynaecologists and Obstetricians (FIGO) that 'cloning for the purpose of implantation into the human uterus for the development of a pregnancy' should be prohibited, *Transcrip*t, p.33

10 Professor Roger Short, *Transcript*, p.7

11 Professor Robert Williamson, *Transcript*, p.15

12 Professor Sue Serjeantson, *Transcript*, p.64

13 Human Genetics Society of Australasia, *Submissions*, p.S508. The Australian Research Council also agreed with this definition, *Submissions*, p.S225

> embryo cloning. Possibly you could clone a person and that would be reproductive cloning or cloning of people.[14]

6.12 However, it was also clear that many submissions expressing opposition to 'reproductive cloning' also included, within their understanding of that term, the use of cloning techniques to produce an embryo but with no intention of seeking the production of a whole human being. Such an embryo might be produced for research purposes or as part of medical treatment. Most organisations expressing this view were of a religious nature and their views were supported by many members of the public.

6.13 The Catholic Archdiocese of Melbourne, for example, argued that no matter what the research is called:

> … 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 [so-called therapeutic cloning] it is for hours, days or weeks until it is used for deriving cells or other materials and destroyed; in the latter [cloning for reproductive purposes] 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.[15]

6.14 Ridley College also submitted:

> The cloning of human embryos or foetuses for the purpose of the production of tissues or organs for transplantation … is really reproductive cloning (which has the aim of producing a human foetus which is genetically identical to another human being), because it does involve the production of such a foetus (or embryo) but not with the aim of allowing this foetus to come to term and be born, but with the aim of using it for "spare parts".[16]

6.15 As noted in Chapter 2, the Committee recognises that much of the terminology used in describing research involving cloning technologies is ambiguous and unhelpful. The following discussion of cloning for reproductive purposes centres on the use of the somatic cell nuclear transfer technique for reproductive purposes because that is the focus of current attention. The arguments presented would apply equally to any further developments in the technology that aim to achieve the same end.

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

15 Catholic Archdiocese of Melbourne, *Submissions*, p.S512. The Coalition for the Defence of Human Life submitted that '…*any* cloning procedure which is successful in producing a human embryo is reproductive', *Submissions*, p.S268

16 Ridley College, *Submissions*, pp.S29 and S30

WHAT COULD REPRODUCTIVE CLONING BE USED FOR?

6.16 It may well be asked what use could be made of reproductive cloning technology. Several suggestions have been made. The most commonly suggested reason would be to assist people who cannot have children by means of existing assisted reproductive technologies to reproduce. It may also enable people to avoid passing on genetic diseases such as mitochondrial diseases. Other suggestions have included enabling people to clone a dying or deceased child or relative, enabling homosexual couples or single women to have children and enabling parents to choose the characteristics of their offspring.

OVERWHELMING OPPOSITION TO CLONING FOR REPRODUCTIVE PURPOSES

6.17 The Committee strongly opposes cloning for reproductive purposes, that is, the use of somatic cell nuclear transfer techniques or the use of any future technology for the production of a whole human being.[17] This is consistent with the overwhelmingly strong opposition to cloning for reproductive purposes that was expressed by nearly all who provided submissions or gave evidence to the inquiry. This evidence is outlined in the following paragraphs.

WHY DO PEOPLE OPPOSE CLONING FOR REPRODUCTIVE PURPOSES?

6.18 A variety of reasons was expressed for this strong view that cloning for reproductive purposes would be unethical. Most people relied on more than one reason for their opposition. The most common arguments cited in favour of the view that cloning for reproductive purposes should be prohibited are outlined below. These include:

- the lack of any medical need for cloning for reproductive purposes;
- cloning for reproductive purposes would constitute an infringement of human dignity;

17 The Committee reiterates that these comments do not extend to existing techniques of assisted reproduction, namely IVF and GIFT

- 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.

Each of these arguments will be addressed in turn.

6.19 The previous chapter outlined the four factors AHEC considered should be taken into account when pondering the ethical issues raised by proposals to engage in human cloning. These were the ethical significance of:

- the objectives or goals for which cloning might be pursued as a means;
- the circumstances in which cloning might take place;
- cloning in itself; and
- a social policy which permits cloning in some circumstances but not in others or of a policy which prohibits it altogether.

6.20 These factors were reflected in the reasons people gave for opposing cloning for reproductive purposes. In many cases these reasons were not articulated in the same form as in the AHEC report. Most concerns focused on the ethical significance of cloning in itself, as is shown in arguments that cloning for reproductive purposes infringes human dignity. The ethical significance of the objectives for which cloning might be pursued is shown in concerns about the effect on notions of the family, individuality and concepts of identity. The ethical significance of the circumstances in which cloning for reproductive purposes might occur is reflected in the strongly expressed concerns about its safety.

No Medical Need For Cloning for Reproductive Purposes

6.21 Scientists who gave evidence agreed generally that cloning for reproductive purposes would be 'unethical, unsafe and should be prohibited'.[18] They were also generally emphatic that there is no medical

18 For example, Professor Serjeantson from the Australian Academy of Science stated that both the Academy and AHEC agreed in believing that 'reproductive cloning to produce human foetuses was unethical and unsafe and should be prohibited', *Transcript*, p.79 and AAS,

need or medical justification for cloning for reproductive purposes. Professor Trounson, for example, stated that he:

> …would like to assure the Committee that the scientists working in this area have very strong feelings that the cloning of the human person, or reproductive cloning, is not something we think is medically justified … We are very firmly against reproductive cloning or the cloning of people.[19]

6.22 In Professor Trounson's view 'you would have to say that [cloning for reproductive purposes] is for selfish reasons. You want to replace a child who died or, for some other reason, you want to see yourself as a cloned individual'.[20]

6.23 Professor Williamson emphasised to the Committee that the Murdoch Children's Research Institute 'unequivocally' sees:

> …no medical reason that could justify reproductive cloning. We have considered this. We deal with every one of the genetic and acquired genetic disorders in Victoria. We are responsible for this and can see no justification.[21]

6.24 Professor Short shared this opposition to cloning for reproductive purposes.[22]

Infringement Of Human Dignity

6.25 The most common reason given for regarding cloning for reproductive purposes as unethical was that it would be 'contrary to human dignity'.[23]

Submissions, p.S245. Professor Felix Beck stated 'in general terms it is widely accepted that the cloning of a human being is unacceptable', *Submissions,* p.S683

19 Professor Alan Trounson, *Transcript*, pp.3, 4

20 Professor Alan Trounson, *Transcrip*t, p.17

21 Professor Robert Williamson, *Transcript,* p.8

22 Professor Roger Short, *Transcript*, p.7. The Human Genetics Society of Australasia also stated that it 'cannot see any circumstance either medical or social, which would make the cloning of an individual desirable'. In the Society's view this included the risk of mitochondrial diseases for which 'other reproductive strategies are possible and ethically preferable', *Submissions,* p.S508. In his submission Professor Trounson also noted that the Australian Society for Reproductive Biology and the Fertility Society of Australia (which represent the scientific and medical staff involved in work in the areas of human infertility and IVF) have passed resolutions stating that 'cloning human persons is not an appropriate scientific or medical activity', *Submissions,* p.S170. The Australian Research Council also agreed that 'independent of ethical issues, the ARC can see no valid scientific reasons to carry out reproductive cloning', *Submissions,* p.S225

23 George W Marshall and Marie T Marshall, *Submissions*, p. S209. See also Mrs Pauline Burke, *Submissions,* p.S713; Mrs O'Donohue, *Submissions,* p.S223; The Royal College of Nursing, *Submissions,* p.S283; the Caroline Chisholm Centre for Health Ethics, *Submissions,* p.S488; Mr Klaus Clapinski, *Submissions,* p.S279; Dr David Gawler, *Submissions,* pp.S623 and S626; Right

This was generally because its projected objectives would involve the use of people as the means to an end decided upon by someone else and not as an end in themselves. A similar concept was expressed by those who argued that cloning for reproductive purposes would turn people into commodities.[24]

6.26 Dr Pike of the Southern Cross Bioethics Institute explained what he understood by 'respect' and 'dignity':

> Respect refers to the condition or state of being esteemed or honoured. It is to prize or to value, and furthermore it includes in its meaning to refrain from interfering with or to spare…. Dignity … implies an inherence of value or quality which is intrinsic to, in this case, human beings… It is the dignity attached to humanness per se… It is this deep-seated inherent dignity which underscores the human rights documents and various codes of medical ethics which mark all human kind as worthy of the highest respect.[25]

6.27 For Dr Amin John Abboud:

> … any research, procedure or investigation that affects the dignity of people which we have defended at length in society is to be discouraged. Cloning attacks fundamentally the dignity of the human person making him subservient to the needs of others.[26]

6.28 Dr Eloise Piercy submitted:

> The cloning of human beings, whether to bring about the birth of a baby or to be suppressed within early embryonic life (such as for the purpose of obtaining embryonic stem cells) is an affront to human dignity. … Clones are a means to an end and in being such, are treated with less dignity than other humans. Indeed, unconditional respect for human dignity, regardless of age, size, intellect or physical capacity is the cornerstone of civilised society. Human cloning contravenes this respect and violates the

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to Life Australia, *Submissions*, p.S166; Ovulation Method Research and Reference Centre of Australia, *Transcript*, p.34

24 For example Mr Sidhu of Youth Concerned with Cloning stated that cloning for reproductive purposes was 'commodification where the status of a human being goes from that of a unique special individual with inherent dignity to that merely of a complex cellular structure and something that can be bought and sold', *Transcript*, p.30 and Youth Concerned with Cloning, *Submissions*, p.S543. See also Dr Eloise Piercy, *Submissions*, p.S582

25 Dr Gregory Pike, *Transcript*, p.32. Dr Nicholas Tonti-Filippini also provided a lengthy submission which focused on reasons why UNESCO and other international bodies consider cloning to be contrary to human dignity. His submission also explores the meaning of the concept of 'human dignity', *Submissions*, pp.S595-604

26 Dr Amin John Abboud, *Submissions*, p.S641

> principles of equality and non-discrimination among human beings. It represents a line we should not cross.[27]

6.29 The Social Responsibilities Committee of the Anglican Diocese of Melbourne seemed to reflect the views of many in saying that the

> … central ethical issue in cloning is the widely accepted moral principle that human beings may never be treated merely as a means to an end, but only as an end. Many of the suggested reasons for reproductive cloning that might be employed have a strongly instrumental character to them, for they contemplate bringing a person into existence for reasons outside the person themselves. Examples would be the replacement of a lost relative or the making available of compatible tissue for transplanting into another.[28]…
>
> It is not the genetic identity but the human act of control that is the crucial point in this argument regarding the unacceptability of cloning. It is this act of deliberate control which makes us morally responsible for the decision which we have made. … It is the element of control which provides a fundamental ethical case against human cloning. … By definition, to clone is to exercise unprecedented control over the genetic dimension of another individual …[29]

6.30 The Catholic Archdiocese of Melbourne acknowledged that 'Australians approach ethical issues from a variety of perspectives' but said that 'some basic "common morality" is a necessary underpinning of our community life and the flourishing of each individual within our community'.[30] One such common principle:

> … is respect for the inherent dignity of every member of the human family from which their equal and inalienable rights are derived.[31]

6.31 The General Synod of the Anglican Church of Australia submitted the Committee should recognise:

> … the reverence in which the human person and the human body as constituent parts are held from a variety of religious and secular

27 Dr Eloise Piercy, *Submissions,* p.S581

28 Social Responsibilities Committee of the Anglican Diocese of Melbourne, *Submissions,* p.S305

29 Social Responsibilities Committee of the Anglican Diocese of Melbourne, *Submissions,* p.S303

30 Catholic Archdiocese of Melbourne, *Submissions,* p.S518

31 Catholic Archdiocese of Melbourne, *Submissions,* p.S518

> perspectives and adopt social policy and legislation which reflects the sacredness and inviolability of the human person.[32]

6.32 Allied to this concern the Australian Family Association asked whether we are 'playing God with cloning? Are there certain things we should not interfere with?'[33]

6.33 The Executive Council of Australian Jewry regarded this as the 'theological question' but argued:

> … cloning, which is based on pre-existing human genetic material, is not humans playing God but using God-given material, albeit not through normal methods of procreation… [E]very medical intervention represents interference with Divine providence and the physician is regarded in Judaism as doing God's work.[34]

The Council went on to say that although:

> … Judaism does not therefore say that cloning is prohibited in itself …[it] advises one to pause before one permits that which can lead down a variety of slippery slopes.[35]

The Council therefore supported prohibiting the cloning of whole human beings.

6.34 The ethical argument against cloning for reproductive purposes on this ground was encapsulated in the submission by Ridley College:

> Human dignity is affirmed by a wide range of religious and secular traditions. Since human dignity is not only innate, but also relational, it may be violated or threatened when an individual does not experience being valued or treated as worthy in herself, but rather is treated as merely a means to some further end … Another way of expressing this concern is in terms of the danger of commodification of children…[36]

The Effect Of Cloning For Reproductive Purposes On The Family And Personal Relationships

6.35 Significant social issues arise from the possible creation of whole human beings by artificial means such as the use of somatic cell nuclear transfer techniques. Because such persons could be developed in a laboratory,

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32 General Synod of the Anglican Church of Australia, *Submissions*, p.S340

33 Australian Family Association, *Submissions*, p.S697. See also Daniel and Jenny Garrard, *Submissions*, p.S123 and Robyn Hipkiss, *Submissions*, p.S183

34 Executive Council of Australian Jewry, *Submissions*, p.S727

35 Executive Council of Australian Jewry, *Submissions*, p.S728

36 Ridley College, *Submissions*, pp.S33 and S34

through fusion of the nucleus of a somatic cell with an enucleated egg, the resulting person need have no connection with any family or other social structure (indeed the providers of the somatic cell and the egg may be dead). This raises questions such as who would be allowed to create such people, who would be responsible for the resulting person, who would have the right to make decisions in relation to the person's welfare and/or upbringing and what duties governments and the broader society would have towards the person. What are the consequences for a person of being created without clearly understood social connections? Where and how would such a person find a place within our society? The potential social consequences of such a development are far reaching and complex. They have not yet been properly considered by the community and the Committee has serious misgivings about them. These social consequences are at least as significant as the concerns surrounding the safety of cloning techniques highlighted in Chapter 3.[37]

6.36 The suggested effect of cloning for reproductive purposes on personal relationships and the family was one of the most common reasons for regarding cloning for reproductive purposes as unethical. For many people, such concerns were closely related to those about the lack of respect for human dignity implied by cloning for reproductive purposes.

6.37 Two reasons were advanced generally as to why cloning for reproductive purposes would have an adverse effect on human relationships and the family:

- the almost identical genetic nature of the cloned person to the person who was the source of the somatic cell would distort our understanding of human relationships. Related to this were concerns about the maintenance of individuality and what kind of identity a cloned person would have; and
- the asexual nature of cloning for reproductive purposes would have an adverse effect on personal relationships and family formation.

6.38 In relation to the effect on our understanding of human relationships of the genetically almost identical nature of the cloned person to the genetic donor, the Australian Family Association posed a number of questions:

> What will become of relationships? Primarily what is a clone? Is he or she a child or a sibling to the donor? Is the donor a mother, father, guardian, sibling, representative or what? Would the parents of the donor be the clone's actual parents? What will

37 See paragraphs 3.15-3.19

> clones do to family relationships and definitions… clone relationships will only further unravel the family unit.[38]

6.39 For the Queensland Bioethics Centre:

> To clone a human being is to bring into existence a new human being and at the same time deprive that human being of the normal relationships which characterise new members of the human family, namely genetic, gestational and social relationships, a web of relationships which we characterise as being a family. … In the process of cloning a human being this being is deprived *through the choice of others* of having parents. Even the person who supplies the genetic material is more an older sibling (a kind of twin) than a parent [emphasis in the original].[39]

6.40 The Caroline Chisholm Centre for Health Ethics submitted that cloning:

> …would deprive the child of the genetic basis of father, mother and other family relationships which are very significant and important for every human individual since these pertain to the core of our personal identity in the general community …[40]

6.41 Dr Nicholas Tonti-Filippini was also very concerned about the effect of cloning for reproductive purposes on human relationships more generally. The potentially very distant relationship between the clone and anyone else is particularly problematic. He points out that the connection between the source of the tissue and the person cloned may be very tenuous (or non-existent if the source of the tissue is dead).[41] In his view:

> …cloning fragments the interconnectedness of human beings, because it allows a human being to be created without direct connections with a family.[42]

6.42 The Social Responsibilities Committee of the Anglican Diocese of Melbourne expressed similar concerns:

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38 Australian Family Association, *Submissions*, pp.S695-696

39 Queensland Bioethics Centre, *Submissions*, p.S708

40 Caroline Chisholm Centre for Health Ethics, *Submissions*, p.S488 and Rev Dr Norman Ford, *Transcript*, p.30. See also Queensland Right to Life, *Submissions*, p.S264; Dr David Gawler, *Submissions*, p.S627; Australian Family Association, *Transcript*, p.111. The Council for Marriage and the Family said that 'the principle of the family being a sanctuary of life is at stake. It is this sanctuary which is about protecting the child and family members. The family is the basic community of society which is unique and unrepeatable… The family is where a child will come to experience the meaning of human dignity, care, love and acceptance regardless of their abilities. In circumstances involving cloning this knowledge is distorted', *Transcript*, p.37

41 Dr Nicholas Tonti-Filippini, *Submissions*, p.S594

42 Dr Nicholas Tonti-Filippini, *Submissions*, p.S604

> Cloning appears to undermine this structure of the family. Cloning allows the separation of the sex act from the intimacy of the relationship, and brings a genetic difference from other humans who have genetic contribution from two parents. Only one partner would be necessary and this would undermine the basis of the genetic mixture that occurs naturally. Such a change has the potential to distort the relationship …[43]

6.43 In this context a particular concern for many people was that a possible consequence of the use of cloning for reproductive purposes would be the capacity it would offer same-sex couples to have children.[44]

6.44 The asexual nature of human reproductive cloning and the effect of this on human and family relationships drew significant comment. Several submissions quoted Professor Leon Kass' statement:

> … asexual reproduction does violate nature's boundaries, confounds the understanding of normal human relationships and reduces human beings to mere products to be manufactured at another's will and for another's purposes.[45]

6.45 The Australian Catholic Bishops Conference expressed the view that the wide ranging issues arising from cloning:

> …need to be seen in the context of the consistent teaching of the Church (espoused also by many fellow travellers) about the dignity of procreation and its central place in marriage … this practice [of cloning for reproductive purposes] distorts the human meaning of procreation, which is no longer considered or practised for reproductive reasons but programmed for medical and experimental (and therefore commercial) purposes.[46]

The practice of cloning, the Conference went on to say:

> …is encouraged by the progressive depersonalisation of the generative act (introduced by the practice of extracorporeal fertilisation) which becomes a technological process making the

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43 Social Responsibilities Committee of the Anglican Diocese of Melbourne, *Submissions,* p.S301

44 See Social Responsibilities Committee of the Anglican Diocese of Melbourne, *Submissions,* p.S301; Pro-Life Victoria, *Submissions,* p.S674; Right to Life Association NSW, *Submissions,* p.S502; the Catholic Archdiocese of Melbourne, *Submissions,* p.S512

45 Leon Kass, 'The Wisdom of Repugnance', *The New Republic*, 2 June 1997. This article was also cited in the AHEC report, Chapter 3, paragraph 3.28. Kass' article was also referred to by Dr David Gawler, *Submissions*, p.S628; Australian Catholic Bishops Conference, *Submissions,* p.S745. Pro-Life Victoria also submitted that 'cloning is asexual in a more radical sense than IVF', *Submissions,* p.S674

46 Quoting from Centre for Bioethics of the Catholic University of the Sacred Heart, Milan, 'Can Human Cloning be Therapeutic', Australian Catholic Bishops Conference, *Submissions,* p.S755

> human being an object to be used by anyone who can reproduce him in the laboratory.[47]

6.46 The Coalition for the Defence of Human Life seemed to sum up many of the arguments in this area:

> Humans are bodily beings. Their understanding of themselves includes ideas that are biological: humans are the kinds of beings that are sexually generated, the kind of beings that have mothers, grandfathers, aunts, brothers and sisters, etc. This is, so to speak, the biological basis of our common understanding of human equality, the human family, and mutual human obligations. Any procedure that seems to depersonalise human reproduction weakens the biological basis of these important ideas, by introducing a radical inequality between some humans who are manipulators and manufacturers, and other humans who are artefacts, objects, products, commodities.[48]

Identity And Individuality

6.47 Related to the broader concern about the effect of cloning for reproductive purposes on human relationships were more specific concerns about the potential for cloning for reproductive purposes to be seen to diminish individuality and lead to problems of identity for cloned persons (especially ones produced for any of the reasons outlined in paragraph 6.16 above). These more specific concerns are also, of course, related to the argument that cloning for reproductive purposes would infringe human dignity.

6.48 Pro-Life Victoria, for example, argued that regarding each individual being as 'unique' has 'underpinned the way in which our society values human life'.[49] Cloning for reproductive purposes, however, means that a cloned human being would be 'deliberately created to be identical genetically to another human being'.[50] The resultant lack of individual genetic identity, it argued, may lead a child to face confusion, bewilderment, tension, self-consciousness and psychological problems 'relating to individual identity and incompleteness'.[51] Pro-Life Victoria also expressed concern that acceptance of children may then become conditional.[52]

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47 Australian Catholic Bishops Conference, *Submissions*, p.S755

48 Coalition for the Defence of Human Life, *Submissions*, p.S269

49 Pro-Life Victoria, *Submissions*, p.S670

50 Pro-Life Victoria, *Submissions*, p.S673

51 Pro-Life Victoria, *Submissions*, pp.S673-674. See also Dr David Gawler, *Submissions*, p.S626

52 Pro-Life Victoria, *Submissions*, pp.S673-674

6.49 The Human Genetics Society of Australasia regarded cloning for reproductive purposes as ethically unacceptable not only because the 'scientific and medical consequences are currently unknown', but also because it 'would reduce the autonomy of the child who has been cloned, particularly if the genome of the person cloned replicates that of an existing adult or child (intergenerational cloning) or if multiple clones are generated…'[53]

6.50 The argument that cloning for reproductive purposes would necessarily undermine individuality and identity was, however, disputed by Ridley College, among others. It argued that concerns about loss of individuality and identity rested on an assumption that uniqueness and individual identity require a unique genome. In its view this is not the case and it cited the example of identical twins who have identical genomes but usually develop into completely distinct individuals.[54] Dr Nicholas Tonti-Filippini agreed with this criticism and argued that concerns about identity and individuality have little basis in scientific fact[55] but he did point to the existence of what he called 'cultural genetic determinism' and the expectations society may have of people with nearly identical genomes.[56]

6.51 Both the Catholic Archdiocese of Melbourne and the Social Responsibilities Committee of the Anglican Diocese of Melbourne submitted that concerns relating to identity and individuality were but one reason, among many, for exercising great caution in these matters. The Catholic Archdiocese of Melbourne submitted:

> Reverence for the sacredness of human life and of the family counsel both *inventiveness* and *caution* in interventions involving human beings and especially in experimentation upon them. In particular, concerning human cloning, respect must be shown for the *integrity of the person* in his or her fundamental nature and unique identity, for the *shared nature and diversity of the human family*, for *human life in its origins,* and for *human fertility and parenthood* [emphasis in original].[57]

6.52 The Social Responsibilities Committee of the Anglican Diocese of Melbourne stated:

> … no-one knows what would be the effects on human identity and relationships of creating someone who is the twin of their father or

53 Human Genetics Society of Australasia, *Submissions,* p.S508

54 Ridley College, *Submissions,* p.S31

55 Dr Nicholas Tonti-Filippini, *Submissions,* pp.S592-593

56 Dr Nicholas Tonti-Filippini, *Submissions,* p.S595

57 Catholic Archdiocese of Melbourne, *Submissions,* p.S519

> mother, but born in a different generation and environment. … There are sufficient uncertainties for applying the precautionary principle.[58]

Safety

6.53 A prominent cause for concern about any prospect of cloning technology being applied to the reproductive cloning of humans was the safety of the procedure.[59]

6.54 Professor Beck noted that 'even if it proved possible to adapt the technology to the human, the medical risks at present would be excessive'.[60] The Consumers Health Forum also submitted that it had taken into account the views of the Australian Academy of Science and the Murdoch Institute For Research into Birth Defects which both considered that cloning for reproductive purposes would be likely to be medically unsafe.[61]

6.55 The Humanist Society of Victoria supported a ban on reproductive cloning of human beings out 'of concern for the safety of the procedures and the physical outcomes of the nuclear transfer method'.[62]

6.56 Queensland Right to Life noted that publicity about cloning makes:

> … no mention of cloning mistakes. Previous experiments with animal cloning have resulted in mutations, premature ageing of the animal and transmission of genetic defects. The "pro-cloning" literature speaks as if it could only produce good results.[63]

6.57 The Social Responsibilities Committee of the Anglican Diocese of Melbourne considered that:

> There are sufficient unknowns about physical problems in pregnancy with cloned sheep and cattle to suggest that human cloning experiments would violate normal medical ethics. There is no experiment that could be done to prove the safety of human

58 Social Responsibilities Committee of the Anglican Diocese of Melbourne, *Submissions,* p.S304

59 The scientific evidence on this issue was discussed in Chapter 3 at paragraphs 3.15-3.19

60 Professor Felix Beck, *Submissions,* p.S683

61 Consumers Health Forum, *Submissions,* p.S761

62 Humanist Society of Victoria, *Submissions,* p.S151. Others to oppose cloning for reproductive purposes on grounds of safety included the Women's Action Alliance (Vic), *Submissions,* p.S782; Dr Eloise Piercy, *Submissions,* p.S582; Dr David Gawler, *Submissions,* p.S623; Professor Roger Short, *Transcript,* p.27; Ridley College, *Submissions,* p.S32 and Dr David Elder, *Submissions,* pp.S195-196

63 Queensland Right to Life, *Submissions,* p.S264

> cloning without causing serious risk to humans created in the process.[64]

6.58 The National Caucus of Disability Consumer Organisations also argued:

> The many failures prior to the so-called "successful" cloning of Dolly must occasion significant caution. Clearly Dolly may also have been regarded as having impairment—created by the very technology which is supposed to have been therapeutic in bring[ing] her to life. Yet because the media was so focussed on the technological determinist message, it forgot critically to ask what right we as a society have to use a technology which occasions the limitations and harms experienced by Dolly—what society would call a disability… [The technology] will also reinforce stereotypes which see disability as a condition to be avoided at all costs rather than being treated and supported.[65]

6.59 The Coalition for the Defence of Human Life criticises the Australian Academy of Science for recommending that 'reproductive cloning to produce human fetuses is unethical and unsafe and should be prohibited'. The Coalition stated it:

> … is unethical in the first place *because* it is unsafe. Dolly the sheep was the sole survivor out of 277 sheep embryos. In the interests of science, such odds may be acceptable in sheep; in humans they would be entirely unacceptable.[66]

Eugenics And Diversity

6.60 Some, such as Professor Beck, expressed concern about the potential for cloning for reproductive purposes, if permitted, to reintroduce the concept or practice of eugenics.[67] Professor Felix Beck argued that 'if at all widely practised the exercise would constitute a gross extension of the discredited "principles" of eugenics current before the Second World War …'[68] The Queensland Right to Life also saw cloning as introducing 'other highly contentious philosophies [for example] eugenicism—cloning can be used to select for various characteristics and potentialities'.[69]

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64 Social Responsibilities Committee of the Anglican Diocese of Melbourne, *Submissions*, p.S304

65 National Caucus of Disability Consumer Organisations, *Submissions*, p.S775

66 Coalition for the Defence of Human Life, *Submissions*, p.S269

67 Eugenics is a term used to describe an applied science that seeks to improve the human race by application of the principle of selective breeding. William Outhwaite and Tom Bottomore (eds)**,** *Blackwell Dictionary of Twentieth-Century Social Thought*, Blackwell, Oxford, 1993

68 Professor Felix Beck, *Submissions*, p.S683

69 Queensland Right to Life, *Submissions*, p.S264

6.61 Concerns were also raised about the implications of cloning for reproductive purposes for Indigenous people and people with disabilities. The Consumers Health Forum agreed that cloning for reproductive purposes is 'ethically unacceptable':

> …disability and indigenous communities, in particular, are concerned that developments in gene technology promote a narrow view of "normality" rather than valuing diversity…[70]

6.62 The National Caucus of Disability Consumer Organisations submitted:

> Regardless of our views of the status of the embryo, fetus, zygotes and human tissue, there is no doubt that there are significant public concerns at a variety of developments involving genetics and cloning. Issues for people with a disability include the exclusion of our perspectives from many ethical debates and the way in which our bodies are often the site for intended therapy, and yet rarely are our voices sought or heeded in the development of technology.[71]

Potential For Coercion

6.63 Some, such as Dr Eloise Piercy, also pointed out the implications of cloning for reproductive purposes for women. Dr Piercy raised the 'serious potential for coercion' caused by the requirement for ova and the requirement that women gestate foetuses in order for such cloning to occur.[72] Ridley College also submitted:

> …that women's bodies would be required as sources of ova and of wombs for gestation of cloned individuals (whether they are allowed to develop to term, or sacrificed at some stage). A person cannot be isolated from her body, and therefore the "use" of a woman's body is an exploitation of her whole person… There is a real danger of the commodification of women's bodies …[73]

IS THERE SUPPORT FOR CLONING FOR REPRODUCTIVE PURPOSES?

6.64 The evidence revealed meagre, if any support in Australia for cloning for reproductive purposes.

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70 Consumers Health Forum, *Submissions*, p.S760

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

72 Dr Eloise Piercy, *Submissions*, p.S582

73 Ridley College, *Submissions*, p.S34

6.65 The Committee is aware that arguments in support of the reproductive cloning of whole human beings have gained some currency overseas since the inquiry commenced. In the United States, for example, some have argued that to prohibit cloning for reproductive purposes would infringe reproductive freedom.[74] Some submissions suggested it was possible that views on this matter might change in the future. Professor Beck argued:

> … it is possible to imagine situations in which cloning procedures carried out to produce whole human beings might be considered socially acceptable.[75]

6.66 These situations might include the prevention of the transmission of mitochondrial diseases[76] and Professor Beck urged that 'we do not serve the cause of humanity by closing our minds'.[77]

6.67 Only one or two people expressed any support at all for cloning for reproductive purposes. Gerald Calvert stated:

> I see nothing wrong with the act of cloning anything, providing it is to someone's advantage, and to no one's disadvantage apart from the unborn, who ultimately will be suppressed in favour of the living. God, if he exists is responsible for it being possible to clone anyway. If he doesn't, then does it really matter?[78]

6.68 Dr David Swanton was very critical of the AHEC report. His view, in summary, is that:

> … the only sound, objective, non-discriminatory, argument taking a universal point of view against human cloning is that of safety, and when the safety of the technology has been resolved (to be as safe as for example IVF technology) no valid ethical argument would then remain against human cloning.[79]

6.69 The Committee strongly disagrees. It is clear that a concern about the safety of cloning for reproductive purposes is not the only ground on which opposition to cloning for reproductive purposes may be based and this chapter has outlined those other arguments in detail.

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74 The Consumers Health Forum cited this argument in its submission but rejected its application in the Australian context on the basis that the risks involved outweigh any potential benefits, *Submissions*, p.S761

75 Professor Felix Beck, *Submissions*, p.S683

76 Professor Felix Beck, *Submissions*, p.S683

77 Professor Felix Beck, *Submissions*, p.S684. Dr Loblay considered that at some future time there may be pressure from certain groups to use this technology for reproductive purposes but that '*current* community values are such as to make this unacceptable [emphasis in original]', *Exhibit* 8

78 Mr Gerald Calvert, *Submissions*, p.S46

79 Dr David Swanton, *Submissions*, p.S114

CONCLUSIONS

6.70 The Committee finds no case has been made in favour of cloning for reproductive purposes. There is no evidence that views have changed on this matter since submissions were provided to the Committee. In fact, indications are that public opposition to cloning for reproductive purposes may have increased given the reaction to media announcements of the intention of some individuals overseas to attempt to clone a whole human being.

6.71 The Committee agrees with the emphatic opposition to cloning for reproductive purposes that was expressed in the evidence to the inquiry.

6.72 The Committee believes that cloning for reproductive purposes is unacceptable. While the Committee holds this view unanimously, individual members reached this conclusion for a variety of reasons encompassing ethical, medical, legal and / or social considerations.

6.73 The Committee emphasises that these conclusions are equally applicable to the use of any future technologies for the purpose of the artificial creation of whole human beings.[80]

6.74 The Committee also believes that currently there is no good reason to allow manipulation of the germ line.

80 The Committee reiterates that these conclusions do not extend to existing *in vitro* fertilisation and assisted reproductive technologies, such as IVF and GIFT

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.
>
> 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).

8

Current Australian regulatory framework—legislative

INTRODUCTION

8.1 Previous chapters have focused on the scientific and ethical issues raised by human cloning. The third area of the Committee's inquiry concerned the appropriate regulatory regime to govern human cloning and related research. This chapter introduces the regulatory issues. The approach taken by the AHEC report to these issues will be outlined and the chapter will then discuss the current legislative framework for human cloning and related research in Australia. Chapter 9 will complete the discussion of the current Australian regulatory framework by outlining its non-legislative regulation and presenting the Committee's conclusions concerning Australia's current regulatory framework for dealing with these matters. Chapter 10 will outline some of the principal international developments in recent years in the regulation of human cloning and discuss some of the implications of these developments for Australia. In Chapter 11 the Committee will respond to the recommendations in the AHEC report and consider other options for regulating this area of research. Chapter 12 will present the Committee's suggested framework for the regulation of human cloning and its related research in Australia.

OVERVIEW OF THE CURRENT AUSTRALIAN REGULATORY FRAMEWORK

8.2 The discussion in this chapter and Chapter 9 will outline current State and Commonwealth legislative and non-legislative regulation dealing directly or indirectly with research involving human cloning.

8.3 Regulation governing human cloning and research or experimentation involving embryos is most relevant to the inquiry. These areas of regulation will be outlined separately. Other legislative and non-legislative regulation is also relevant. Such regulation includes legislation governing the donation of human tissue and the important role played by institutional ethics committees.

8.4 There is an important distinction between conducting research using embryos and using cell-based therapies in medical treatment. Cell-based therapies, using adult cells, are of long standing.[1] The use of somatic cell nuclear transfer techniques in the course of therapy or medical treatment in contrast is, as was noted in Chapter 3, some distance into the future. These different techniques affect the kind of regulation that will be applicable in different situations. The legislative and non-legislative regulation discussed below focuses principally on that governing the use of embryos and human tissues in research.

8.5 The regulation of human cloning and the use of human embryos in research has evolved as part of the regulation of assisted reproductive technologies. The use of the human embryo in the course of assisted reproductive technologies has been premised on the consent of the genetic parents. There is no comprehensive and consistent approach in Australia to the regulation of human cloning and its related research. This variation between jurisdictions creates frustration and confusion for researchers, practitioners and the general public.

8.6 Three States—Victoria, South Australia and Western Australia—regulate human cloning and research involving the use of embryos by means of the legislative frameworks governing assisted reproductive technologies. All three States have a statutory prohibition on cloning. However, as is discussed below, the interpretation of these prohibitions is uncertain.[2] The recently enacted Commonwealth statutory ban on human cloning in the *Gene Technology Act 2000* can now be added to these statutory prohibitions.

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1 Peter MacCallum Cancer Institute, *Submissions*, p.S888

2 See paragraphs 8.17-8.20 below

8.7 New South Wales, Queensland, Tasmania, the Northern Territory and the Australian Capital Territory do not have any legislative prohibition on human cloning or legislative regulation of research involving human embryos. Regulation in these jurisdictions occurs by means of National Health and Medical Research Council (NHMRC) Guidelines and the self-regulation of assisted reproductive technology providers by the Fertility Society of Australia (FSA) through its Reproductive Technology Accreditation Committee (RTAC) Code of Practice. These modes of regulation are discussed in Chapter 9.

8.8 Following an outline of the AHEC report's discussion of regulatory issues, the legislative regulation will be discussed. Non-legislative methods of regulation are discussed in the next chapter. Non-statutory methods of regulation, as noted above, occur largely by means of NHMRC Guidelines developed by AHEC. These guidelines must be followed by those in receipt of Commonwealth funding.

THE AHEC REPORT'S DISCUSSION OF REGULATORY ISSUES

8.9 An outline of Australian and international regulation relevant to cloning and research involving the use of embryos (as at November 1998) was provided in Chapters 4 and 5 of the AHEC report.

8.10 Chapter 4 of the AHEC report canvassed the current legislative and non-legislative regulation of human cloning and embryo experimentation. It noted the absence of legislative regulation of this area in many of the States and Territories and the inconsistent definition of cloning in the legislation in Victoria, Western Australian and South Australia.[3] Chapter 4 of the AHEC report also briefly canvassed regulation in the areas of the status of children and the donation of human tissue.[4]

8.11 The AHEC report states that substantial limits are placed on research involving embryos in Australia. Specific approval for embryo experimentation is required by legislation in three states (Victoria, Western Australia and South Australia). The effect of those statutory provisions and the NHMRC Statement on Human Experimentation[5] and

3 AHEC report, Chapter 4, paragraph 4.3

4 The Committee did not address issues relating to the status of children, inheritance or family law as they are at one remove from the focus of the inquiry

5 Superseded now by the *National Statement on Ethical Conduct in Research involving Human*s—see paragraphs 9.17-9.20 of Chapter 9

the specific NHMRC *Ethical Guidelines on Assisted Reproductive Technology* which deal with embryo experimentation is to allow research involving embryos only in exceptional circumstances. In the case of the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* such exceptional circumstances require a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed research, the use of a restricted number of embryos and consent to the specific form of research on the part of the gamete providers and their spouses or partners. In States and Territories other than Victoria, Western Australia and South Australia an institutional ethics committee (IEC) is required to grant approval for such research in accordance with these NHMRC Guidelines.[6]

8.12 The AHEC report further commented that embryo splitting and somatic cell nuclear transfer for the specific purpose of cloning an identical human being is either prohibited or against the intention of the regulatory framework established in Victoria, Western Australia and South Australia and the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*. Production of embryonic stem cell lines would be in contravention of both the Victorian and Western Australian legislation and the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*.[7]

8.13 However, in its conclusion to Chapter 4 of its report, AHEC expresses its concern that:

> … a private, rather than publicly funded, organisation in a State or Territory other than Victoria, Western Australia or South Australia might consider a venture in cloning of a human being or cloning of human *parts* without the approval of an IEC under NHMRC guidelines. Currently, the NHMRC guidelines are only enforceable against institutions receiving NHMRC funding. The possibility exists that a private institution could decide to undertake such work. Without legislation the NHMRC cannot stop private institutions conducting such work.[8]

8.14 In the context of this comment it is worth noting that biotechnology companies are a growth area for investment. It would also appear that most Australian research in this area is occurring in those companies that have managed to recruit the assistance of many of the scientists working

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6 AHEC report, Chapter 4, paragraph 4.17. Institutional ethics committee approval may also be required in Victoria and Western Australia

7 AHEC report, Chapter 4, paragraph 4.32

8 AHEC report, Chapter 4, paragraph 4.34. As was noted in Chapter 4 (this report) there is extensive private sector involvement in this research—see paragraphs 4.8-4.10

in this area in our major universities and other publicly funded research institutions.[9]

8.15 Chapter 5 of the AHEC report outlined international developments current to November 1998. These included the United Nations Educational, Scientific and Cultural Organisation (UNESCO) *Declaration on the Human Genome and Human Rights* and the Council of Europe *Convention on the Protection of Human Rights and Dignity with Regard to the Application of Biology and Medicine* and the *Additional Protocol on Human Cloning*. The chapter also canvassed developments in the United Kingdom and the United States of America and Canada. The AHEC report made no comment on the developments or their relevance or application to Australia.[10]

CURRENT AUSTRALIAN REGULATORY FRAMEWORK—LEGISLATIVE

8.16 The following discussion outlines:

- the legislative provisions prohibiting human cloning at both State and Commonwealth levels;
- the legislative regulation of research involving the use of embryos in Victoria, South Australia and Western Australia; and
- other relevant legislation including Commonwealth legislation governing patents and privacy and state and territory human tissue legislation.

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9 Mr Robert Klupacs, General Manager and Chief Executive Officer of ES Cell International Pte Ltd, for example, discussed the links between that company and the Monash Institute of Reproduction and Development, *Transcript*, p.169 and *Submissions*, p.S892. Dr Smeaton from BresaGen Ltd also referred to BresaGen's links with the University of Adelaide and the work of Professor Peter Rathjen, *Transcript*, p.150

10 These matters are discussed in more detail in Chapter 10. In contrast to Chapter 3 of the AHEC report, Chapters 4 and 5 elicited little comment in evidence to the inquiry. Mr Peter Eddington criticised both Chapters 4 and 5 for failing to draw any conclusions from the material presented, making weak recommendations in the light of the information (for example, not suggesting ways to remedy the inconsistencies in the definitions of the term 'cloning') and failing to provide any comment on the relative value of overseas models. *Submissions*, pp.S86 and 88

Legislative Provisions Prohibiting Human Cloning

8.17 In Victoria, the *Infertility Treatment Act 1995* (Vic) specifically prohibits human cloning. The Act provides that 'a person must not carry out or attempt to carry out cloning'.[11] The term 'clone' is defined in section 3:

> "clone" means to form, outside the human body, a human embryo that is genetically identical to another human embryo or person.[12]

8.18 In Western Australia, section 7 of the *Human Reproductive Technology Act 1991* (WA) provides that it is an offence to carry out any procedure directed at human cloning.[13] It is also an offence to cause or permit a nucleus of a cell of an egg in the process of fertilisation or any embryo to be replaced[14] or to cause or permit the genetic structure of any cell to be altered while the cell forms part of an egg in the process of fertilisation or any embryo.[15] Section 3 defines 'cloning' as follows:

> "cloning" means the use of reproductive technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical, live born and viable.[16]

8.19 In South Australia, the Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 made under the *Reproductive Technology Act 1988* (SA) provide that a 'licensee must not carry out, or cause, suffer or permit to be carried out, the procedure of cloning'.[17] 'Cloning' is defined as:

> …any procedure directed at producing two or more genetically identical embryos from the division of one embryo.[18]

8.20 New South Wales is currently undertaking a review of human tissue legislation. In October 1997, the New South Wales Government issued a

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11 Section 47

12 Other provisions such as sections 24 and 25, discussed below, also enhance the prohibition contained in this section. The Infertility Treatment Authority in Victoria has expressed the view that the provisions of the Act do not cover embryonic stem cell research – see paragraphs 8.52-8.53 below.

13 Section 7(1) (d) (i)

14 Section 7(1) (e)

15 Section 7(1) (f)

16 It is also an offence to produce a chimaera—section 7(1)(d)(iii). A chimaera is defined in section 3 as a single living organism which has a mixed genetic origin as a consequence of combining cells derived from different human embryos or the human and other species

17 Regulation 6. Other provisions, outlined below, also enhance the prohibition contained in this section

18 Regulation 1

discussion paper entitled *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies*. In the forward to this paper, the then NSW Minister for Health, the Hon. Dr Andrew Refshauge, stated that:

> In response to community concern the Government has decided to introduce a law to ensure that two procedures do not develop in New South Wales. The Government has announced the banning of human cloning and trans-species fertilisation involving human gametes or embryos.

The process initiated by the Discussion Paper continues.[19]

New Commonwealth provision

8.21 The recently enacted Commonwealth *Gene Technology Act 2000* contains a prohibition on the cloning of whole human beings.[20] It also prohibits placing human cells into animal eggs or placing a combination of animal and human cells into a human uterus.[21] Section 192B of the Act provides:

> Cloning of human beings is prohibited
>
> (1) A person is guilty of an offence if:
>
> (a) the person engages in conduct; and
>
> (b) the person knows that, or is reckless as to whether, the conduct will result in the cloning of a whole human being.
>
> (2) In this section:
>
> cloning of a whole human being means the use of technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical to the original.

8.22 The coverage of this provision is limited. Section 13 of the *Gene Technology Act 2000* provides that the Act applies, among other areas, to corporations, to things done in the course of trade and commerce, to things done that

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19 AHEC report, Chapter 4, paragraph 4.12 and NSW Minister for Health, *Submissions*, p.S866

20 Senator Vanstone (representing the Minister for Health and Aged Care in the Senate) stated, in March 2001, that the provision is an 'interim measure' until each State and Territory has implemented appropriate legislation in this area. She went on to say that the provision is a strong statement of the government's intention that the cloning of whole human beings will not be carried on in Australia. Senator Vanstone also stated that 'it is expected that further clarification of this intent will be provided', Senate, *Hansard*, 26 March 2001, column 22932

21 Sections 192C and 192D

may cause the spread of disease or pests, for purposes relating to statistics and actions by the Commonwealth or Commonwealth authorities.[22]

Is cloning prohibited?

8.23 It will be immediately apparent that these definitions of 'cloning' are not consistent and that each prohibits slightly different conduct. The AHEC report commented that:

> The importance of clearly defining this term will be of great importance in ensuring adequate regulation of this area of science.[23]

8.24 The Committee agrees. However, a clear definition of prohibited conduct is not provided by any of the four statutory provisions outlined above.

What are the differences?

8.25 The Victorian definition focuses on the formation of a genetically identical human embryo regardless of its proposed use. It is the formation of the embryo rather than the attempt to replicate a person that is prohibited.[24]

8.26 The Western Australian legislative prohibition is directed towards the use of reproductive technology for the purpose of producing duplicates or descendants that are 'genetically identical, live born and viable'. The focus of prohibited conduct is the production of a live born individual. Hence while the Victorian prohibition would apply to the cloning of embryos for any purpose, whether 'therapeutic' or 'reproductive', the Western Australian prohibition is directed towards 'reproductive' cloning.[25]

8.27 The South Australian definition of cloning appears to prohibit cloning by means of the technique of embryo splitting and not by means of somatic cell nuclear transfer.[26] Professor Norman a member of the South Australian Council on Reproductive Technology stated that the Council took the view that the somatic cell nuclear transfer method of cloning was, however, prohibited by regulation 9 of the South Australian Reproductive Technology (Code of Ethical Research Practice) Regulations which states:

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22 These areas reflect specific constitutional powers relied on by the Commonwealth to enact the legislation—see section 13 of the Act. This application is subject to any winding back of the operation of the Act under section 14 and concurrent operation of State laws allowed for under section 16 of the Act

23 AHEC report, Chapter 4, paragraph 4.3

24 The provision would also prohibit reproduction of a person if that embryo is implanted in a woman

25 Western Australia further regulates the creation of embryos and this is discussed below

26 AHEC report, Chapter 4, paragraphs 4.28 and 4.3 and footnote 60

> A licensee must not replace, or cause, suffer or permit the replacement of, the nucleus of a cell of an embryo, or of an ovum in the process of fertilisation, with any other nucleus.[27]

South Australian reconsideration of its definition

8.28 Professor Norman explained that the Council readdressed the South Australian definition of cloning as a result of recent scientific advances:

> Council noted that the definition in the Codes might imply that cloning experimentation on cells is permissible despite the guidelines of the [NHMRC] that do not allow such research[28]…While [current] prohibitions were quite satisfactory for the technology currently available,[29] the Council was mindful that scientific advances in cloning techniques in the future could alter this. It was particularly noted by the Council that South Australian law does not legislate against the cloning of human organs or tissues.[30]

8.29 Professor Norman indicated that the Council established a cloning working party whose brief was to develop a new definition of cloning for the Reproductive Technology (Code of Ethical Research Practice) Regulations that would reflect current research.[31]

8.30 The proposed new definition of human cloning would read:

> Cloning is defined as the practice of forming an embryo or an entity capable of embryogenesis which is genetically identical to, or substantially identical to, another human being, living or deceased.[32]

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27 Professor Robert Norman, *Submissions*, p.S718. The somatic cell nuclear transfer method of cloning involves the replacement of the nucleus of an unfertilised ovum (egg / oocyte) not an ovum in the process of fertilisation or an embryo

28 This is a reference to the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996) especially Guideline 11.3. The *Ethical Guidelines* are discussed in Chapter 9, paragraphs 9.9 – 9.16

29 This is a reference to regulation 9 (quoted in paragraph 8.27) and 8 which provide that a licensee must not alter or cause, suffer or permit to be altered, the genetic structure of a cell while the cell forms part of an embryo or an ovum in the process of fertilisation

30 Professor Robert Norman, *Submissions*, p.S718

31 Professor Robert Norman, *Submissions*, p.S718

32 Professor Robert Norman, *Submissions*, p.S719. Any changes to the definition of 'cloning' in the Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 (SA) are still being considered

8.31 Professor Norman submitted that 'the ambit of the Council [only] includes human reproductive technology relating to gametes and embryos'.[33] Hence, while this new definition would:

> …therefore exclude the use of human gametes for cloning, it does leave open the possibility of using somatic cells for cloning with methods that do not incorporate human oocytes.[34]

What about the new Commonwealth definition?

8.32 The new Commonwealth definition of human cloning has most in common with that in Western Australia but does not refer to the production of a 'live born and viable' person. The reference to 'duplicates and descendants' seems to indicate an intention only to prohibit cloning for the purposes of reproduction.[35]

The problems in using the term 'genetically identical'

8.33 A significant difficulty with all of these legislative definitions of 'cloning' is that they rely on the concept of the resulting product being 'genetically identical'. This is presumably in reliance upon scientific explanations of the process of somatic cell nuclear transfer. However some argue that this description may not be entirely accurate in reality. The process of cloning (described in Chapter 2) involves the replacement of the nucleus of a donated egg with the nucleus of a somatic donor cell. Surrounding the nucleus in the egg is cytoplasm that contains DNA—known as mitochondrial DNA. This DNA will also form part of the genetic inheritance of any offspring and may lead to slight differences from the original donor of the somatic cell. In addition, during each cycle of cell division the DNA within a cell, nuclear and mitochondrial, is replicated. Mutations may occur in this process which means that the product of cell division also is not genetically identical to the cell from which it was produced. These differences may be small, although the product of cloning is likely to be less identical than monozygotic twins. This may lead to argument about whether in fact the cloned entity is entirely 'identical'.

8.34 As the following discussion suggests, the process will probably produce a clone 'substantially identical' to, but not completely genetically identical

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33 Professor Robert Norman, *Submissions*, p.S719

34 Professor Robert Norman, *Submissions*, p.S719

35 An alternative argument could be made that the use of the term 'whole human being' leaves open the possible application of the provision to the creation of embryos for research purposes since it is unclear whether the term 'whole human being' should be taken to refer to an embryo, a foetus, a newborn child or an adult

to, the original.[36] The possibility that the requirement for 'genetic identicality' or a 'genomic copy' could reduce the effectiveness of provisions prohibiting cloning of human beings was accepted by the NHMRC and AHEC.[37] Associate Professor Thomson, the Deputy Chair of AHEC, stated that 'science has now made it clear that human organisms, although called clones, are not genetically identical'.[38] Dr Tobin, a member of AHEC, expressed concern as to how a ban on reproductive cloning expressed in terms of genetic identicality could work when ensuring some small genetic variability in the resulting organism could be enough to avoid it.[39] This problem has also been acknowledged by Professor Don Chalmers, the former Chair of AHEC.[40] Senator Vanstone stated that the term 'genetically identical' has been 'deemed to be sufficient from a legal perspective'.[41] In the Committee's view there must be some doubt about this.

8.35 The Committee is concerned by the narrowness and technicality of the current legislative definitions of cloning and urges that they be replaced by a definition that is broader, more effective and not focused on the requirement of genetic identicality.

8.36 It appears to the Committee that the existing legislative definitions of the term 'cloning' focus on the final product of the process (that is an embryo or a person) being identical. On the other hand, scientific explanations appear to focus on the process itself not the final product. Hence, in the course of the process of transfer, the genomic content of the nucleus of the somatic cell may remain unchanged but by the time the final product has emerged from the interaction with the cytoplasm and any subsequent mutations, the final product will probably not be strictly identical.

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36 This must raise some doubt as to the potential for conviction under section 192B of the *Gene Technology Act 2000* since the scientist presumably would not have engaged in the conduct with the purpose of producing duplicates genetically identical to the original. Although the interpretation of this provision would be a matter for a court, since the penalties for committing this offence are so severe (ten years gaol) the offence will probably be strictly construed

37 Professor Nicholas Saunders, *Transcript*, p.201

38 Associate Professor Colin Thomson, *Transcript*, p.203

39 Dr Bernadette Tobin, *Transcript*, p.203

40 Stephen Brook, 'Dark Side of the Clone', *Weekend Australian*, 17 March 2001, p.26

41 Senator Vanstone (representing the Minister for Health and Aged Care in the Senate), 26 March 2001, Senate, *Hansard*, column 22931

The application of the Commonwealth provision

8.37 The application of section 192B of the *Gene Technology Act 2000* also complicates the operation of the existing state provisions. Under Section 109 of the Constitution, a law of the Commonwealth on a particular subject that falls within its constitutional power will prevail over an inconsistent State law on the same subject to the extent of the inconsistency. The *Gene Technology Act 2000* does not purport to apply in all areas[42] (and does permit the concurrent operation of some state laws) but it does apply to corporations.[43]As was discussed in Chapter 4 private sector corporations are increasingly engaged in this field of research. If the intention of the Commonwealth is that the definition of cloning in section 192B is to be interpreted so as to permit so called 'therapeutic cloning' (and hence an embryo is not a human being for the purposes of section 192B), the status of State provisions, such as that in Victoria which prohibits cloning to produce an embryo, must be an open question.

8.38 The intention and operation of the Commonwealth provision and its interaction with existing State provisions prohibiting human cloning must be clarified immediately. This matter is discussed further in Chapter 12. In the Committee's view the prohibition on human cloning in section 192B of the *Gene Technology Act 2000* is insufficient and inappropriate.

So which would be the best definition?

8.39 The proposed South Australian approach to the definition of human cloning does minimise the difficulty caused by the focus in existing provisions on genetic identicality by adding the words 'substantially identical to …'. The proposed addition of the words 'an entity capable of embryogenesis' would also incorporate 'embryo like' entities generated by means other than fertilisation. However, this approach does not focus on the intention to produce 'live born and viable' whole human beings.

8.40 The focus of effective criminal prohibitions on reproductive cloning should be on the intention to produce a whole human being other than by means of existing assisted reproductive technologies. If the retention of some concept of genetic similarity is sought, the inclusion of the words '…or substantially identical to…' would appear to be a worthwhile safeguard against arguments such as those outlined above concerning the

42 See sections 13, 14 and 16 of the *Gene Technology Act 2000*

43 Whether this includes universities is an unresolved question. Universities are commonly constituted as corporations but whether a university is a 'trading corporation' by virtue of selling educational services or the results of research is an open question, Department of the Parliamentary Library, Bills Digest No 11 2000-01, *Gene Technology Bill 200*0, footnote 34

weaknesses of the current provisions**.** However, it may also be necessary to guard against the possibility of the substantial alternation of some DNA in the course of the creation of human embryos by somatic cell nuclear transfer. This could perhaps occur by means of the substitution of sufficient genetic material from another human tissue source so that the result was no longer 'substantially genetically identical' to the first donor source and then transferring the resulting embryo to a woman's uterus. [44]

Legislative Regulation Of Research Involving The Use Of Embryos

Overview

8.41 Most of the current sensitivities surrounding cloning research involve research using human embryos, either as a result of creating embryos for research purposes or using surplus embryos from assisted reproductive technology programs to extract embryonic stem cells. The current legislation concerning embryo experimentation applies directly to such research.

8.42 The current legislation governing human embryo experimentation reflects a tension between the view that the human embryo (if not a human being) certainly deserves respect, and the view that some experimentation ought to be allowed to gain knowledge that will assist in resolving infertility or improving health outcomes.[45]

8.43 None of the three States with statutory regimes totally prohibits research using embryos but substantial limits are placed on any such research. The focus of the legislation is on regulating destructive research, that is research that will harm the embryo or leave it in a condition that will not enable implantation in a woman. The balance in all three pieces of legislation falls in favour of according a special status to the human embryo and ensuring the protection of that status.

8.44 It should be noted, however, that non-destructive research does not necessarily equate with research that will have therapeutic benefits for the embryo. Research on an embryo may be harmless without being of any therapeutic benefit to it.[46]

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44 Chapter 12 outlines conduct that the Committee considers should be prohibited

45 The AHEC report notes that various reports on the matter in the 1980s also reflect this tension, AHEC report, Chapter 4, paragraph 4.5

46 NSW Government Discussion Paper, *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies*, paragraph 4.2

8.45 A cautionary note must be sounded before discussing the current legislative provisions regulating experimentation on human embryos:

> The complexities of the concepts being discussed and the limitations of the words and definitions in these Acts make precise interpretation of the legislative effect of the Acts on the application of cloning technology almost impossible.[47]

8.46 It is clear that new forms of research arising from cloning technologies, such as the extraction and use of embryonic stem cells, have exposed the problem of trying to apply old definitions to new research.

Victoria

8.47 The *Infertility Treatment Act 1995* (Vic) regulates both assisted reproductive technologies and experimentation on embryos. It is administered by the Infertility Treatment Authority. The Act establishes parameters of permitted research utilising human embryos by setting out the conditions under which research on human embryos may be undertaken and prohibiting certain types of research.[48] The Authority must approve all embryo research. Any scientist or practitioner wanting to undertake such research must be approved and any approved research must be in a place that is licensed by the Authority in accordance with the Act.

8.48 Destructive research on embryos as defined in the Act is banned.[49] Destructive research is research on an embryo if it is unfit for transfer to a woman or, in the case of an embryo that is fit for transfer to a woman, the research would harm the embryo, reduce the likelihood of a pregnancy resulting from the transfer of the embryo or make the embryo unfit for transfer to a woman. The Infertility Treatment Authority may not approve research utilising a human embryo if the research would lead to any of those effects.[50]

8.49 The Act is complicated by the technicalities surrounding the definition of the term 'embryo'.[51] The Authority may not grant approval for certain

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47 Dr Sandra Webb, Executive Officer, WA Reproductive Technology Council, *Therapeutic Cloning for Tissue Repair: The legal situation in Western Australia and South Australia, Exhibit* 2

48 Section 22

49 Section 24

50 Section 25

51 Section 3 defines an 'embryo' as 'any stage of human embryonic development at and from syngamy'. Syngamy is defined as 'that stage of development of a fertilised oocyte where the chromosomes derived from the male and female pronuclei align on the mitotic spindle'. A zygote is defined as 'the stages of human development from the commencement of penetration of an oocyte by sperm up to but not including syngamy'. The definitions reflect

kinds of research if it involves the 'formation or use of a zygote if the research proposes that the zygote continue to develop to syngamy'.[52] Hence destructive research on embryos is prohibited after syngamy. In the case of a zygote (a pre-syngamy embryo) these prohibitions do not apply but an approval for research on zygotes is required under the Act.[53]

8.50 Prohibited practices (in addition to cloning) include forming an embryo outside the body of a woman except for the purposes of a treatment procedure,[54] importing or exporting a gamete, zygote or embryo into or out of Victoria without the approval of the Authority [55] and altering the genetic constitution of a gamete intended for use in a fertilisation procedure.[56]

8.51 Consent to research involving the formation of a zygote or use of an embryo or zygote must be obtained from each person who produced a gamete to be used in the research and their spouse. The consent must be specific to the particular procedure or research and there are detailed provisions relating to the requirements for informed consent.[57]

8.52 Research involving tissue derived from human embryos such as embryonic stem cells would appear to fall outside the Act (although not if an embryo was destroyed in Victoria in order to obtain them). The Infertility Treatment Authority News contained the following statement issued by the Authority:

> For the purposes of the *Infertility Treatment Act 1995*, ES cells are neither gametes nor embryos. Therefore they are not within the requirements related to research, nor within the approval processes in relation to import or export of gametes and embryos prescribed in section 56. The Authority, therefore, has no statutory power under the *Infertility Treatment Act 1995* to prescribe certain actions or requirements in relation to the importation of ES cells into Victoria, or in relation to their use in Victoria.[58]

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the stages of embryonic development from a zygote through syngamy to an embryo—see Chapter 2, paragraphs 2.9-2.16 for an explanation of this process

52 Section 26

53 Sections 26 and 49

54 Section 49

55 Section 56

56 Section 39

57 Sections 27-32. Part 4 of the Act also contains additional procedures relating to consent

58 ITA News, May 2000. See also Professor Alan Trounson, *Transcript*, p.12; Human Research and Ethics committee of the Monash Medical Centre and Southern Health Care Network, *Submissions*, pp.S138-139 and Rev Dr Norman Ford, *Submissions*, p.S833

8.53 It would also appear that stem cells that are derived from embryos created by means of somatic cell nuclear transfer would not fall within the Act. Such embryos are formed without the use of sperm. The definition of the term 'embryo' is quite specific and builds on the definitions of 'zygote' and 'syngamy' (both of which rely on the fertilisation of an egg by sperm). Stem cells derived from reprogrammed adult cells would also fall outside the Act.

South Australia

8.54 The *Reproductive Technology Act 1988* regulates both assisted reproductive technologies and experimentation involving embryos. The Act establishes a statutory system of licensing of those who carry out these procedures.

8.55 The Act establishes the South Australian Council on Reproductive Technology. Its functions include advising the Minister on questions arising from reproductive technology, promoting informed public debate, advising the Minister on all matters falling under the legislation including the conditions to be included on licences and the establishment of a code of ethical practice.[59]

8.56 The Act prohibits carrying out research involving experimentation with 'human reproductive material'[60] except in pursuance of a licence.[61] Section 14 of the Act requires that a licence be subject to a condition prohibiting research that may be detrimental to an embryo. The Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 made under the Act[62] set out the conditions for ethical research practice.[63]

8.57 Research that is prohibited under the Reproductive Technology (Code of Ethical Research Practice) Regulations includes—culturing or maintaining embryos outside the body, research on embryos more than 14 days old, mixing human and animal reproductive material, altering the genetic structure of a cell while that cell forms part of an embryo or an ovum in the process of fertilisation, replacing the nucleus of a cell of an embryo or of an ovum in the process of fertilisation with any other nucleus or placing any cells extracted from an embryo into the body of any person.[64]

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59 Section 10

60 Defined in section 3 as 'a human embryo, human semen, a human ovum'

61 Section 14

62 Section 20(4)

63 These Regulations define an embryo as 'a human embryo'

64 Regulations 3-13 list research that is prohibited under the Regulations. Regulations 15, 16 and 17 set out consent provisions including the requirement that consent must be given for the

8.58 Hence the legislative framework in South Australia is relatively restrictive. However, research involving embryonic stem cells would not be precluded by the Act nor would research involving adult stem cells.[65]

8.59 Professor Norman went on to state that the working party established to review the definition of 'cloning' in the Reproductive Technology (Code of Ethical Research Practice) Regulations was:

> …sympathetic to the concept of human embryonic stem cells being established for therapeutic use, either as a generic stem cell line or as a personalised stem cell line. It did not seek to prohibit the use of human somatic cells for this purpose provided that no human gametes were utilised in the production of these stem cell lines.[66]

Western Australia

8.60 The *Human Reproductive Technology Act 1991,* like the regulatory regime in South Australia, regulates assisted reproductive technology and research involving embryos and establishes a statutory system of licensing for those who carry out these procedures.

8.61 The Act establishes a regulatory structure and Code of Practice. It is administered by the Commissioner of Health who implements the licensing system on advice from the Western Australian Reproductive Technology Council.

8.62 Under section 3 of the Act, 'embryo' is defined as:

> A live human embryo, in the stage of development which occurs from—
>
> (a) the completion of the fertilisation of the egg; or
>
> (b) the initiation of parthenogenesis,
>
> to the time when, excluding any period of storage, 7 completed weeks of the development have occurred.

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particular research to be conducted. Regulation 20 of the Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995 is in similar terms

65 Professor Norman noted that the SA Committee was given an opinion that the potential is still open for human somatic cells to be placed in animal oocytes to form human embryonic stem cells or for mature cell lines to be de-differentiated. He stated these would be outside the terms of reference of the Council and not included in the Act, *Submissions*, p.S719

66 Professor Robert Norman, *Submissions*, p.S719. Professor Norman also noted that there is a theoretical possibility that cells obtained from the inner cell mass of an embryo could be used to establish ES cell lines without the destruction of the embryo. South Australian regulations prohibit the use of sperm or oocytes for human cloning and also the destruction of embryos to produce cell lines, Professor Robert Norman *Submissions*, p.S719

Prior to that stage the egg is referred to in the Act as an 'egg in the process of fertilisation'.[67]

8.63 Section 7 of the Act sets out a range of offences. These include altering the genetic structure of any cell while the cell forms part of an egg in the process of fertilisation or any embryo, conducting unapproved research or diagnostic procedures with an egg in the process of fertilisation or an embryo, replacing the nucleus of a cell of an egg in the process of fertilisation or any embryo and causing or permitting an embryo to be maintained or kept outside the body of a woman after 14 days (excluding any period of storage) from the time the gametes were mixed. Hence nuclear transfer is ruled out but only where that involves an embryonic cell.

8.64 Embryo research is strictly regulated. The conditions are such that, in effect, little embryo research can be approved. Section 14(2) directs that such research must be intended to be therapeutic and not likely to harm the embryo, while section 17(b) directs that, as a matter of principle, the Council shall prohibit the development of any egg in the process of fertilisation or any embryo other than with a view to its future implantation into a particular woman.[68]

8.65 Hence research involving human cloning for 'therapeutic' purposes is restricted in many ways by the Act although the actual definition of 'cloning' would not rule it out.[69]

8.66 The Council must provide specific and general approval for research projects involving gametes obtained in the course of an IVF procedure or intended for use in an artificial fertilisation procedure, an egg in the process of fertilisation or any embryo.[70] Council may also require that approval also be sought from a specific IEC recognised by the Council.

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67 'Parthenogenesis' in 'relation to an embryo means development initiated in the absence of, and other than by, fertilisation'—section 3

68 The definition of 'embryo' means that asexually produced embryos would be included in the restriction on the development of embryos other than for implantation, Dr Sandra Webb, Executive Officer, WA Reproductive Technology Council, *Therapeutic Cloning for Tissue Repair: The legal situation in Western Australia and South Australia, Exhibit* 2. Further, in *Directions given by the Commissioner of Health* to set the standards of practice under the Act for licensees, Direction 8.6 provides that any person to whom the licence applies must not develop, or authorise the development of an embryo other than with a view to its future implantation in a particular woman and the relevant consent should indicate this intention, *WA Gazette*, 171, 3 October 1997, *Exhibit 2*

69 *Exhibit 2*. See the discussion above concerning the various legislative definitions of cloning

70 Section 20

8.67 A Western Australian Parliamentary Select Committee reviewed the *Human Reproductive Technology Act 1991* in 1997/98 and reported in 1999.[71] The Select Committee recommended that the prohibition on the development of embryos for research should be retained.[72] It also recommended that the way be left open for the development of 'therapeutic cloning' technology.[73]

Other Relevant Legislation

Commonwealth

8.68 There are Commonwealth statutes that directly impinge upon various aspects of research involving human cloning or research involving the use of embryos but it is important to reiterate the distinction between conducting research and applying the products of the research (such as, for example, cell based therapies) which, as was noted in Chapter 3, is still some distance away. This distinction reflects the regulation to which various matters will be subject.[74]

8.69 Imports of biological material or material for use in cloning or related research (such as embryonic stem cells for instance) are regulated by the *Quarantine Act 1908* and administered by the Australian Quarantine and Inspection Service (AQIS).

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71 Western Australia, Select Committee on the Human Reproductive Technology Act 1991, *Report*, 1999

72 Report, Recommendation 6f

73 This term is a common one to describe the use of cloning techniques for the development of DNA, cells or tissues for transplantation. The problems arising from the use of the term 'therapeutic cloning' were discussed in Chapter 2 and 3 at paragraphs 2.31-2.37 and 3.22. The former Western Australian Government advised that it generally supported the recommendations of the Select Committee but was still considering the recommendations that would bring those parts of the Act relating to embryo research more into line with the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*. Any decision on this matter may affect what sort of 'therapeutic cloning' may be permissible in WA since 'therapeutic cloning' involves the use of embryos

74 An area of regulation that would arise after the research process that forms the focus of this report is the possible use of stem cells in medical treatment or clinical trials. This, strictly, falls outside the framework of this report which centres on research involving human cloning and research using embryos. The use of cell lines and the conduct of clinical trials would fall within the remit of the *Therapeutic Goods Act 1989* which establishes a national system for controls relating to the safety, quality, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. Essentially any product for which therapeutic claims are made must be entered in the Australian Register of Therapeutic Goods before the product can be supplied in Australia. Clinical trials would also involve institutional ethics committees (IECs) the operation of which is discussed in Chapter 9

8.70 The grant of a patent for the protection of intellectual property resulting from the research work is regulated by the *Patents Act 1990*. IP Australia submitted that:

> … issues concerning the patenting of human beings and biological material are often raised in the context of the regulation of human cloning.[75]

8.71 Patents 'cover, generally, any device, substance, method or process that is new, inventive and useful' and a standard Australian patent has a term of up to 20 years.[76] IP Australia stated that in Australia patenting is allowed across all technologies provided that the invention fulfils the statutory requirements of the Patents Act. Under section 18(1) of the Patents Act a patentable invention is an invention that is a manner of manufacture, is novel and involves an inventive step and is useful.[77]

8.72 However an express exclusion concerns the patenting of human beings. Subsection 18(2) of the Patents Act prohibits patenting 'human beings, and the biological processes for their generation'.[78]

8.73 To date, IP Australia submitted, there has been no judicial consideration of subsection 18(2) and it 'remains unclear which inventions would be strictly caught by that provision'.[79] In the absence of such judicial consideration IP Australia notes that it is required to give applicants the benefit of the doubt in relation to the patentability of inventions concerning human material.[80]

8.74 Nonetheless, consistent with subsection 18(2) IP Australia states that it will not grant patents for the following: human beings, foetuses, embryos or fertilised ova; or wholly biological processes that begin with fertilisation and end with the birth of a human being.[81]

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75 IP Australia, *Submissions*, p.S721

76 IP Australia, *Submissions*, p.S723. Some pharmaceutical patents can have their terms extended for a further five years

77 IP Australia, *Submissions*, pp.S723-724

78 IP Australia, *Submissions*, p.S724

79 IP Australia, *Submissions*, p.S724

80 IP Australia cited the High Court decision in the case of *Commissioner of Patents v Microcell* (1959) 102 CLR 232, which held that the Commissioner ought not to refuse acceptance of an application and specification unless it appears practically certain that a patent granted on a specification would be invalid. IP Australia, *Submissions*, p.S724

81 IP Australia, *Submissions*, p.S724. IP Australia submitted (in February 2000) that it had granted 4 patents for cloning processes applicable to non-human mammals and routinely grants patents for both human and animal cell lines, DNA sequences and non-human animal varieties provided the inventions meet the statutory requirements for patentability. IP Australia, *Submissions* p.S724. IP Australia also submitted that it is its understanding that its practice in granting patents for inventions involving human genes, cell lines and tissue is

8.75 IP Australia points out that the use of inventions such as human genes, cell lines and tissue 'would still be subject to other regulatory legislation'. The nature of a patent right is a 'negative' right. It does not create a right for a patentee to use their invention, it merely constitutes a right for a patentee to prevent others from using their invention.[82]

8.76 A more contentious issue is the possible application of the regulatory procedures established by the *Gene Technology Act 2000* to research involving cloning techniques applicable to humans. The Act establishes a system of licensing for bodies undertaking genetic modification. The real problem in ascertaining whether the Act may apply to research involving cloning technologies lies in the difficulty of interpreting central terms such as 'gene technology' and 'genetically modified organisms ' as they are defined in section 10. The Committee received evidence supporting both the proposition that the Act would regulate cloning technologies and that it would not.[83] The exclusion of somatic cell nuclear transfer from the definition of 'gene technology' in section 10[84] appears to resolve at least some of the uncertainty.[85]

Privacy

8.77 Research involving the use of cloning technologies raises many serious issues relating to privacy. These issues concern, among other matters, the

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consistent with section 18(2). However, it recognises that there may be ambiguity over what constitutes a human being or the biological process for the generation of a human being. IP Australia, *Submissions*, p.S724

82 IP Australia, *Submissions*, p.S725

83 Dr Nicholas Tonti-Filippini submitted that the Act would regulate producing human embryos by means of somatic cell nuclear transfer. He also argued that the use of human cells to develop specific cells for transplant would be included because the change from being a stem cell to forming cultured cells of a particular tissue type would involve genetic modification and fall within the Act. Dr Nicholas Tonti-Filippini, *Submissions*, pp.S846-847. The inclusion of cloning processes within the processes established by the *Gene Technology Act 2000* was opposed by Professor Roger Short, *Submissions*, p.S867 and the AAS who stated 'an overlap in the technical language does not imply an overlap in the relevant issues', AAS, *Submissions*, p.S845

84 Regulation 4, Gene Technology Regulations 2001 SR 106. Regulation 4 provides that for the purposes of section 10 of the Act, the definition of 'gene technology does not include somatic cell nuclear transfer if the transfer does not involve genetically modified material'

85 Hon Dr Michael Wooldridge, MP, Minister for Health and Aged Care, stated that while cloning of human beings by somatic cell nuclear transfer is not covered by the *Gene Technology Act 2000*, 'if a person proposed to genetically modify human cells for research or for clinical trials, this would require approval from Gene Technology Regulator and the Therapeutic Goods Administration in the case of clinical trials, *Submissions*, p.S856. The AMA stated that the manipulation of human cells in the laboratory would be regulated under the Act, *Submissions*, p.S841. The Caroline Chisholm Centre for Health Ethics advocated excluding both ES cell lines and human embryo cloning from the Act, *Submissions*, p.S843

collection of genetic data about egg or embryo donors, or the originators of cells, and possible trade in such data. The privacy of the identity of egg and embryo donors is also an issue warranting consideration. Once embryonic stem cells are extracted, the embryonic stem cell would provide the same genetic information about a person as ordinary DNA screens or genetic tests. Thus a complete genetic profile of individuals can be gained from the development of embryonic cell lines as well as from ova, sperm, embryos and other reproductive material. Genetic information (including, for example, predictive information about a person) could also be gained from the examination of the health status or suitability of eggs or cells for use in research.[86]

8.78 The Attorney-General's Department submitted that:

> Privacy issues in relation to research involving cloning of human DNA or cells arise in particular where genetic analysis is required to identify the individuals from whom the genetic material used in the research was obtained. This could be necessitated by a need to assess the health status of the tissue by reference to the health and genetic make up of the cell donor and his or her family.[87]

8.79 The *Privacy Act 1988* (Cth) is relevant to the collection, storage, use and disclosure of personal information by Commonwealth agencies. The use of personal information for research is not exempt from the Information Privacy Principles (IPPs) in the Privacy Act. The Attorney-General's Department submitted that under section 95 of the Privacy Act a Commonwealth agency may, in relation to medical research, deal with personal information in ways that may otherwise infringe the (IPPs) if that research conforms to guidelines devised by the NHMRC and approved by the Privacy Commissioner.[88] Such guidelines have been developed and approved and were published in March 2000.

8.80 Privacy issues in relation to cloning and the use of embryos in research cannot be divorced from genetic information and testing issues generally.

8.81 On 9 August 2000 the Attorney-General and the Minister for Health and Aged Care jointly announced an inquiry to be conducted by the Australian Law Reform Commission and AHEC into the 'human rights, privacy and discrimination issues posed by advances in gene technology'.

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86 Dr John Smeaton gave evidence regarding the development of commercial cell lines, *Transcript*, p.149 as well as evidence concerning the assessment of the quality of embryos – *Transcript* p.161

87 Attorney-General's Department, *Submissions*, p.S537

88 Attorney-General's Department, *Submissions*, p.S539. The Privacy Amendment (Private Sector) Act 2000 will extend the Privacy Act to the private sector

The terms of reference, announced on 7 February 2001, are to inquire into whether a regulatory framework is required to:

- protect the privacy of human genetic samples and information;
- provide protection from inappropriate discriminatory use of human genetic information; and
- reflect the balance of ethical considerations relevant to the collection and uses of human genetic samples and information in Australia.

8.82 The Attorney-General and the Minister for Health and Aged Care should ensure that the matters raised above are investigated as part of this inquiry and kept under review pending the report of the inquiry with a view to legislating on these matters if necessary. The final report is due on 30 June 2002.

State and Territory human tissue legislation

8.83 Apart from the legislation discussed above concerning assisted reproductive technology the most relevant legislation at State and Territory level is that regulating the donation and use of human tissue.[89] The AHEC report notes:

> Current human tissue legislation may apply to some aspects of proposed cloning techniques. Where a cloning technique uses material from one body for transplantation to another or for research or other purposes, the consent provisions of the human tissue legislation would apply.[90]

8.84 The importance of the legislation governing the donation and use of human tissue to the issues under discussion in this report lies in the fact that research involving cloning technologies requires embryos (to extract embryonic stem cells), ova (if embryos are to be created specifically for research using somatic cell transfer techniques)[91] and / or human tissue (to gain adult stem cells or somatic cells for cloning purposes).

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89 Other State and Territory legislation that may also be relevant regulates access to and use of health information held by authorities, consumer protection and professional conduct (see the NHMRC *National Statement on Ethical Conduct in Research involving Humans*, p.5). The discussion of such legislation is beyond the scope of this report

90 AHEC report, Chapter 4, paragraph 4.24

91 These have been discussed above in relation to legislative provisions regulating these matters and discussion in the next chapter will outline non-legislative regulation of the use of embryos and ova

8.85 All States and Territories have enacted legislation regulating the donation and transplantation of human tissue.[92] These statutes cover the removal and donation of tissue for transplant, scientific research or therapeutic use and post mortem examination.

8.86 The most common definition of 'tissue' is that it includes:

> An organ, or part, of a human body or a substance extracted from, or from a part of, a human body.[93]

8.87 All the State and Territory legislation provides that living adults may consent to donate regenerative tissue for transplantation or for therapeutic, medical or scientific purposes. Adults may consent to donate non-regenerative tissue for transplantation only. Donations may also be made from deceased persons provided consent procedures have been followed.[94] Regenerative tissue is defined, in general, as 'tissue that, after injury or removal, is replaced in the body of a living person by natural processes of growth or repair'.[95]

8.88 These provisions do not extend to foetal tissue, sperm and ova.[96] In all jurisdictions it is an offence to attempt to buy or sell or trade human tissue.[97] It is also an offence to remove tissue from a body (living or dead) without consent or authority.[98]

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92 ACT: *Transplantation and Anatomy Act 1978*; NSW: *Human Tissue Act 1983*; NT: *Human Tissue Transplant Act 1979*; Queensland: *Transplantation and Anatomy Act 1979*; SA: *Transplantation and Anatomy Act 1983*; Tasmania: *Human Tissue Act 1985*; Victoria: *Human Tissue Act 1982*; WA: *Human Tissue and Transplant Act 1982*

93 See for example: Victoria: s 3; SA: s 5; Tasmania: s 3; NT: s 4. Queensland is the only jurisdiction to use a different definition

94 See for example: Victoria: sections 7 and 8; Tasmania: sections 7 and 8; NT: sections 8 and 9; SA: sections 9 and 10; Qld: sections 10-11. More restrictive rules apply in the case of children. Donations after death require the pre-death consent of the deceased or next of kin after death. Such tissue may be used for transplantation, therapeutic, scientific or medical purposes—see for example—Victoria: s 26; NT: s 18; SA: s 21; Tasmania: s 23. The Human Tissue Amendment Bill 2001, currently before the NSW Parliament would amend some of these procedures in relation to post-mortems in NSW

95 See for example—Queensland: s 4; Victoria: s 3; NT: s 4; SA: s 5 and Tasmania: s 3

96 NSW has special provisions relating specifically to blood or semen donation (part 3A of the Act), the latter applying to semen obtained or received for the purposes of using it for the artificial insemination of a woman. The donor must sign a certificate relating to medical suitability. See also - Victoria: s 5; WA: s 6; Tasmania: s 3; NT: s 5; SA: s 7; Queensland: s 8. The provisions refer to 'foetuses' although they would probably also apply to embryos

97 See for example: Victoria: s 38 and 39; SA: s 35; Queensland: s 40 and 42; Tasmania: s 27

98 See for example: SA: s 38; Tasmania; s 30; WA: s 33

8.89 Provisions generally exclude the operation of the legislation from the removal of tissue in the course of medical procedures and the use of tissue so removed.[99]

8.90 Also relevant in this context is the NHMRC *National Statement on Ethical Conduct in Research involving Humans* (discussed in Chapter 9) which contains a segment dealing with research utilising human tissue, subject to approval by an institutional ethics committee (IEC).[100] The National Statement provides that:

> Samples collected for diagnostic purposes in the course of treatment[101] may also be used for teaching or quality assurance activities and for research. … Hospitals and pathology laboratories are required by law to retain archival samples for diagnostic or forensic purposes. Accordingly, most hospitals have collections of stored samples, the use of which may lead to important advances in the understanding and treatment of disease. [102]

8.91 The National Statement indicates that research involving the use of such human tissue samples may be approved by an IEC in accordance with the National Statement.[103] Human tissue legislation is currently being reviewed.[104]

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99 See for example: SA: s 37; NT: s 26; Tasmania; s 28; WA: s 32. Legislation in, for example NSW and Victoria, provide that if there is to be an autopsy no further consent is required to retain and use the tissue, provided it was removed for the purpose of the autopsy and the coroner does not object

100 NHMRC, *National Statement on Ethical Conduct in Research involving Humans,* pp.43-45

101 As noted above these are excluded from the human tissue legislation

102 *National Statement*, p.43. This excludes foetal tissue, reproductive tissue and tissue from autopsy to which additional guidelines or legislation might apply—*National Statement*, p.43

103 The *National Statement* indicates that in granting such approval IECs should consider issues such as consent, confidentiality, privacy, storage of samples and data, accountability in care and use of such samples. Consent should generally be required for the use of human tissue samples for research and should be specific to the purpose for which the tissue is to be used. However, an IEC may waive consent requirements in accordance with the *National Statement* – *National Statement*, pp.43-45

104 The review of human tissue legislation and procedures in most jurisdictions has arisen in the context of press reports in 2001 of the retention of human tissue and body parts without consent, or following autopsies, for use in research. In NSW, the Minister for Health appointed senior counsel Brett Walker SC to head an inquiry into practices at a Sydney morgue, *Sydney Morning Herald,* 9 March 2001, p.1; Australian Associated Press, 20 March 2001. Mr Walker's report entitled *Inquiry into Matters Arising from the Post-Mortem and Anatomical Examination Practices of the Institute of Forensic Medicine* was publicly released on 17 August 2001. The Western Australian Government ordered an investigation into current state practices for the removal and retention of body parts in WA and pledged to introduce an enforceable code of conduct in relation to such matters. The issue of consent for the use of body parts will be a particular focus of investigation, AAP, 22 March 2001 and *West Australian*, 21 March 2001, p.5. The Victorian Government has set up a working party to review the retention, use and

How does this apply to cloning research?

8.92 Associate Professor Loane Skene summarised the application of human tissue legislation in the context of human cloning:

> The law requires, before any tissue or any invasive procedure is undertaken on a person, that they be informed about what is proposed and any material risks associated with that, and in the light of that information they make a choice about whether to undertake that procedure [and give consent].[105]

8.93 The situation becomes more complicated, Associate Professor Skene noted, where tissue (such as an ovum):

> … had been taken with the woman's consent and was being stored somewhere, another issue arises as to whether there are any property rights in that stored tissue that would prevent the research being undertaken. The law on that in fact is very unclear as to whether you have to go back to that person and ask them for permission again [or whether the initial consent covers any type of unspecified conduct].

Informed consent is:

> … adequate to protect the taking of the tissue in the first place, but the use of tissue that has been taken with consent for purposes other than the original purposes for which it was taken is quite unclear.[106]

Comment

8.94 The 'ownership' of human tissue is a complex matter and the law, as Associate Professor Skene has stated, is uncertain. It is also not clear at law who, if anyone, 'owns' stored or other genetic material or human tissue. Hence it is unclear who has the right to 'possess' and 'use' it. This uncertainty has posed some difficulties for assisted reproductive technology clinics especially where persons who may be thought to have

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disposal of tissue obtained through autopsy from both hospital and coronial morgues and to review the *Human Tissue Act 1982*. This Act remains the legal benchmark in Victoria although the Victorian Institute of Forensic Medicine voluntarily changed its procedures to require consultation with next of kin for both diagnostic and research autopsies, *The Age*, 20 March 2001

105 Associate Professor Loane Skene, *Transcript*, p.57

106 Associate Professor Loane Skene, *Transcript*, p.57. Dr Nicholas Tonti-Filippini raised similar issues concerning the status of an ovum (egg): whether it can be owned; if so, by whom and who has the right to consent to its use. The same issues pertain to use of genetic material more generally. Dr Nicholas Tonti-Filippini, *Transcript*, p.57

'rights' in relation to stored genetic material, for example donors or couples for whom embryos were formed, cannot or will not express views as to what should be done with such material.[107]

8.95 The current and potential research involving the use of cloning technologies opens a new series of questions on the donation and use of human tissue. Tissue removed as part of medical procedures, as the result of an autopsy or in other ways could be a source of stem cells or somatic cells for research purposes. Human tissue has potential uses now that are different from those envisaged in the past and the ramifications of the creation of adult or embryonic stem cell lines (or banks of them) from adult cells or embryos are significant. The use of such tissue, both inadvertent and deliberate, needs to be considered. The potential for the identification of the genetic characteristics of human tissue donors is also an issue that requires consideration in this context.

8.96 The current framework of human tissue legislation does not easily accommodate these possibilities. The legislation is premised on a once-only 'donation' of organs or tissues. As such, it is an unconditional gift and once a person has donated organs or tissues they forfeit any right to attach any conditions to their use.[108]

8.97 The Committee did not receive evidence that directly canvassed issues arising from the use of human tissue more generally (as opposed to embryonic tissue) in cloning related research. It urges that matters relating to consent to the removal of human tissue and its use in this area of research be examined within any current review of human tissue legislation and taken into account when drafting the legislative provisions relating to consent recommended in Chapter 12.[109]

8.98 The Committee suggests that the following issues, in particular, be examined in the context of such a review:

- whether it should be required that consent be granted by the individual from whom human material or adult cells originate to the use of the human material or cells in the particular research procedure proposed and to the continued use of the cells or material in the future. It may be necessary that specific consent be granted, not only to 'research'

107 NSW Government Discussion paper *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies*, paragraph 6.1

108 NSW Government Discussion Paper, *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies*, paragraph 6.3

109 See Chapter 12, paragraphs 12.68-12.76. The evidence of Dr John Smeaton regarding the proposed development of cell banks indicates the urgent necessity of such a review, *Transcript*, p.150

generally, but to the particular research proposed if human tissue or cells are to be used in research involving the use of cloning technologies. The successful development of adult stem cell therapies may result in adult cell lines becoming a commercial product as some are seeking to do in the case of embryonic stem cell lines.[110] Genetic information about the originator of the material may also be acquired from cell lines;

- whether the use of human tissue from deceased persons for this area of research should only be made with the written consent of the originator of the tissue prior to death; and
- whether a person should be able to direct that all human tissue removed from his/her body (for example during medical or surgical procedures) be destroyed.

110 See the evidence of Dr John Smeaton, *Transcript*, pp.149-168 and Mr Robert Klupacs, *Transcript*, p.170

9

Current Australian regulatory framework — non-legislative

INTRODUCTION

9.1 The previous chapter outlined the legislative framework governing the regulation of human cloning and research involving the use of embryos in Australia. This chapter completes the overview of Australia's regulation of these matters by outlining the non-legislative mechanisms that regulate human cloning and related research in Australia. The Committee will present its conclusions on the current regulation of human cloning in Australia at the end of the chapter.

NON-LEGISLATIVE REGULATION OF CLONING AND RESEARCH INVOLVING THE USE OF EMBRYOS

Overview

9.2 In NSW, Queensland, Tasmania, the ACT and the Northern Territory, where there is no legislation specifically regulating human cloning or embryo research, regulation is undertaken by non-legislative means. This primarily involves compliance with National Health and Medical Research Council (NHMRC) guidelines, the Reproductive Technology Accreditation Committee (RTAC) Code of Practice and the approval of

research by institutional ethics committees (IECs) in reliance on NHMRC guidelines.

National Health and Medical Research Council (NHMRC)

Overview

9.3 The NHMRC[1] requires all institutions or organisations that receive NHMRC funding for research to establish an IEC[2] and to subject all research involving humans, whether funded by the NHMRC or not, to ethical review by that IEC using the *National Statement on Ethical Conduct in Research Involving Humans* as the standard for that review.[3]

9.4 The NHMRC has issued a significant number of Guidelines covering a wide range of issues. The following discussion will focus on the two sets of Guidelines most relevant to this inquiry—the *National Statement on Ethical Conduct in Research Involving Humans* (the *National Statement*) (1999) and the *Ethical Guidelines on Assisted Reproductive Technology* (1996) (the *Ethical Guidelines*).[4]

9.5 The infringement of a provision(s) of NHMRC Guidelines does not constitute an offence. Sanctions for the breach of any guidelines involve the loss of access to research funds from the NHMRC or publication of the names of the infringers in Parliament.[5]

9.6 Associate Professor Loane Skene summarised the effect of the NHMRC Guidelines system as follows:

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1 The functions of the NHMRC are set out in the *National Health and Medical Research Council Act 1992*, section 7. They are primarily to inquire into, issue guidelines on and advise the community on matters related to health and health related research. The NHMRC carries out its functions through a network of committees such as AHEC – see generally Part 5 of the Act. AHEC is established under section 35 of the Act. Requirements as to its membership are provided in section 36 of the Act. Guidelines developed by AHEC must be laid before each House of Parliament (section 35(4)). AHEC also monitors and advises on IECs

2 NHMRC, *National Statement on Ethical Conduct in Research Involving Humans*, p.3. NHMRC refers to these bodies as Human Research Ethics Committees (HRECs). However the term 'institutional ethics committees'(IECs) has been the term most commonly used during the inquiry and for the sake of consistency that term is used here

3 NHMRC, *National Statement on Ethical Conduct in Research Involving Humans*, p.3

4 Other guidelines issued by the NHMRC that may be relevant in various contexts include: Supplementary Note 5 to the National Statement, 'The human fetus and the use of human fetal tissue', (1983); *Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies* (1999)*; Guidelines under Section 95 of the Privacy Act 1988* (Cth) (March 2000)

5 AHEC report, Chapter 4, paragraph 4.14. The *National Statement* states that observance of the procedures set out in the *National Statement* is mandatory for continuing eligibility for NHMRC research funds, pp.2-3. See also AHEC, *Submissions*, p.S811

> The NHMRC Guidelines apply throughout Australia. They are not, of course, law because they are as they are described—guidelines. This does not mean that they do not have legal effect. With regard to guidelines they are a statement of accepted practice… the guidelines can be enforced by the withdrawal of funding, if it is a project funded by the NHMRC; by peer pressure, which may prevent the publication of research that is undertaken that does not follow the guidelines; and the NHMRC has power to name somebody who offends against the guidelines in federal parliament… there are inducements to compliance. … However, they are not directly enforceable, so somebody who fails to comply with the NHMRC Guidelines cannot, on that account alone, be prosecuted or sued.[6]

9.7 Associate Professor Skene's summary of the effect of the NHMRC Guidelines system is applicable to both the *National Statement* and the *Ethical Guidelines* discussed further below.

9.8 NHMRC Guidelines are developed by people with considerable expertise and knowledge, but the public has little understanding of the process or the capacity to participate in it. The growth and spread of cloning research and the substantial involvement of the private sector in it[7] renders it very difficult for a body such as the NHMRC or AHEC to monitor this area of risk. The leverage of the NHMRC is very much tied to its capacity to grant or withhold funding and hence its real capacity to influence the private sector must be problematic as AHEC itself acknowledged.[8] In such an environment sanctions such as the loss of research funding may have minimal influence.[9]

Ethical Guidelines on Assisted Reproductive Technology (1996)

9.9 The NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996) (the *Ethical Guidelines*) were cited in the AHEC report and its recommendations address the provision of assisted reproductive technology services and research involving the use of embryos.[10]

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6 Associate Professor Loane Skene, *Transcript*, p.44

7 See the evidence of Dr John Smeaton, *Transcript*, pp.149-168 and Mr Robert Klupacs, *Transcript*, p.169

8 AHEC report, Chapter 4, paragraph 4.34

9 This may not be the case in other areas of research where the system of NHMRC Guidelines may still be entirely appropriate

10 It is noted in the *Ethical Guidelines* that they do not address issues of eligibility, surrogacy, consent for posthumous use, genetic diagnosis and selection or gene therapy - p.v. They state that in those states where there is specific legislation this must be observed. Where both State

9.10 Guideline 6 of the *Ethical Guidelines* deals with research on embryos. It notes that research involving early human embryos raises profound moral and ethical concerns and states that there are differences of opinion amongst Australians regarding the moral status of the human embryo that cannot be resolved.[11]

9.11 In those States and Territories without relevant legislation, Guideline 6 states that research on human embryos may only take place according to the *Ethical Guidelines*. The *Ethical Guidelines* differentiate between 'therapeutic' and 'non-therapeutic' research involving embryos. Professor Saunders, the Chairman of the NHMRC, stated:

> …the use of the word "therapeutic" in the context of these guidelines means therapeutic as it relates to the embryo itself… doing something to the embryo with the intention of having a therapeutic outcome for the embryo…[12]

So Guideline 6.2 states:

> Embryo experimentation should normally be limited to therapeutic procedures which leave the embryo, or embryos, with an expectation of implantation and development.

9.12 Professor Saunders described 'non-therapeutic' research as

> …research or interventions, …on the embryo which are not directed at the embryo's well being but the well being for some other technology…It is not to say that non-therapeutic research cannot have other therapeutic applications in adults or babies or whatever. It is just that, in the context of these guidelines, there is a need to distinguish between doing something on the embryo for the sake of the embryo—which in these guidelines is considered therapeutic—versus the other.[13]

9.13 Such non-therapeutic research is to be approved by an IEC only in exceptional circumstances. In relation to 'non-therapeutic' research involving embryos Guideline 6.4 states:

> Non-therapeutic research which involves the destruction of the embryo, or which may otherwise not leave it in an implantable

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law and the *Ethical Guidelines* apply the State law prevails (Guideline 1.1). The *Ethical Guidelines* also contain consent provisions and provisions concerning the storage of gametes and embryos and record keeping

11 Guideline 6 is reproduced in full at Appendix F of this report

12 Professor Nicholas Saunders, *Transcript*, p.196

13 Professor Nicholas Saunders, *Transcript*, p.196

> condition, should only be approved by an IEC in exceptional circumstances. Approval requires:
>
> - a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed research;
> - that the research involves a restricted number of embryos; and
> - the gamete providers, and their spouses or partners, to have consented to the specific form of research …[14]

Professor Saunders indicated that if permission were to be given by an IEC for such non-therapeutic research it would be considered and granted on a case-by-case basis.[15]

9.14 The *Ethical Guidelines* were formulated before development of the somatic cell nuclear transfer cloning technique and do not refer to artificially created embryos. The *Ethical Guidelines* refer to research involving embryos created in the course of assisted reproductive technology. In relation to the production of embryos surplus to assisted reproductive technology requirements (discussed in Chapter 7 as a possible source of embryos for research involving cloning technologies), Guideline 6 states that clinics should seek to avoid the likelihood of production of embryos in excess of the needs of the couple.

9.15 Guideline 11 of the *Ethical Guidelines* includes among a list of practices that are 'ethically unacceptable and should be prohibited'—developing embryos for purposes other than for their use in an approved assisted reproductive technology treatment program, culturing an embryo *in vitro* for more than 14 days, placing an embryo in a body cavity other than in the human female reproductive tract, commercial trading in gametes or embryos, paying donors of gametes or embryos beyond reasonable expenses and:

> …experimentation with the intent to produce two or more genetically identical individuals, including development of human embryonal stem cell lines with the aim of producing a clone of individuals.

9.16 So the intentional creation of embryos for research is prohibited.[16]

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14 This particular guideline was criticised in some quarters. Mr / Ms Hartwig wondered what constituted 'exceptional circumstances' and stated that every circumstance could be claimed to be exceptional, *Submissions,* p.S24. See also Queensland Right to Life, *Submissions,* p.S264

15 Professor Nicholas Saunders, *Transcript,* pp.197-198

16 Dr Robert Loblay submitted that when this was drafted the possibility of cloning intact human individuals by somatic cell nuclear transfer was not anticipated. However, the intent of this Guideline was to proscribe the use of cloning techniques for reproductive purposes. In the light of recent developments, a more explicit rewording of this Guideline may be appropriate, *Submissions,* p.S678. Professor Julian Savulescu submitted that Guideline 11.3 has the effect of

The National Statement on Ethical Conduct in Research Involving Humans (the National Statement)

9.17 The *National Statement on Ethical Conduct in Research Involving Humans* (1999) (the *National Statement*)[17] affects the general design of research projects and the approval process for research.[18]

9.18 The National Statement does not define 'research involving humans'. Rather it focuses on trying to define what needs to be considered and approved by an IEC.[19] Evidence received by the Committee in respect of IECs is at paragraphs 9.24-9.36 below.

9.19 It is the responsibility of each institution and organisation to develop criteria to classify which of its activities are reviewable by its IEC and which are not.[20] Thus there may be variations in the classification of activity between and among institutions and organisations.[21] Research concerning human cloning and its related technologies would fall within the *National Statement*.

9.20 The *National Statement* covers a wide range of matters including research involving the use of human tissue samples (discussed in Chapter 8) and human genetic research.[22] In the case of research involving assisted reproductive technologies and embryo experimentation, the *National Statement* refers to the legislation in Victoria, South Australia and Western Australia and the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*.[23]

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banning ES cell research but it is understood in practice to refer to ES cell research for the purpose of cloning a human being, *Submissions*, p.S650

17 This replaces the guidelines entitled NHMRC *Statement on Human Experimentation and Supplementary Notes* except for Note 5 which has not yet been revised. These earlier guidelines were referred to in the AHEC report, Chapter 4, paragraph 4.17

18 The *National Statement* has been endorsed by the Australian Vice-Chancellors Committee, the Australian Research Council, the Australian Academy of the Humanities, the Australian Academy of Science and the Academy of the Social Sciences of Australia. It has been supported by the Academy of the Technological Sciences and Engineering. AHEC submitted that compliance with the *National Statement* is mandatory for all research funded by the Australian Research Council and the NHMRC as well as all research undertaken in Australian universities. Members of the four learned academies, AHEC submitted, are bound to apply the guidelines contained in the *National Statement* to their work. AHEC, *Submissions*, p.S811

19 NHMRC, *National Statement*, p.7

20 This should be decided according to whether the activity involves human participation or definable human involvement and has a purpose of establishing facts, principles or knowledge or obtaining or confirming knowledge. The features of human involvement will be the focus in deciding whether it is subject to IEC review. NHMRC, *National Statement*, pp.7 and 8

21 NHMRC, *National Statement*, p.8. See also AHEC, *Submissions*, p.S811

22 NHMRC, *National Statement* See pp.43-45 and pp.46-50 respectively

23 NHMRC, *National Statement* p.34

The Reproductive Technology Accreditation Committee (RTAC)— Code Of Practice

9.21 Self-regulation is also a feature of the regulation of assisted reproductive technology and hence of embryo research. The Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (a professional body) administers this self-regulation. The RTAC has issued a *Code of Practice for Units using Assisted Reproductive Technology* (Code of Practice) with the RTAC setting professional and laboratory standards for clinical practice. The Code of Practice encourages all centres practising assisted reproductive technology to have an active research program.[24]

9.22 For its part the RTAC Code of Practice[25] lists the following activities as unacceptable:

- keeping or using an embryo after the appearance of the primitive streak or after 14 days, whichever is the earlier;
- placing an embryo in a non-human animal;
- replacing the nucleus of a cell of an embryo with a nucleus taken from the cell of another person, another embryo or fetus;
- cloning human embryos in attempts to produce babies; and
- mixing gametes or embryos of different parental origin to confuse the biological parentage of the conceptus.[26]

9.23 The interaction of these various sets of guidelines is complex. Accreditation by the RTAC is not mandated but to become accredited a provider of assisted reproductive technology must comply with the Code of Practice which in turn requires compliance with NHMRC guidelines.[27] Dr Loblay submitted that:

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24 Accreditation is not mandated – NSW Government Discussion Paper, *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies,* paragraph 2.3. Guideline 2.1 of the *Ethical Guidelines* states that whether or not it is required by State law, reproductive medicine units must obtain accreditation by the RTAC. Such accreditation must include consideration of a number of matters including compliance with NHMRC guidelines, the RTAC Code of Practice and maintenance of proper professional standards

25 The RTAC Code of Practice deals with a range of matters including staff and resources, provision of information to patients, consent requirements, laboratory standards, treatment methods, record keeping, ethics and research, quality control and accreditation periods (normally three years)

26 This list does not include the creation of embryos for research purposes. This is different to the NHMRC *Ethical Guidelines*. The RTAC Code of Practice also provides that the NHMRC *Ethical Guidelines* must be adhered to and all aspects of the research program monitored by the IEC of the hospital or institution concerned

27 The South Australian Reproductive Technology (Code of Ethical Research Practice) Regulations also cross refer to the RTAC Code of Practice - see for example section 14

> … self-regulation is inappropriate in the field of [assisted reproductive technology]. Whilst it is entirely proper—necessary even—for the [Fertility Society of Australia] to be represented on any…accrediting body, such a body should be completely independent of the professional association to which those being accredited belong… A combination of the profit motive and the intense competition between …[clinics] operating in the private sector adds to the moral hazard.[28]

Institutional Ethics Committees

9.24 The discussion above indicates that institutional ethics committees (IECs) established within institutions or organisations to assess research proposals according to ethical criteria are central to the regulation of a large number of activities from general research involving humans to clinical trials. Most particularly, they are important to the regulation of research involving human cloning, the utilisation of embryos in research or the use of human tissue. This is especially the case in those States and Territories without legislation governing human cloning or embryo research.

9.25 The *National Statement* includes guidelines concerning IECs. These guidelines outline the composition of an IEC, appointment of members, procedures, use of advocates and interpreters, recording of decisions, monitoring of approved research, suspension or discontinuation of research and provision of compliance reports to the NHMRC.[29] IECs are expected to be constituted and to operate in accordance with the *National Statement*.[30]

9.26 This reliance on IECs as well as their structure and operation was the subject of comment and criticism during the course of the inquiry.

9.27 The Queensland Bioethics Centre noted the significant role of IECs and claimed that all scientific research falling outside Commonwealth funding would also fall outside the scope of the IEC process.[31] The *National*

28 Dr Robert Loblay, *Submissions,* p.S680

29 NHMRC, *National Statement,* pp.15-22

30 An independent review of the role and functioning of institutional ethics committees was initiated by the then Commonwealth Minister for Human Services and Health, the Hon. Dr Carmen Lawrence, in August 1994. The Review Committee was chaired by Professor Chalmers, then Chair of AHEC, and reported in March 1996 – Report to the Minister for Health and Family Services**,** *Report of the Review of the Role and Functioning of Institutional Ethics Committees*, Commonwealth of Australia, March 1996

31 Queensland Bioethics Centre, *Submissions,* p.S707. See also Catholic Archdiocese of Melbourne, *Submissions*, pp.S522-523

Statement has been endorsed by all the leading academies and hence would exercise strong persuasive power but the system would have only persuasive value as far as private sector research is concerned. This limitation was accepted to some extent by Dr P. Geoffrey Matthews, the Chairman of the Human Research and Ethics Committee of the Monash Medical Centre, who commented that there:

> …certainly is a limitation from the funding point of view that all projects do not have to come through these institutional ethics committees.[32]

9.28 The Queensland Bioethics Centre also criticised the lack of public accountability in the process and the 'in house' nature of the committees. It went on:

> To leave oversight of this important area to such committees would do little to inspire confidence in the community that justice was being done, whatever the good intentions of individual committee members.[33]

9.29 Dr Nicholas Tonti-Filippini questioned the adequacy of these committees given that they exercise such significant power[34] and commented that 'the more important they become, the more important it is that they be properly structured'.[35] He described IECs as a:

> … non-accountable, non-representative, largely in-house system of review whose processes and conclusions are not accessible to the community and not subject to scrutiny.[36]

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32 Dr Matthews, *Transcript*, p.56

33 Queensland Bioethics Centre, *Submissions*, p.S707 and Mr Raymond Campbell, Queensland Bioethics Centre, *Transcript*, p.98

34 Dr Nicholas Tonti-Filippini, *Transcript*, p.47

35 Dr Nicholas Tonti-Filippini, *Transcript*, p.55. The Consumers Health Forum expressed a particular concern about the composition of IECs, claiming that there is no means of ensuring lay people can effectively represent the interests of any group which will be affected by research proposals being considered let alone the broader community. The Forum cited concerns that consumer representatives wield much less influence than other members of IECs and are susceptible to direct and indirect co-option. It commented that this is likely to be a particular problem where the researchers involved are considered world experts and their influence is very strong, *Submissions*, p.S795

36 Dr Nicholas Tonti-Filippini, *Submissions*, p.S588. See also the Catholic Archdiocese of Melbourne, *Submissions*, pp.S522-523 and Youth Concerned with Cloning, *Submissions*, p.S548. The Privacy Commissioner, in an information paper entitled *The Privacy Implications of Genetic Testing* (1996), noted that in granting approval for NHMRC Privacy Guidelines he had expressed reservations about the structure of the guidelines system in that it produces a legally binding outcome from what are voluntary citizens' committees (p.50). He also argued that it was a matter for debate whether the most effective available institutional structure is one that leaves monitoring of scientists in relation to genetic information with their peers in

9.30 Dr Tonti-Filippini suggested that establishing IECs on a more impartial basis with a majority of members from outside the institution may assist in resolving some problems but at present IECs could not be regarded, in his view, as sufficient for regulatory purposes.[37]

9.31 Dr Robert Loblay, Chairman of the Ethics Review Committee of the Central Sydney Area Health Service, submitted that the relationship between IECs and reproductive medicine units should be clearly defined to ensure that ethical scrutiny is conducted at arms' length by an independent IEC and that such independence is particularly important in the private sector.[38] In Dr Loblay's view IECs should be required to review *all* clinical and research practices conducted in a reproductive medicine unit but an 'IEC can only review what is put before it'.[39] Under present guidelines, reproductive medicine units:

> … have the discretion to define "innovative practices" as they see fit, and thereby to evade ethical scrutiny when it suits them.[40]

9.32 Dr Loblay noted in this context that many clinical practices introduced within IVF, where there were variations from previous practices, were never submitted to an IEC before 1996. The NHMRC *Ethical Guidelines* now require that innovative clinical practice undergoes ethical scrutiny[41] but some practitioners have had difficulty adjusting to this cultural change and it was still open to the interpretation of a practitioner whether to submit a new procedure or activity for ethical review.[42]

9.33 Dr Loblay argued that there were no suitable sanctions for failure to submit proposals for ethical review and stated: [43] 'In order for us to do this kind of regulation effectively there need to be those kind of sanctions in place'.[44]

9.34 Conflicts of interest were more likely where the institutional (and therefore the IEC) focus was more narrow such as, for example, in a private reproductive medicine unit where the focus of the IEC is solely on

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the same institution working voluntarily and part-time. Subtle and organisational pressures and conflicting priorities might arise in such a situation, in his view, pp.49-50

37 Dr Nicholas Tonti-Filippini, *Transcript*, p.47

38 Dr Robert Loblay, *Submissions*, p.S679

39 Dr Robert Loblay, *Submissions*, p.S680 and *Transcript*, p.127

40 Dr Robert Loblay, *Submissions*, p.S680

41 See Guideline 2 of the *Ethical Guidelines*

42 Dr Robert Loblay, *Transcript*, p.127

43 Dr Robert Loblay, *Submissions*, p.S680 and *Transcript*, pp.127-128

44 Dr Robert Loblay, *Transcript*, p.128. Dr Loblay suggested the most appropriate sanction would be withdrawal of accreditation, *Submissions*, p.S680

the unit's work, Dr Loblay suggested. He suggested also that there may be less risk of such narrow focus in a larger institution and saw some advantages in area-based rather than institution-based ethics committees. He noted the difficulty in finding a balance between reviewing research in the context where it is occurring and reflecting broader community views.[45]

9.35 Dr Matthews could see the advantages of IECs in this contextual review of research in the form of direct supervision, on-site inspections and ensuring that research proposals are well considered and well expressed.[46] He did note, however, that IECs are 'relatively unfamiliar with the specific processes' related to human cloning and its attendant research and stated that genetic research:

> …contain[s] many new implications for human ethics…. Such developments, covering such a broad range of change, are largely beyond the scope and resources of any single institution.[47]

9.36 Professor Thomson, the Deputy Chair of AHEC, accepted that there are inadequacies in the transparency and accountability of IECs. He also stated that there:

> …is presently some extensive work on the notion of compliance and better methodology in seeing that the processes of [IECs] do conform and that there is some way of assuring that quality happens.[48]

CONCLUSIONS

9.37 Great social sensitivity concerning the use of embryos and embryonic tissue in research was reflected in the discussion in Chapter 7. This sensitivity has led to special regimes being put in place to regulate the use of embryos and embryonic tissue, as discussed in Chapter 8 and this chapter.

9.38 Professor Chalmers thought that 'we as a community would like to arrange our treatment of the embryo in ways which advance the dignity and respect for that embryo'.[49] He asked:

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45 Dr Robert Loblay, *Transcript*, p.126

46 Dr P. Geoffrey Matthews, *Submissions*, p.S701

47 Dr P. Geoffrey Matthews, *Submissions*, pp.S701-702

48 Associate Professor Colin Thomson, *Transcript*, p.199

49 Professor Donald Chalmers, *Transcript*, p.43

> … do we say no to every form of research or do we say there may be limited, exceptional circumstances that would allow us to move from the position of absolute protection of the embryo?[50]

9.39 The Committee concluded at the end of Chapter 7 that some balance needs to be struck between the special status of the human embryo and protection for that status on the one hand and facilitating research that may be of great benefit to society on the other. In many ways the current regulatory framework reflects that balance although differences exist between legislative provisions and non-legislative guidelines.

9.40 Dr Loblay summarised the disadvantages of non-legislative guidelines: they have no legal authority, compliance is voluntary, they cannot be enforced by the courts and there are no legal sanctions. The advantages, he considered, were flexibility in specific circumstances, responsiveness to rapidly changing technology, accurate reflection of community and professional values and expectations and indirect enforcement.[51]

9.41 The Committee acknowledges the advantages listed by Dr Loblay but considers they are outweighed by the disadvantages.

9.42 Regulation of assisted reproductive technology, embryo experimentation and now human cloning continues to become more complicated. In addition to legislation in three States there is a system of self-regulation coupled with non-legislative national guidelines administered by institutional ethics committees. The system is confused, inconsistent and ad hoc. It is hard for the public to understand and it lacks openness and transparency. Dr Tobin, a member of AHEC, acknowledged that the range of ethical views in the community about the status of the human embryo is represented on AHEC and to some extent these views cannot be reconciled.[52] The NHMRC *Ethical Guidelines on Assisted Reproductive Technology* and the AHEC report both represent the compromise positions arrived at by AHEC on these matters. Hence there is not a consistent ethical view underpinning either of these documents.[53] They represent a balance of ethical views.

9.43 The Committee agrees with the thrust of the criticisms that were made of institutional ethics committees. Each IEC is an individual body established within a particular research institution and will deal with each research application it receives on an individual basis. Therefore it may be

50 Professor Donald Chalmers, *Transcript*, p.43. Professor Chalmers thought that the latter was the position reflected in paragraph 6.4 of the NHMRC *Ethical Guidelines*

51 Dr Robert Loblay, *Submissions*, p.S678

52 Dr Bernadette Tobin, *Transcript*, p.194

53 Dr Bernadette Tobin, *Transcript*, p.206

anticipated that the outcome of IEC consideration of research applications may vary between IECs. There may be differences, possibly significant, in both the nature of research that is approved or rejected and / or in the conditions an IEC may attach to its approval**.** The two key elements governing the kind and degree of applicable regulation in these areas of research appear to be the jurisdiction in which the activity occurs and the source of funding for that activity.

9.44 The difficulties posed by this complicated system of regulation are highlighted by the differences in the definition of 'cloning' in various jurisdictions. These different definitions prohibit different conduct in different parts of the country. The resulting confusion is increased by other differences in the definition of such basic terms as 'embryo'.

9.45 Such fundamental inconsistencies do not assist researchers, businesses, investors or citizens who must try to navigate their way through this confusing and intricate array of regulatory instruments. It is also unfair that such different regulation applies to citizens living in different states. There appears to the Committee to be no obvious basis for maintaining such a variety of regulation.

9.46 Thus the Committee views the current regulatory environment in this area as deeply unsatisfactory. It appears to be out of date and ill equipped to cope with the challenges of current demands and a changing environment.

9.47 The current framework of non-legislative guidelines and IECs are the product of an era when the majority of research funding was provided by government and most research occurred within tertiary institutions that were publicly funded. For many areas of research that may still be the situation and the current framework entirely suitable to the needs of those involved.

9.48 However, in the area of human cloning and cloning related research including human embryo research, this environment has changed significantly. There is a heavy involvement of significant private sector funding in this research. Universities are under commercial pressure also. The result is a greater necessity for speed, efficiency, clarity and consistency in decision making.

9.49 In addition, this changing environment must reduce the capacity for IECs, composed largely of voluntary members and relying on non-legislative NHMRC guidelines, to be able to operate effectively in such an environment. If the current framework (outside those states with existing legislation) continues it is likely to lead to the evolution of a system increasingly similar to that in the United States (see Chapter 10). There the public sector is regulated and the private sector, where much of the

research is undertaken, is subject to limited regulation**.** One of the greatest inadequacies of the current regulatory framework in the United States is its differing application to the public and private sectors. The Committee considers that consistent regulation must be applied to both publicly and privately funded research.

9.50 The current regulatory framework cannot be allowed to continue. The questions raised by human cloning and research involving the use of embryos are complex social and ethical questions and should not be left to individual ethics committees to decide. Nor should the answer to such fundamental questions depend on geography or source of funding. It is vital to ensure public knowledge of, and confidence in, the regulatory processes in place. Consistency and transparency are necessary and in Chapter 12 the Committee will outline a regulatory framework that it believes will best facilitate this outcome.

10

International regulatory framework

INTRODUCTION

10.1 This chapter focuses on efforts to regulate cloning and related research at the international level. It also addresses the relevance of these efforts to Australia's consideration of appropriate regulation.

10.2 At the multilateral level, the discussion begins with the *Universal Declaration on the Human Genome and Human Rights* developed by the United Nations Educational, Scientific and Cultural Organisation (UNESCO). Article 11 of this Declaration forms the basis of the first recommendation in the AHEC report: that the Commonwealth Government should reaffirm its support for the UNESCO Declaration, in particular Article 11.

10.3 The Committee will then consider the *Convention for the Protection of Human Rights and Dignity with Regard to the Application of Biology and Medicine* together with its *Additional Protocol on Human Cloning,* both developed by the Council of Europe. The Additional Protocol was the first binding international instrument to ban cloning for reproductive purposes. These instruments represent the first attempt by communities of nations at the international level to grapple with the issues raised by embryo experimentation and human cloning.

10.4 The Committee is also aware that many other international legal regimes may be relevant to various aspects of cloning related research. A particular example is the international framework governing intellectual property issues such as the Paris *Convention for the Protection of Industrial Property 1883* and the World Trade Organisation (WTO) *Agreement on*

Trade-Related Aspects of Intellectual Property Rights (TRIPS).[1] The Committee has not examined this framework in detail.

10.5 Many countries are considering the appropriate regulation of human cloning and its related research. In the United States of America and the United Kingdom considerable work has been undertaken on the most appropriate regulation of this research. Given the similarity of their legal and political systems to Australia's, their responses to the issues raised are comparable and useful. They are addressed in the remainder of the chapter.

10.6 The chapter concludes with the Committee's observations on the relevance of these international developments to Australia's approach to regulating human cloning and research involving the use of embryos.

UNITED NATIONS: UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANISATION (UNESCO) DECLARATION

10.7 The *Universal Declaration on the Human Genome and Human Rights* (the Declaration), developed by UNESCO, was adopted unanimously by UNESCO's 186 member states (including Australia) on 11 November 1997.[2] The United Nations General Assembly endorsed the Declaration on 10 March 1999.[3]

10.8 Material developed by UNESCO seeks to explain the Declaration and its aims:

> What exactly does this text set out to do and why is UNESCO promoting the promulgation of guidelines that seek to prohibit the application of a revolutionary scientific development? … The answer to this question is that UNESCO is committed to ensuring that, like all other forms of knowledge, science effectively serves the cause of human progress and that the Declaration is concerned with making science accord with ethics in the new Promethean age we are now entering.[4]

1 IP Australia, *Submissions*, pp.S722-723 and S726

2 Attorney-General's Department, *Submissions*, p.S531

3 United Nation General Assembly, Resolution 53/152. The French and German governments are reported to have asked the UN Secretary-General to begin work on an international convention to ban the cloning of humans for reproductive purposes. The governments are reported to have asked for negotiations to begin at the next General Assembly in September 2001, *The Times*, 9 August 2001, http://www.thetimes.co.uk/article/0,3-2001272895,00.html

4 'Reproductive Human Cloning: Ethical Issues', Division of the Ethics of Science and Technology, UNESCO, 26 February 1998, p.4, *Exhibit* 50

10.9 The impact of the Declaration was noted by the Attorney-General's Department:

> As a Declaration this instrument is not binding under international law however it may be regarded as reflecting current international thinking on these issues.[5]

10.10 Hence, unlike an international treaty, the Declaration does not include any mandatory provisions requiring States to take action to implement it domestically but it does 'set out a framework of principles to guide Member States in the development of national legislation'.[6]

10.11 UNESCO states that although the Declaration:

> … does not have binding force…[it] represents a moral commitment of all Member states of UNESCO to adhere to a coherent set of ethical principles in the field of genetics.[7]

10.12 Part C of the Declaration, containing Articles 10, 11 and 12, is most relevant to the inquiry. This Part of the Declaration 'expresses the fundamental principles that might guide research on the human genome'.[8] Article 10 states the overarching principle of primacy of respect for human rights over research in biology and that respect for human dignity and fundamental freedoms of individuals and groups of people overrides freedom of scientific inquiry:

> No research or research 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.[9]

10.13 Article 11 prohibits practices contrary to human dignity and is the only operative provision which refers to reproductive human cloning or any form of cloning. Article 11 states:

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5 Attorney-General's Department, *Submissions*, p.S532

6 Attorney-General's Department, *Submissions*, p.S532. UNESCO preparatory documents note that part of the reason for developing a Declaration rather than a Convention was the rapid pace of the scientific developments in this area, Committee of Governmental Experts for the Finalization of a Declaration on the Human Genome, Presentation of the 'Revised Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights', 20 December 1996, BIO -97/CONF.201/4, 6 May 1997, p.4, *Exhibit* 48

7 'Reproductive Human Cloning: Ethical Issues', Document prepared by the Division of the Ethics of Science and Technology, UNESCO, 26 February 1998, p.5, *Exhibit* 50

8 Attorney-General's Department, *Submissions*, p.S533. Articles 14, 15 and 16 are also relevant. Attorney-General's Department, *Submissions*, p.S534

9 Article 10 of the Declaration. See also Attorney-General's Department, *Submissions*, p.S533

> Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organisations are invited to cooperate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.[10]

10.14 Article 12 promotes equality of access to the benefits of scientific progress and recognises that scientific research is part of freedom of thought, but indicates that scientific research should have as its ultimate aim the relief of suffering and the improvement of human health.[11]

How Should Article 11 Of The Declaration Be Interpreted?

10.15 Given the importance that AHEC assigned to the Commonwealth government reaffirming its support for the Declaration, in particular Article 11,[12] it is important to try to understand the prohibition on reproductive cloning in Article 11. 'Practices contrary to human dignity' is clearly a broad term. Indeed, the Article invites States and competent international organisations to cooperate in 'identifying such practices'.[13] There is no explicit mention in the Declaration of embryo experimentation or the creation of embryos for research purposes or the creation of a transgenic organism for research purposes.[14] UNESCO did not deal with the issue of human cloning in detail and this is not surprising given the nature of the instrument and its primary focus on genetic research more generally rather than human cloning specifically.

10.16 The Attorney-General's Department, in its first submission to the inquiry, interpreted the express reference to reproductive cloning to mean '… the replication of a whole human being with an identical gene set with a viable post-natal existence'.[15] The Department noted that 'any research or research applications aimed at achieving reproductive human cloning would therefore also violate Article 10' and 'it remains unclear to what

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10 Article 11 of the Declaration

11 Attorney-General's Department, *Submissions*, p.S534

12 AHEC report, Chapter 6, p.43, Recommendation 1

13 Article 24 of the Declaration indicates that germ-line intervention is another practice that could be contrary to human dignity

14 Attorney-General's Department, *Submissions*, p.S535 and *Transcript*, p.135

15 Attorney-General's Department, *Transcript*, p.135. For the purpose of its submission the Department defined reproductive cloning as 'the application of cloning techniques to produce a duplicate or descendant human being that is genetically identical to an existing human being living or dead with a viable post-natal existence'. It defined 'human tissue cloning' as 'the application of cloning techniques to human cells in order to grow new tissue. This may but does not necessarily involve the use of human embryonic stem cells', *Submissions*, p.S530

extent techniques for cloning human tissue might be implicated by the principles' in the Declaration.[16]

10.17 The Attorney-General's Department, in a further detailed submission, elaborated on the development of the Declaration. The submission outlined the early development of proposals to incorporate a prohibition on 'cloning for the purposes of reproduction'.[17]

10.18 Member States of UNESCO debated whether a range of specific practices should be included in the final text during the development of the Declaration. The Attorney-General's Department submission outlines this discussion in detail[18] and notes that the Drafting Committee elaborating the Declaration 'decided to accept a proposal to insert in the text a reference to the prohibition of practices which were contrary to human dignity, such as cloning of human beings for reproductive purposes'.[19] Preliminary discussions during the preparation of the Declaration referred to the:

> …necessary distinction between human reproductive cloning aimed at the birth of an individual and non-reproductive human cloning techniques for research, diagnostic or therapeutic purposes.[20]

10.19 After canvassing the range of other practices that were discussed in the course of the development of the Declaration, including the use of embryos for research purposes, the Attorney-General's Department states:

> In conclusion, the records indicate that a wide range of practices and issues were raised during deliberations on the development of the instrument. However, there is little evidence of any in depth analysis or consideration … [of these issues]. There is no evidence of any particular analysis of the issue of the creation of embryos for research purposes by any means occurring either in the lead up to the Revised Preliminary Draft or the finalization of the Declaration …[21]

16 Attorney-General's Department, *Submissions*, p.S535

17 Attorney-General's Department, *Submissions*, pp.S876-877

18 Attorney-General's Department, *Submissions*, pp.S877-880

19 Attorney-General's Department, *Submissions*, p.879. Final Report of the Committee of Governmental Experts for the Finalization of a Declaration on the Human Genome, UNESCO, 25 July 1997, Paris, BIO-97/CONF.201/9, p.9, paragraph 40, *Exhibit* 46

20 'Reproductive Human Cloning: Ethical Issues', Division of the Ethics of Science and Technology, UNESCO, 26 February 1998, p.1, *Exhibit* 50

21 Attorney-General's Department, *Submissions*, pp.S880-881

10.20 Dr Nicholas Tonti-Filippini argued that the AHEC report had misinterpreted the meaning of the ban in the Declaration on human reproductive cloning:

> … UNESCO did not make a distinction between cloning a human embryo for therapeutic or research purposes only and cloning a human embryo to have it develop to adulthood.[22] …
> [The] inclusion of the word "reproductive" was to distinguish the reproduction of a human being via cloning from the reproduction of a somatic cell or cell line which is now a well established practice in medicine. At no stage did the International Bioethics Committee or UNESCO endorse the view that reproductive cloning did not include cloning human embryos for research purposes.[23]

10.21 The Queensland Bioethics Centre also argued that the distinction between 'reproductive' and 'therapeutic' cloning was not used by UNESCO in its Declaration:[24]

> It does not appear in the Declaration itself and … [the Centre was informed that] it does not appear in the official documents used in the development of the Declaration. At no stage did UNESCO endorse the view that reproductive cloning did not include cloning human embryos for research purposes.[25]

10.22 The submission from the Attorney-General's Department also considered the argument raised by Dr Tonti-Filippini in some detail. The Department concluded that it:

> … does not find any evidence that "reproductive cloning of human beings" was intended to cover, in addition to the reproductive cloning of whole human beings, the creation of embryos for research purposes or other uses of cloning techniques involving human embryos. References to cloning as a practice contrary to human dignity as they appear throughout the [International Bioethics Committee] and UNESCO record suggest that it was the full reproduction of a whole human being alone that was intended to be covered by the phrase 'reproductive cloning of human beings'. Nor is there any clear evidence that Member States were required to form a collective view as to whether the creation of embryos for research purposes or a range of other practices would be contrary to human dignity and

22 Dr Nicholas Tonti-Filippini, *Submissions*, p.S588
23 Dr Nicholas Tonti-Filippini, *Submissions*, p.S591
24 Queensland Bioethics Centre, *Submissions*, p.S706
25 Queensland Bioethics Centre, *Submissions*, p.S706

> therefore inconsistent with the general principle enshrined by Article 11.[26]

10.23 A resolution on the implementation of the Declaration[27] provided for a system of follow-up to promote its implementation and invited the Director-General of UNESCO to prepare a global report on the issues dealt with in the Declaration. The first report, published on 23 August 1999, states in relation to Article 11 that:

> This prohibition concerns the reproductive cloning of human beings and should not be interpreted as prohibiting other applications of cloning.[28]

This report, however, does not resolve the issue, as 'other applications of cloning' could refer to the cloning of cells or tissue.

10.24 In the light of all of the above, the Attorney-General's Department considers that:

> It would be reasonable to expect that if 'reproductive cloning of human beings' included a global ban on the creation of human embryos for research purposes, that it would have been reflected in the record of the Committee of Experts, and found its way into documents produced since the adoption of the Declaration. Similarly, if there was an in-depth discussion and consensus reached that a particular practice violated the principle of 'respect for human dignity' and was therefore brought within the scope of the first sentence of Article 11, the Department would expect this to be reflected in the official record also.[29]

10.25 The Department concludes that:

> Consequently, it appears that the Committee of Governmental Experts did not intend to pronounce a universal prohibition on the deliberate creation of embryos for research purposes or for sources of tissue for therapeutic purposes. This is consistent with the approach adopted by Member States that the Declaration was intended to articulate key principles and provide an ethical framework to guide Member States in the development of national

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26 Attorney-General's Department, *Submissions,* p.S882

27 UNESCO Resolution 29 C / Resolution 17 entitled 'Implementation of the Universal Declaration on the Human Genome and Human Rights'

28 Division of the Ethics of Science and Technology of UNESCO, *Global Report on the Situation World-Wide in the Fields relevant to the Universal Declaration on the Human Genome and Human Rights,* BIO – 503 / 99 / CIB – 6 / 2, 23 August 1999, p.13, *Exhibit* 47

29 Attorney-General's Department, *Submissions,* p.S882

> policy and law to regulate scientific research, primarily in the field of genetics.[30]

10.26 The Attorney-General's Department notes that such an interpretation does not mean that practices such as the deliberate creation of embryos for research purposes or for sources of tissue for therapeutic purposes are therefore to be regarded as permissible under the Declaration. Rather the issues arising from these practices are a matter of domestic policy to be settled by Australia.[31]

10.27 In the light of the above, it is clear that Article 11 of the Declaration covers the use of cloning technology to produce whole human beings. However, there are differing views internationally as to the further operation of the Article. The breadth of the wording and the non-binding nature of the Declaration provide scope for countries to determine the operation of the provisions of the Declaration domestically.

EUROPE: BIOMEDICINE CONVENTION

10.28 In November 1996 members of the Council of Europe approved the *Convention for the Protection of Human Rights and Dignity with regard to the Application of Biology and Medicine* (the Biomedicine Convention).[32] The Convention 'provides a broad framework of principles to guide the development of the national legislation [of member states] regulating biology and medicine'.[33]

10.29 The Attorney-General's Department noted:

> A number of particularly contentious issues, including human cloning, and embryo protection, were deferred for particular attention and are the subject of additional protocols.[34]

10.30 The Biomedicine Convention differs from the UNESCO Declaration in relation to embryo experimentation, Article 18 of the Convention states:

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30 Attorney-General's Department, Submissions, pp.S882-883

31 Attorney-General's Department, *Submissions*, p.S883

32 The Council of Europe was set up in 1949 and consists of 41 European states. Australia is not a party to the Convention. Whilst neither the Convention nor its Additional Protocol on Human Cloning (to be discussed below), impose binding legal obligations on Australia, the Convention and the Protocol may be signed by States that are not members of the Council of Europe but which have participated in their elaboration, for example, Australia. AHEC report, Chapter 5, paragraph 5.7 and http://conventions.coe.int/Treaty/EN/cadreprincipal.htm. Other countries in this category are Canada, the Holy See, Japan and the United States

33 Attorney-General's Department, *Submissions*, p.S535

34 Attorney-General's Department, *Submissions*, p.S535

> 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.[35]

Britain, as the only Member State to allow the creation of embryos for research, is entitled to opt out of this provision when the Convention is ratified by the UK Parliament. Germany, Poland and Belgium abstained from support for the Convention because the Convention does not impose a total ban on embryo research.[36]

Convention Protocol Banning Human Cloning

10.31 The first binding international instrument to ban cloning for reproductive purposes was the Additional Protocol to the *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, on the *Prohibition of Cloning of Human Beings*.[37] It was adopted by the Parliamentary Assembly on 22 September 1997 and by the Council of Europe on 12 January 1998.[38]

10.32 Only states that have signed the Biomedicine Convention may also sign the Protocol which supplements the Convention.[39] The Protocol builds on Articles 1, 13 and 18 of the Biomedicine Convention.[40]

10.33 Article 1 contains a prohibition on reproductive cloning and Article 2 prohibits any exceptions to this ban. Article 1 states:

> 1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
>
> 2. For the purpose of this article, the term human being "genetically identical" to another human being means a

35 Attorney-General's Department, *Submissions*, p.S536

36 House of Commons Library, *Cloning Research Paper* 97/43, 27 March 1997, p.31

37 For the text of the Protocol see - http://conventions.coe.int/treaty/en/Treaties/Html/168.htm. See also the *Charter of Fundamental Rights of the European Union* (Official Journal of the European Communities, 2000/C 364/01) adopted in Nice, France on 7 December 2000. It expressly prohibits reproductive cloning of human beings, eugenic practices (in particular those aimed at the selection of persons) and making the human body and its parts as such a source of financial gain (Article 3). The Charter does not contain a provision on embryo research

38 Attorney-General's Department, *Submissions*, p.S536

39 See Articles 3 and 4 of the Protocol. Member States of the Council of Europe, the European Community and other states that have participated in the Protocol's elaboration may sign it. As noted above, Australia is one such country

40 Explanatory Report on the Protocol, http://conventions.coe.int/treaty/en/Reports/Html/168.htm. Paragraph 1

> human being sharing with another the same nuclear gene set.[41]

The interpretation of the Protocol

10.34 The Explanatory Report on the Protocol[42] states that it is necessary to distinguish between three situations—the cloning of cells, the use of embryonic stem cells in cloning techniques and the cloning of human beings. Only the last is covered by the Protocol.

10.35 The Explanatory Report outlines the thinking behind the Protocol:

> Deliberately cloning humans is a threat to human identity, as it would give up the indispensable protection against the predetermination of the human genetic constitution by a third party. Further ethical reasoning for a prohibition to clone human beings is based first and foremost on human dignity which is endangered by instrumentalisation through artificial human cloning.[43]

10.36 The precise behaviour that is prohibited by the Protocol is 'any attempt artificially to produce genetically identical human beings'. The Report states that the Protocol 'explicitly restricts genetic identity to sharing the same nuclear gene set….'[44]

10.37 The Report also states:

> The term "nuclear" means only genes of the nucleus—not the mitochondrial genes—are looked at with respect to identity, which is why the prohibition of cloning human beings also covers all nuclear transfer methods seeking to create identical human beings. The term "the same nuclear gene set" takes into account the fact that during development some genes may undergo somatic mutation.[45]

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41 The Protocol is limited to a ban on reproductive cloning by means of, for example, embryo splitting or somatic cell nuclear transfer. It does not address issues such as cloning of cells and the use of embryonic stem cells in cloning techniques. These issues will be dealt with in a further protocol on embryo protection which has not yet been developed, Attorney-General's Department, *Submissions*, p.S536

42 The text of the Explanatory Report does not constitute an instrument providing an authoritative interpretation of the text of the Protocol, although it might facilitate understanding of the provisions http://conventions.coe.int/treaty/en/Reports/Html/168.htm

43 http://conventions.coe.int/treaty/en/Reports/Html/168.htm, paragraph 3

44 http://conventions.coe.int/treaty/en/Reports/Html/168.htm, paragraph 5

45 http://conventions.coe.int/treaty/en/Reports/Html/168.htm, paragraph 7

10.38 On the meaning of the term 'human being', the Report states that 'it was decided to leave it to domestic law to define the scope of the expression … for the purposes of the application of the present Protocol'.[46]

10.39 The Protocol stipulated that it would come into effect after five States had ratified the text.[47] It was ratified by Slovakia, Slovenia, Greece, Spain, Georgia and Romania and took effect on 1 March 2001. Twenty-two of the Council of Europe States have now signed the Protocol.[48]

The European Group on Ethics

10.40 The European Group on Ethics in Science and New Technologies (EGE) is a multi-disciplinary body answering directly to the President of the European Commission.[49] Its role is to advise the European Commission and also the European Parliament and the Council of Ministers—which may all refer questions to it—on how the ethical values of European society can be taken into consideration in the scientific and technological development promoted by European Community policies.

10.41 Its opinion on 'Ethical Aspects of Human Stem Cell Research and Use'[50] was adopted unanimously by the Group and made public on 14 November 2000. The opinion seeks to clarify for European institutions the ethical questions relating to the exercise of their powers in this area. Such powers could include financing research or adopting safety standards. It also adopts as a basis for its views Europe's 'legal and ethical pluralism—a reminder that it is for each member state to legislate on the derivation of stem cells from human embryos'.[51]

10.42 The opinion states that, while the Group recognises the major interest of research on human stem cells, it considers that at present 'the creation of embryos by somatic cell nuclear transfer ["therapeutic cloning"] for research on stem cell therapy would be premature' since there are

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46 http://conventions.coe.int/treaty/en/Reports/Html/168.htm, paragraph 6. The Netherlands lodged a declaration at the time of signature stating that: 'In relation to Article 1 of the Protocol, the Government of the Kingdom of the Netherlands declares that it interprets the term 'human being' as referring exclusively to a human individual, ie a human being who has been born'. European Treaty Office, http://conventions.coe.int

47 Article 5 of the Protocol provides for entry into force after five ratifications including four member states

48 http:// conventions.coe.int/Treaty/EN/cadreprincipal.htm. The Protocol has taken effect as an international instrument. The effect of the Protocol within the member states of the Council of Europe is subject to the constitutional arrangements of each of the member states

49 This body is a product of the European Union not the Council of Europe

50 The European Group on Ethics makes public in Paris its opinion on '*Ethical Aspects of Human Stem Cell Research and Use*', Paris, 14 November 2000, IP/00/1293

51 '*Ethical Aspects of Human Stem Cell Research and Use*', Paris, 14 November 2000, IP/00/1293

alternative sources of human stem cells such as spare embryos, foetal tissues and adult stem cells.

10.43 The Group therefore recommended a specific European Community budget for research on alternatives such as adult stem cells, the broad dissemination of the results of such research at European level without it being hidden for reasons of commercial interest, an ethical assessment of research on stem cells financed by the European Community budget prior to the launch of the project and steps to ensure that the demand for spare embryos and oocyte (egg) donation does not increase the burden on women undergoing fertility treatment.

10.44 In relation to the use of stem cells in clinical testing, the Group stressed the need for safety and the protection of the health of the patients. It mentioned the risk that the transplanted stem cells could cause abnormalities or induce the creation of cancerous tumours and stressed that the potential benefits for the patients should be taken into account but not exaggerated.[52]

UNITED STATES OF AMERICA

10.45 Regulation of human cloning and embryo research has been undertaken at both national and state level in the United States. In that respect, the regulatory environment in the United States has some similarity to Australia.[53]

10.46 The most significant feature of the regulation of human cloning and embryo research at the federal level in the United States is the rigid separation between the public and private sectors. Federal funding for human embryo research is, in fact, banned under provisions attached to the spending bills that fund the National Institutes of Health (NIH), the leading provider of research funds in the United States.[54] On the other hand little, if any, federal regulation applies to research involving the use

52 In a resolution of 7 September 2000, the European Parliament stated its opposition to the creation of supernumerary embryos and to therapeutic cloning. European Parliament, B5-710, 751, 753 and 764/2000. A report by the International Bioethics Committee of UNESCO contains a useful summary of national legislation in several countries. International Bioethics Committee UNESCO, 'The Use of Embryonic Stem Cells in Therapeutic Research' – a report of the IBC on the ethical aspects of human embryonic stem cell research, BIO-7/00/GT-1/2(Rev.3), Paris, 6 April 2001

53 There is a variety of complex legislation in the 50 States of the United States. The national initiatives are most relevant to Australia. For this reason, as well as to keep the discussion as brief as possible, the discussion will canvass only federal regulation

54 Meredith Wadman, 'Backing for anti-cloning bill reopens embryo debate', *Nature*, Volume 388, 7 August 1997, p.506

of embryos if it is funded by the private sector, although the Food and Drug Administration (FDA) has recently asserted jurisdiction over reproductive cloning as long as safety issues are raised.[55]

10.47 The following discussion outlines:

- the US federal regulatory response to the cloning of Dolly the sheep and more recent media reports of efforts to clone a human being; and
- the regulatory initiatives regarding embryonic stem cell research.

Human Cloning For Reproductive Purposes

10.48 In March 1997 in the immediate aftermath of the announcement of the cloning of Dolly, President Clinton directed that no federal funds should be allocated to any research procedure for the cloning of human beings. In addition the President requested that the National Bioethics Advisory Commission (NBAC)[56] examine and report within 90 days on the ethical and legal implications of human cloning through somatic cell nuclear transfer techniques.[57]

10.49 The NBAC's report thus focused on human reproductive cloning.[58] The NBAC noted that there were no federal regulations prohibiting the use of private funds for the purpose of cloning human beings.[59] It was unable:

> … to agree at this time on all the ethical issues that surround the issue of cloning human beings in this manner. It seems clear to all of us, however, given the current stage of science in this area, that any attempt to clone human beings via somatic cell nuclear transfer techniques is uncertain in its prospects, is unacceptably dangerous to the fetus and, therefore, morally unacceptable.[60]

10.50 The NBAC recommendations included:

- a continuation of the moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer;

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55 See paragraphs 10.56 – 10.58 below

56 The NBAC was established by President Clinton in 1995 to advise and make recommendations to the National Science and Technology Council and to others on bioethics issues and their policy implications

57 AHEC report, Chapter 5, paragraph 5.13. National Bioethics Advisory Commission (NBAC), *Cloning Human Beings: Executive Summary*, June 1997

58 NBAC, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission*, June 1997

59 NBAC, *Cloning Human Beings: Executive Summary*, June 1997

60 NBAC, *Cloning Human Beings: Executive Summary*, June 1997, Letter to the President, 9 June 1997

- an immediate request to all firms, clinicians, investigators [researchers], and professional societies in the private and non-federally funded sectors to comply voluntarily with the intent of the federal moratorium;
- federal legislation be enacted to prohibit anyone from attempting, in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning. It was critical, however, that such legislation include a sunset clause to ensure a Congressional review of the issue after a specified time period (three to five years).[61]

10.51 The NBAC also concluded:

- any regulatory or legislative actions undertaken to effect the prohibition on creating a child by somatic cell nuclear transfer be written carefully so as not to interfere with other important areas of scientific research;
- if a legislative ban is not enacted, or if a legislative ban is ever lifted, clinical use of somatic cell nuclear transfer techniques to create a child should be preceded by research trials governed by the twin protections of independent review and informed consent, consistent with existing norms of human rights protection;
- the United States Government cooperate with other nations and international organisations to enforce any common aspects of their respective policies on the cloning of human beings.[62]

10.52 The NBAC did not close off the possibility of regulating rather than banning the use of such procedures in the future.[63] The position adopted by the NBAC is not totally consistent with the UNESCO Declaration which expressly prohibits reproductive human cloning on the basis that it is contrary to human dignity.[64]

10.53 On 9 June 1997, President Clinton introduced into Congress the Cloning Prohibition Bill 1997. It proposed that a review of the prohibition of human cloning be undertaken by the NBAC five years after the passage of the legislation. The Bill would have prohibited the cloning of humans or research for the purpose of cloning a human embryo and also would have prohibited any federal funds being used for any such research.[65]

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61 NBAC, *Cloning Human Beings: Executive Summary*, June 1997

62 NBAC, *Cloning Human Beings: Executive Summary*, June 1997. See also testimony by Dr Thomas Murray a member of the NBAC to the Subcommittee on Oversight and Investigations of the House of Representatives Energy and Commerce Committee of Congress at the hearings on issues raised by human cloning research, http://www.house.gov/commerce/hearings/03282001/-141/Murray 206.htm, 28 March 2001

63 NBAC, *Cloning Human Beings: Executive Summary*, June 1997

64 The same point was made by AHEC, AHEC report, Chapter 5, paragraph 5.15. See earlier discussion in this report at paragraphs 10.15-10.27

65 AHEC report, Chapter 5, paragraph 5.16

10.54 Attempts to legislate a prohibition on cloning a human being through Congress foundered in 1998. Patients' groups successfully argued that a cloning ban would also bar the use of somatic cell nuclear transfer techniques for therapeutic purposes. Groups opposed to the use of embryos in research would not accept a bill that might have allowed the creation of human embryos only for researchers to then destroy them.[66]

10.55 A number of Bills relating to either human cloning and/or stem cell research were introduced into Congress during the latter half of 2000 and the first half of 2001.[67] These take generally one of two approaches—either to completely ban the cloning of human embryos no matter what the purpose or to prohibit reproductive cloning only.[68] President Bush announced his support for legislation which would ban all forms of human cloning and recently made an announcement relating to the conduct of embryonic stem cell research (see paragraph 10.72 below).[69] On 31 July the House of Representatives voted to ban human cloning. The legislation (proposed by Representative Weldon) would make it a crime to clone a child or to create embryos for medical research. The bill is yet to be considered by the Senate.[70]

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66 Aaron Zitner, LA Times, http://www.latimes.com/cgi-bin/print.cgi, 25 March 2001. The States of California, Michigan, Louisiana and Rhode Island ban any type of cloning both publicly and privately funded- Miriam Falco and Matt Smith, CNN, http://www.cnn.com/2001/HEALTH/03/28/human.cloning/ 28 March 2001. Dr Thomas Murray, a member of the NBAC, in evidence to a Congressional hearing (discussed below) stated that NBAC staff had surveyed state laws in 1999. At that time five states (not named) had enacted legislation to directly prohibit human cloning and ten states had laws regulating research on embryos and fetuses that could also restrict cloning activities, http://www.house.gov/commerce/hearings/03282001-141/Murray 206.htm, 28 March 2001

67 At the time of the completion of this report nine Bills dealing with human cloning and/or stem cell research had been introduced into either the House of Representatives or the Senate of the US Congress

68 The 'Human Cloning Prohibition Act of 2001' (HR 1644) introduced by Representative Dave Weldon would completely ban the cloning of human embryos no matter what the purpose. It would allow some forms of scientific research such as research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants or animals other than humans. The 'Cloning Prohibition Act of 2001' (HR 2172), introduced by Representative James Greenwood, would prohibit 'reproductive cloning' only, that is, the use or attempted use of human somatic cell nuclear transfer technology with the intent to initiate a pregnancy. The Bill would not apply to the use of somatic cell nuclear transfer technology to clone molecules, DNA, cells or tissues. Another Bill, the Stem Cell Research Act of 2001 (HR 2059), introduced by Representative James McDermott, would provide for the conduct of embryonic stem cell research using only embryos that have been donated from *in vitro* fertilisation clinics within set parameters. The Bill would require that the research conducted on the stem cells must not result in the creation of human embryos or in reproductive cloning. http://www.senate/gov/search/index.html

69 Francis Temman, 'Bush Administration backs ban on human cloning', 22 June 2001

70 Lisa Richwine, 'US House approves a broad ban on human cloning', http://biz.yahoo.com/rf/010731/n31177001_5.html

Food and Drug Administration (FDA) regulatory control

10.56 Recent announcements of attempts to clone a human being (discussed in Chapter 3) have led to Congressional Committee hearings such as those conducted by the Subcommittee on Oversight and Investigations of the House of Representatives Energy and Commerce Committee in March 2001.

10.57 At these hearings the Food and Drug Administration (FDA) which has the authority to regulate medical products (including biological products, drugs and devices) responded to what it called the 'incorrect' view that there are no legal controls in place in the United States governing the use of cloning technology to clone a human being.[71] It:

> … views the use of cloning technology to clone a human being as a cause for public health concern…Because of unresolved safety questions on the use of cloning technology to clone a human being, FDA would not permit the use of cloning technology to clone a human being at this time.[72]

10.58 The FDA issued a rule for cellular and tissue based products in January 2001 that establishes the regulatory framework for human cells, tissue, cellular and tissue-based products and requires establishments to register with the Agency and list their products.[73] Some have expressed doubt as to whether the FDA has authority to regulate the matter even though the agency has claimed jurisdiction.[74]

Research Involving Embryonic Stem Cells

10.59 The NBAC issued a report—*Ethical Issues in Human Stem Cell Research*[75]—examining issues connected with research involving embryonic stem cells

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71 Dr Kathryn Zoon, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, http://www.house.gov/commerce/hearings/03282001-141/zoon205.htm, 28 March 2001

72 Dr Kathryn Zoon, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, http://www.house.gov/commerce/hearings/03282001-141/zoon205.htm, 28 March 2001

73 The established FDA process in overseeing clinical research is based on Title 21, Code of Federal Regulations, 312.42, Congressional evidence of Dr Zoon, 28 March 2001

74 http://energycommerce.house.gov, 28 March 2001 and Aaron Zitner, LA Times, http://www.latimes.com/cgi-bin/print.cgi, 25 March 2001. Michael Soules, for example, President of the American Society of Reproductive Medicine, gave evidence to Congressional hearings that he was satisfied that the FDA had requisite authority in this area and did not see the need for any further legislation, http://www.house.gov/commerce/hearings/03282001-141/soules208.htm, 28 March 2001. Rick Weiss, 'Legal barriers to human cloning may not hold up', Washington Post, 23 May 2001, http://washingtonpost.com/wp-dyn/health/specials/genetherapy/A61636-2001May22.html12/07/2001

75 NBAC, *Ethical Issues in Human Stem Cell Research*, Rockville, Maryland, January 2000

in January 2000. It concluded that federal funds should not be provided for making embryos solely for the generation of human embryonic stem cells. Federal funding for the use and derivation of embryonic stem cells should be limited to two sources of such materials: cadaveric foetal tissue and embryos remaining after fertility treatments. It recommended that an exception be made to the present statutory ban on federal funding of embryo research to permit federal agencies to fund research involving the derivation of human embryonic stem cells from these sources under appropriate regulations that include public oversight and review. It also recommended that federal agencies should not fund research involving the derivation or use of human embryonic stem cells from embryos made solely for research purposes using *in vitro* fertilisation (IVF).

10.60 Further NBAC recommendations included that federal agencies not fund research involving the derivation or use of human embryonic stem cells from embryos made using somatic cell nuclear transfer into oocytes (eggs). The NBAC also recommended that, in giving informed consent for the donation of excess embryos after fertility treatments, the option of donation to stem cell research should only be presented after the donor has decided to discard (not donate to another couple or store) the embryo.[76]

National Institutes of Health (NIH)—stem cell guidelines

10.61 On 23 August 2000 the National Institutes of Health (NIH) published their final guidelines for embryonic stem cell research—'National Institutes of Health Guidelines for Research using Human Pluripotent Stem Cells'—(the Guidelines). The Guidelines became effective on 25 August 2000. Compliance with the Guidelines will be imposed as a condition of the award of a grant of research funding.[77]

10.62 A moratorium on research using human pluripotent stem cells derived from human embryos and foetal tissue put in place by the Director of NIH in January 1999 was lifted on 25 August 2000.[78]

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76 These recommendations are similar to the subsequent National Institutes of Health (NIH) Guidelines for Research using Human Pluripotent Stem Cells discussed below

77 National Institutes of Health, *Guidelines for Research Using Human Pluripotent Stem Cells*, http://www.nih.gov/news/stemcell/stemcellguidelines.htm. In June 2001 the National Institutes of Health issued a report on the state of the science on stem cells: *Stem Cells: Scientific Progress and Future Directions.* This had been requested by the Secretary of Health and Human Services in February 2001. See http://www.nih.gov/news/stemcell/scireport.htm

78 The Guidelines define 'human pluripotent stem cells' as 'cells that are self-replicating, are derived from human embryos or human fetal tissue, and are known to develop into cells and tissues of the three primary germ layers. Although human pluripotent stem cells may be derived from embryos or fetal tissue, such stem cells are not themselves embryos'. These

10.63 The Guidelines:

> … prescribe the documentation and assurances that must accompany requests for NIH funding for research using human pluripotent stem cells from human embryos or fetal tissue. The *Guidelines* state specific criteria for informed consent and establish a Human Pluripotent Stem Cell Review Group to review documentation of compliance with the NIH *Guidelines*. In addition, the *Guidelines* delineate areas of research involving human pluripotent stem cells that are ineligible for NIH funding.[79]

Requirements established in the Guidelines

10.64 The US NIH Guidelines require:

- for studies using cells derived from human embryos, NIH funds may be used only if the cells were derived from frozen embryos created for the purposes of fertility treatment and in excess of clinical need;
- no use of inducements, monetary or otherwise, for the donation of the embryo, and a clear separation between the fertility treatment and the decision to donate embryos for this research;
- investigators [researchers] who propose to use human pluripotent stem cells from foetal tissue will follow both the Guidelines and all laws and regulations governing human foetal tissue and human foetal tissue transplantation research;
- the informed consent specify whether or not information that could identify the donor(s) will be retained;[80]
- the donation of human embryos or foetal tissue be made without any restriction regarding the individual(s) who may receive the cells derived from the human pluripotent stem cells for transplantation;
- review and approval of the derivation protocol by an Institutional Review Board;[81]

Guidelines were described by Professor Alan Trounson as the 'international gold standard', *Transcript*, p.12

79 NIH News Release - 'NIH Publishes Final Guidelines for Stem Cell Research', http://www.nih.gov/news/pr/aug2000/pd-23.htm, 23 August 2000

80 To ensure that human embryos donated for research are in excess of the clinical need of the individuals seeking fertility treatment and to allow potential donors time between the creation of embryos for fertility treatment and the decision to donate for research purposes, only frozen human embryos should be used to derive human pluripotent stem cells. In addition, individuals undergoing fertility treatment should be approached about consent for donation of human embryos to derive pluripotent stem cells only at the time of deciding the disposition of embryos in excess of the clinical need

- informed consent to have been obtained from individuals who sought fertility treatment and who elect to donate human embryos in excess of clinical need for human pluripotent stem cell research purposes.[82]

10.65 The NIH state:

> Federal law currently restricts the use of Department of Health and Human Services (DHHS) funds for human embryo research. DHHS funds cannot be used for the derivation of stem cells from human embryos. The Congressional restriction, however, does not prohibit funding for research utilizing human pluripotent stem cells because such cells are not embryos.[83]

Thus, while NIH funded researchers may conduct research on embryonic stem cells once they are derived from the embryo, they may not actually derive the stem cells because that would result in the destruction of the embryo.

10.66 The Guidelines make no distinction based on the country in which a human pluropotent stem cell line is developed. All stem cell lines to be used in such stem cell research funded by NIH must meet the same requirements. This would apply to Australian researchers seeking NIH funding.[84]

10.67 In relation to compliance, the NIH state:

> Compliance with the *Guidelines* will be largely determined prior to the award of funds. Follow-up to ensure continued compliance with the *Guidelines* will be conducted in the same manner as for all other conditions of all other NIH grant awards. It is the responsibility of the investigator [researcher] to file progress reports, and it is the responsibility of the funded institution to ensure compliance with the NIH *Guidelines*. NIH staff will also monitor the progress of these investigators as part of their regular duties.[85]

10.68 Work involving human pluripotent stem cells that is ineligible for NIH funding includes research in which human stem cells are used to create or

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81 Such bodies are generally equivalent to an institutional ethics committee (IEC) in Australia.

82 The requirements for the informed consent process are listed in Chapter 12 – see paragraph 12.77

83 NIH Fact Sheet on Human Pluripotent Stem Cell Guidelines, http://www.nih.gov/news/stemcellfactsheet.htm, 23 August 2000. The NIH cited advice by the DHHS General Counsel to the same effect, *National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells*, http://www.nih.gov/news/stemcell/stemcellguidelines.htm

84 Professor Alan Trounson, *Transcript*, p.25

85 NIH Guidelines, http://www.nih.gov/news/stemcellguidelines.htm

contribute to a human embryo, the use of stem cells that were derived from human embryos created for research purposes rather than fertility treatment, derivation or use of stem cells derived using somatic cell nuclear transfer, research in which stem cells are combined with an animal embryo and research in which stem cells are derived using somatic cell nuclear transfer for the purposes of reproductive cloning of a human.[86]

10.69 These new Guidelines to allow federal funding of human embryonic stem cell research drew both praise and opposition. Opposition arose because the research requires the destruction of the embryos to obtain the stem cells. Federal law forbids research on the embryo itself. The likely practical effect of the Guidelines is that privately funded researchers will derive the stem cells from embryos and then provide them to NIH funded researchers for use in federally funded research projects.[87]

Review of federal funding using the NIH Guidelines

10.70 There were reports in early 2001 that President Bush would block NIH research funding under the new Guidelines. President Bush was reported as saying in January 2001 that federal money should not be used for research on foetal tissue or on so-called stem cells derived from embryos. He was said to support adult stem cell research and research using stem cells from foetuses that died a natural death (but not from aborted foetuses).[88]

10.71 By February 2001 it was reported that there was a struggle over ES cell research at the political level in the United States pitting opponents of embryo research against patients' advocates and scientists. Rather than banning NIH funding of embryonic stem cell research the Bush administration sent the issue to be reviewed by the US Department of Health and Human Services.[89]

10.72 A decision on whether federally funded research can continue on human stem cells taken from embryos was expected by mid-2001.[90] On 9 August

86 Professor Alan Trounson noted that the Guidelines would not permit the creation of embryos for the purposes of therapy, *Transcript*, p.26

87 The announcement by President Bush of his approval of federal funding for research on existing lines of embryonic stem cells (see paragraph 10.72) throws some doubt on the current status of these Guidelines as they would have permitted federal funding for the use of embryos surplus to assisted reproductive technology programs to obtain embryonic stem cells.

88 Ron Fournier, 'Bush Won't Fund Stem Cell Research' http://dailynews.yahoo.com/h/op/20010126/tsbush-abortion.html, 26 January 2001 and Lisa Richwine, Reuters, 29 March 2001

89 Robin Toner, New York Times, http://www.nytimes.com, 18 February 2001

90 BBC news, http://news.bbc.co.uk, 7 March 2001

2001 President Bush announced his approval of federal funding for research on existing lines of embryonic stem cells. He stated:

> As a result of private research, more than 60 genetically diverse stem cell lines already exist. They were created from embryos that have already been destroyed, and they have the ability to regenerate themselves indefinitely, creating ongoing opportunities for research.
>
> I have concluded that we should allow federal funds to be used for research on these existing stem cell lines, where the life-and-death decision has already been made.
>
> Leading scientists tell me research on these 60 lines has great promise 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. This year your government will spend $250 million on this important research.
>
> I will also name 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 bio-medical innovation.
>
> This council will consist of leading scientists, doctors, ethicists, lawyers, theologians and others, and will be chaired by Dr Leon Kass, a leading bio-medical ethicist from the University of Chicago.[91]

President Bush's proposal will go to Congress. Private funding of such research would not be affected by any change of policy by the new administration over NIH funding of stem cell research. The most probable impact of a change in policy would be to slow the pace of research because fewer researchers would be able to participate.[92] Following President

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91 ABCNews.com, http://abcnews.go/com/sections/plitics/DailyN…/stemcells_Bush_transcript010809.htm 9 August 2001

92 Lauran Neegaard, Associated Press, 25 January 2001 and Aaron Zitner, LA Times, http://www.latimes.com, 15 March 2001

Bush's address, the NIH issued a statement which included the following points:

> Using the more than 60 existing cell lines from around the world, many more researchers will now be able to explore the potential of human embryonic stem cells, in addition to the extensive work already sponsored by NIH using human adult stem cells. We believe this combined research has high potential both for opening new doors in basic scientific understanding and for discovery of new treatments for some of our most devastating diseases.[93]

10.73 Following President Bush's announcement on 9 August regarding federal funding for research on existing stem cell lines, the NIH, which will oversee federal funding of this research, is reported to have held meetings with parties which have rights to the stem lines. The NIH is endeavouring to develop a policy to end uncertainty over access to the research and is reported to have promised to provide researchers at NIH and elsewhere as much access as possible to stem cells.[94] On 27 August 2001 the NIH issued an 'Update on Existing Human Embryonic Stem Cells' in which it listed the ten entities that have advised it they have derived human embryonic stem cells that meet the President's criteria. The Update reported that NIH is creating a Human Embryonic Stem Cell Registry that will list the human embryonic stem cells that meet the eligibility criteria, and NIH welcomes grant 'applications proposing research using such stem cells, including requests to use existing funds or for supplements to existing grants to conduct such research.' Initially the Registry will contain only basic information about the cells.[95]

10.74 It has been reported that many of the stem cell lines approved for research funding under President Bush's new policy have been mixed with mouse cells. To ensure that animal diseases are not transmitted to people the FDA has required special safety testing of cell therapies that use animal products. It appears therefore that FDA guidelines would make it difficult to use these cells in human tests because the cells would be treated as though they were transplants of animal tissue, and this might rule out their use on some groups of patients.[96] A subsequent report stated that

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93 NIH Acting Director, Ruth Kirschstein, MD, National Institutes of Health, 9 August 2001, http://www.nih.gov/news/pr/aug2001/od-09.htm

94 'NIH aims to craft stem-cell policy', *The Boston Globe*, 23 August 2001; http://www.boston.com/dailyglobe2/235/…NIH_aims_to_craft_stem_cell_policy+.shtm

95 US Department of Health and Human Services, National Institutes of Health Update on Existing Human Embryonic Stem Cells, 27 August 2001, http://www.nih.gov/news/stemcell/082701list.htm

96 At the same time it was reported that when researchers are ready to begin tests scientists will be able to grow stem cells without mouse cells or will be able to work within the FDA's guidelines, Gillis, Justin and Connolly, Ceci, 'Stem Cell Research Faces FDA Hurdle',

provided the stem cell lines met FDA safety requirements, they could still be used. However, until details of the cell lines are known, the use that can be made of them will not be certain.[97]

UNITED KINGDOM

10.75 The United Kingdom has approached the regulation of human cloning and its related research from within an existing framework of legislative regulation of assisted reproductive technologies and embryo experimentation. That existing regulation has allowed research involving the use of embryos since 1990 under strict regulation and for purposes specified in legislation as detailed below. More recently, the licensing regime in the United Kingdom was expanded by the Human Fertilisation and Embryology (Research Purposes) Regulations 2001. These Regulations enable the issue of a licence for research to extract stem cells from an embryo and to deliberately create an embryo for research by somatic cell nuclear transfer.[98]

The Human Fertilisation and Embryology Authority

10.76 In 1984 the *Report of the Committee of Inquiry into Human Fertilisation and Embryology*—the Warnock Report, named after the inquiry Chair Dame Mary Warnock—was issued.[99] It recommended the establishment of a statutory body to oversee the practice of certain fertility treatments and human embryo research in the UK.[100]

10.77 The *Human Fertilisation and Embryology Act 1990* (UK) (the HFE Act) was passed in 1990. It established the Human Fertilisation and Embryology Authority (HFEA). The HFEA has comprehensive authority and jurisdiction over all clinics and laboratories dealing with gametes or

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Washington Post, 23 August 2001; http://www.washingtonpost.com/wp-dyn/articles/A53580-2001Aug23.html

97 'Current Stem Cells May Get FDA's OK', 24 August 2001, http://dailynews.yahoo.com

98 See paragraph 10.93 below

99 Report of the Committee of Inquiry into Human Fertilisation and Embryology, HMSO, July 1984 (cm.9314)

100 The conduct of medical research is also governed by guidance produced by the Department of Health and a wide range of professional bodies and, if carried out in the National Health Service, requires approval from a research ethics committee. Chief Medical Officer's Expert Group Reviewing the Potential of Developments in Stem Cell Research and Cell Nuclear Replacement to Benefit Human health, *Stem Cell Research:- Medical Progress with Responsibility*, (Chief Medical Officer's Report) Department of Health (UK), June 2000, p.32

embryos[101] whether those clinics and laboratories are in the private sector or the public sector.

10.78 The HFEA's principal tasks are to license and monitor those clinics that carry out *in vitro* fertilisation (IVF), donor insemination and human embryo research.[102] The HFEA also regulates the storage of gametes and embryos and keeps a register of all licensed treatments carried out in the UK.

10.79 Every centre in the UK that offers clinical treatment involving assisted reproductive technologies, storage of gametes or embryos or which carries out research involving the use of human embryos must be licensed by the HFEA. All licensed centres may be subject to an annual inspection.[103]

10.80 The approval of a properly constituted independent ethics committee is a prerequisite to the HFEA considering an application for a research licence to enable research using human embryos. In addition, all applications for a research licence are submitted for peer review.[104]

10.81 The HFE Act makes it a criminal offence to bring about the creation of an embryo outside the human body or to keep or use an embryo without a licence from the HFEA.[105] The HFE Act also sets out the parameters within which the HFEA may issue treatment, storage or research licences. Sections 3(3) and (4) of the HFE Act provide that:

> (3) A licence cannot authorise –
>
> (a) keeping or using an embryo after the appearance of the primitive streak,

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101 An embryo is defined in the HFE Act as 'a live human embryo where fertilisation is complete and references to an embryo include an egg in the process of fertilisation and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote (Section 1). There is a clear ambiguity in this definition given that somatic cell nuclear transplant does not involve 'fertilisation' as such but transfer of the nucleus. This ambiguity remains. House of Commons Library, *Cloning Research Paper 97/43*, 27 March 1997, p.23

102 Section 16 outlines the procedure for the grant of a licence. Section 12 sets out general conditions relating to all licences granted under the Act. Section 15 sets out general conditions for research licences, including that no embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project (section 15 (4)). The HFE Act does not apply to the keeping of, or research on, stem cells once extracted from an embryo and grown in a laboratory, Chief Medical Officer's Report, p.33

103 Section 9(8). Any particular premises need not be inspected in any particular year if the licence committee considers an inspection in that year unnecessary, section 9(9)

104 Section 25 of the HFE Act provides that the HFEA shall maintain a code of practice giving guidance about the proper conduct of activities carried on in pursuance of a licence granted under the HFE Act. Reference is made to these requirements in the Human Fertilisation and Embryology Authority, Code of Practice at paragraphs 11.6,11.7 and 11.8. Paragraph 11.7 sets out the requirements for the composition of ethics committees for these purposes and notes that the membership of the ethics committee should be approved by the HFEA

105 Section 3 (1)

(b) placing an embryo in any animal,

(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, or

(d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.[106]

(4) For the purposes of subsection 3(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored.

10.82 Schedule 2 of the HFE Act states that the HFEA cannot authorise a research project involving the use of human embryos unless it appears to the HFEA to be necessary or desirable for one of the following purposes:

- promoting advances in the treatment of infertility;
- increasing knowledge about the causes of congenital disease;
- increasing knowledge about the causes of miscarriage;
- developing more effective methods of contraception;
- developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation;
- other such purposes as may be specified in regulations.[107]

10.83 The HFE Act further requires that such research licences may only be granted if the HFEA is satisfied that any proposed use of embryos is necessary for the purposes of the research.[108] Acceptable embryo research is hence governed by the purpose of the research not the source or mode of creation of the embryos to be used in the research.

106 The technique used to produce Dolly involved placing the nucleus from the donor cell into an unfertilised egg, not into another embryo. Because of this it could be argued that Section 3 of the HFE Act is ambiguous. The HFEA has stated that it would not allow human cloning attempts – a licence would not be granted. Embryo splitting is forbidden for treatment purposes under the Code of Practice paragraph 9.11. See also House of Commons Library, *Cloning, Research Paper 97/43*, 27 March 1997, pp.22-23

107 Paragraph 3(2) of Schedule 2 to the HFE Act. Paragraph 3(3) of Schedule 2 of the HFE Act provides that 'Purposes may only be so specified [in regulations] with a view to the authorisation of projects of research which increase knowledge about the creation and development of embryos, or about disease, or enable such knowledge to be applied'

108 Paragraph 3(6) of Schedule 2 to the HFE Act. The licence may be given subject to such conditions as are specified in the licence and may authorise the performance of the activities authorised by the regulations in such manner as may be specified in the licence (paragraphs 3(7) and 3(8) of Schedule 2 to the HFE Act). A licence under this paragraph may be given for any period up to a maximum of three years (paragraph 3(9) of Schedule 2 to the HFE Act)

10.84 Schedule 3 of the HFE Act sets out detailed requirements for the giving of valid consent by donors to the use of gametes or embryos. Consent must be in writing and must not have been withdrawn.[109]

10.85 The HFE Act expressly prohibits one type of cloning technique, namely the nuclear substitution of a cell whilst it forms part of an embryo,[110] but the technique used to create Dolly involved nuclear substitution into an unfertilised egg not an embryo. While the HFE Act does not expressly prohibit this form of cloning or embryo splitting, since both involve the use or creation of embryos outside the body, a licence is required. In 1997 the HFEA announced a policy not to issue licenses for any procedures involving embryo splitting or nuclear transfer.

Joint Report By HFEA and Human Genetics Advisory Commission

10.86 In December 1998 a joint Committee of the Human Genetics Advisory Commission (HGAC)[111] and the HFEA published a report entitled *Cloning Issues in Reproduction, Science and Medicine*. The report concluded that the HFE Act has proved effective in dealing with new developments relating to human cloning. It recommended that the existing safeguards be recognised as wholly adequate to forbid human reproductive cloning in the UK. However, it suggested that the Government might consider introducing legislation that would explicitly ban human reproductive cloning (regardless of the technique used) so that the full ban would not depend on the decision of a statutory authority (the HFEA) but would be enshrined in statute. The report also recommended that the Secretary of State for Health should consider specifying in regulations two further purposes for which the HFEA could issue research licences (in addition to those listed in paragraph 10.82 above) so that potential benefits to be derived from cloning technology could be explored. These additional purposes were the development of:

- methods of therapy for mitochondrial disease; and
- therapeutic treatments for diseased or damaged tissues or organs.[112]

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109 Note also that paragraph 7.20 of the HFEA Code of Practice requires that the specific consent of people providing gametes must be provided to the export of those gametes or of embryos produced using them

110 Section 3(3)(d)

111 Established in December 1996 to provide independent advice to the Ministers for Health and Industry in the UK on issues arising from developments in human genetics that have social, ethical and/or economic consequences. This body has merged with others to form part of the Human Genetics Commission— see below. HGAC/HFEA, *Cloning Issues in Reproduction, Science and Medicine,* December 1998, paragraph 1.7, http://www.dti.gov.uk/hgac/papers/papers-d.htm

112 http://www.dti.gov.uk/hgac/papers/papers-d.htm, section 9

10.87 In June 1999 the UK Government issued its response to this report. It reaffirmed that the deliberate cloning of individual humans is unacceptable and welcomed the recognition that the existing safeguards were adequate to prevent it. It requested the Chief Medical Officer to establish an expert advisory group to consider the HGAC / HFEA recommendations for additional grounds to be added to the HFE Act for the grant of research licences.

Chief Medical Officer's Report

10.88 The Chief Medical Officer's Expert Advisory Group was asked to assess developments in stem cell research and research involving cell nuclear replacement and the likely timescales of the research; to establish more clearly the evidence of potential benefits for human health of such research; to consider possible alternatives to research involving embryos which might achieve the same ends and potential technical and safety issues that might arise. In particular the Expert Advisory Group was asked to consider whether regulations should be made to extend the purposes for which human embryos could be used in research.[113]

10.89 In June 2000 the Chief Medical Officer's Expert Advisory Group handed down its report. Its recommendations included:

- permitting research using human embryos (created by *in vitro* fertilisation or cell nuclear replacement) to increase understanding about human disease and disorders and their cell based treatments, subject to the existing controls in the HFE Act;
- the HFEA, in licensing any research using embryos created by cell nuclear replacement, should satisfy itself that there are not other means of meeting the objectives of the research;[114]
- individuals whose eggs or sperm are used to create the embryos to be used in research should give specific consent indicating whether the resulting embryos could be used in a research project to derive stem cells;[115]

113 Report from the Chief Medical Officer's Expert Group Reviewing the Potential of Developments in Stem Cell Research and Cell Nuclear Replacement to Benefit Human Health, *Stem Cell Research:- Medical Progress with Responsibility*, Department of Health, June 2000, p.12

114 There is already a requirement for the HFEA to satisfy itself in relation to any individual research project that the use of embryos is necessary for meeting the objectives of that research – paragraph 3 (b) of Schedule 2 of the HFE Act. See also Government Response to the Recommendations made in the Chief Medical Officer's Expert Group Report, 'Stem Cell Research: Medical Progress with Responsibility', HMSO, August 2000 (Cm 4833)

115 The UK Government in its response to the report requested the HFEA to incorporate such a provision as a condition in relevant research licences. 'Stem Cell Research: Medical Progress with Responsibility', HMSO, August 2000 (Cm 4833)

- the progress of research involving stem cells derived from embryonic sources should be monitored by an appropriate body to establish whether the research is delivering the anticipated benefits and identify any concerns;[116]
- the mixing of human adult (somatic) cells with the live eggs of any animal species should not be permitted;
- the transfer of an embryo created by cell nuclear replacement into the uterus of a woman (so called 'reproductive cloning') should remain a criminal offence; and
- the need for legislation to permit the use of embryo-derived cells in treatments developed from this new research should be kept under review.[117]

10.90 The major recommendation of the report—that research using embryos (created by assisted reproductive technologies or cell nuclear replacement) be permitted in order to increase understanding about human disease and disorders and their cell based treatments—would permit the deliberate creation of embryos by means of somatic cell nuclear transfer.[118]

10.91 In August 2000 the UK Government announced that it accepted the Expert Advisory Group's recommendations in full and would bring forward the necessary legislation to implement them.[119]

Human Fertilisation and Embryology (Research Purposes) Regulations 2001

10.92 The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 implement the primary recommendation of the Chief Medical Officer's Expert Advisory Group. The Regulations were passed

116 The UK Government has requested in its response that the HFEA and the Human Genetics Commission undertake this task. 'Stem Cell Research: Medical Progress with Responsibility', HMSO, August 2000 (Cm 4833)

117 The UK Government has requested in its response that the HFEA and the Human Genetics Commission advise on this. 'Stem Cell Research: Medical Progress with Responsibility', HMSO, August 2000 (Cm 4833)

118 The Chief Medical Officer's Expert Advisory Group report states that, if research is successful, a question could arise over the creation or use of embryos to develop tissue specifically for treatment purposes, particularly if it was necessary to create a particular embryo for patients in order to provide compatible tissue. At present the only treatment services using embryos which can be licensed under the HFE Act are medical, surgical or obstetric services to help women to 'carry children'. The possibility of an amendment to the Act would need to be considered by Parliament if the research suggested that the use of embryo-derived cells for broader treatment purposes was necessary and acceptable. Chief Medical Officer's Report, p.34

119 Chief Medical Officer's Report, p.34

on a conscience vote of both Houses of the United Kingdom Parliament[120] and came into force on 31 January 2001.[121] The Regulations provide that in addition to the purposes specified in paragraph 10.79 above:

> The Authority may issue a licence for research under paragraph 3 of Schedule 2 to the Act for any of the purposes specified in the following paragraph.
>
> (2) A licence may be issued for the purposes of –
>
> (a) increasing knowledge about the development of embryos;
>
> (b) increasing knowledge about serious disease; or
>
> (c) enabling any such knowledge to be applied in developing treatments for serious disease.

10.93 The Regulations legalise embryo research to extract stem cells and deliberate creation of embryos by somatic cell nuclear transfer for research purposes; they faced impassioned opposition from religious leaders and other campaigners in Britain.[122]

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120 The Regulations passed the House of Commons 366-174. A vote in the House of Lords to refer the Regulations to a Select Committee was defeated 212-92. In March 2001 the House of Lords appointed a Select Committee to consider and report on issues connected with human cloning and stem cell research arising from the Regulations. These issues include the ethical, legal, scientific, medical and commercial issues surrounding the regulations, House of Lords, Current Inquiries and Invitations to Submit Evidence, Session 2000-2001, http://www.publications.parliament.uk/pa/Id199697/Idselect/Idscenqs.htm

121 The full implementation of the new Regulations has been delayed by a court challenge. The Prolife Alliance has successfully sought judicial review of the coverage of the Human Fertilisation and Embryology Act 1990. At issue is whether the cloning of human embryos by means of somatic cell nuclear transfer for birth as well as research is legal without a licence from the HFEA because of a loophole in the law. A decision is still pending. The Prolife Alliance is arguing that the definition of 'embryo' in the HFE Act does not include cloned embryos because such embryos do not involve fertilisation. The new Regulations are based on the existing definition. Patrick Goodenough, 'UK court case may upend decision to legalize embryonic cloning', 26 January 2001, 'Loophole May allow Cloning', http://www.cnsnews.com/viewForeignBureaus.asp?Page=/Foreign.../For 20010126g.htm. Dominic Kennedy, *The Times*, 15 January 2001, http://www.latimes.com/egi-bin/print.egi. In response to the challenge the HFEA has stated it will not make any decision on research applications under the new Regulations involving embryos created using cell nuclear replacement until the proceedings have concluded. The HFEA will accept licence applications under the new categories provided embryos have not been created by cell nuclear replacement. HFEA, *HFEA Update*, Issue 5, February 2001, p. 2

122 For example, eleven religious leaders of different faiths joined forces to try to halt the regulations in the House of Lords. The leaders included the Archbishops of Canterbury and York, the Roman Catholic Archbishops of Westminster and Glasgow and the President of the Muslim College, the Chief Rabbi and Orthodox, Sikh, Baptist and Evangelical leaders. They claimed that the 'philosophical and ethical implications' of cloning had not been fully considered. They wanted the matter referred to a select committee. This move was defeated. Victoria Combe, 'Faith leaders join forces to oppose human cloning law', *Daily Telegraph*, http://www.telegraph.co.uk, 15 January 2001. See also *Sydney Morning Herald*, 16 January

10.94 The Parliamentary Under-Secretary of State for Health (Ms Yvette Cooper) stated, during debate on the Regulations in the House of Commons, that 'the purpose of the regulations is to permit embryonic stem cell research' citing the potential of the research for the alleviation of serious disease.[123] She noted that the Regulations:

> … do not change the regulatory framework, the strict limits, the 14-day limit or the need for an individual licence from the HFEA. They also do not permit research if there is any other way of doing the research without embryos. They also still require embryos to be donated with informed consent.[124]

10.95 With respect to the purpose of permissible research, Ms Cooper stated:

> … embryo research should not be permitted for just any old thing. That is why the regulations specify serious disease. We are talking not about the common cold but about spinal injuries, burns, osteoporosis, stroke, cancer, heart disease—about serious disease and disability.[125]

10.96 Ms Cooper reiterated the position of the UK Government on reproductive cloning: 'Human reproductive cloning is illegal. It must stay illegal. Under these regulations it will stay illegal'.[126]

2001, p.8. Reaction to the House of Commons vote was strong in Germany where production of human embryos for research is banned, Mark John, Reuters, 21 December 2000. For reaction to the British changes in Europe see House of Commons Library, *Stem Cell Research and Regulations Under the Human Fertilisation and Embryology Act 1990*, Research Paper 00/93, 13 December 2000, pp.32-34

123 House of Commons, *Hansard*, Debates for 19 December 2000, column 212. Ms Cooper noted that the Parkinson's Disease Society, Diabetes UK, the Alzheimer's Disease Society, the Huntingdon's Disease Association, the Royal Society, the British Medical Association, British Heart Foundation, the Cancer Research Campaign and Breakthrough Breast Cancer all supported the regulations, column 213

124 House of Commons, *Hansard*, Debates for 19 December 2000, column 214. The Under-Secretary of State stated that between 1991 and 1998, 48,000 embryos were used in research after being donated by couples going through IVF treatment while 250,000 embryos created through IVF were destroyed. House of Commons, *Hansard*, Debates for 19 December 2000, column 215. See also Chief Medical Officer's Report, paragraph 3.5 which also stated that 118 embryos were created in the course of research

125 House of Commons, *Hansard*, Debates for 19 December 2000, column 215.

126 House of Commons, *Hansard*, Debates for 19 December 2000, column 220. She further stated that the UK Government would embed the ban on human reproductive cloning in primary legislation, Ibid, column 220. She also stated that the HFEA Act does not distinguish between research on embryos created through IVF and those created through somatic cell nuclear transfer. House of Commons, *Hansard*, Debates for 19 December 2000, column 220

Human Genetics Commission

10.97 On 20 December 1999 the UK Government announced the establishment of a new Human Genetics Commission. The Cabinet Office had reviewed the advisory and regulatory framework for biotechnology in May 1999. It concluded that the system for regulating individual products and processes operated satisfactorily. However, the advisory framework should be more transparent (to gain public and professional confidence); more streamlined (to avoid gaps, overlaps and fragmentation); and ensure a capacity to deal with rapid developments and take broad social and ethical issues fully into account.[127]

10.98 The new Commission incorporates responsibilities formerly addressed by other bodies including the Human Genetics Advisory Commission.[128] Its terms of reference include to:

- analyse current and potential developments in human genetics and advise Ministers on their likely impact on human health and health care and their social, ethical, legal and economic implications;
- advise on strategic priorities in the delivery of genetics services by the National Health Service;
- advise on strategic priorities for research; and
- consider specific issues related to human genetics and related technologies as requested by Ministers.[129]

RELEVANCE OF THESE INTERNATIONAL DEVELOPMENTS TO AUSTRALIA

10.99 There are clearly great differences in approach to matters involving human cloning and embryo research in various countries. The varying approaches outlined in this chapter demonstrate the difficulty in developing or discerning a clear international consensus especially on issues as sensitive as the use of embryos in research.

10.100 Elements of an international consensus are emerging on some issues. It appears to be well accepted (although not in all quarters) that a distinction

127 http://www.hgc.gov.uk. The Food Standards Agency will have similar responsibilities for GM foods and the Agriculture and Environment Biotechnology Commission will have responsibility for all other areas of biotechnology

128 The other bodies were the Advisory Committee on Genetic Testing and the Advisory Group on Scientific Advances in Genetics, http://www.hgc.gov.uk

129 http://www.hgc.gov.uk

must be made between the application of cloning techniques to the replication of a person or the creation of a child and the application of cloning techniques to the creation of tissues and cell lines with the aim of developing therapies for use in the treatment of disease and disability.

10.101 The use of cloning techniques for reproductive purposes has brought international condemnation and there appears to be a consensus against reproductive cloning. The provisions of the UNESCO Declaration, the Protocol to the European Biomedicine Convention, the Charter of Fundamental Rights of the European Union, the regulatory mechanism in the United Kingdom and the legislative attempts to prevent cloning for reproductive purposes in the United States provide clear evidence of this.

10.102 The potential for significant developments and gains to be made from stem cell research is accepted in the United States and the United Kingdom. Recent regulatory developments in the United States and the United Kingdom have reflected attempts to balance the harnessing of this potential with the protection of the human embryo, the special status of which is widely acknowledged in those countries. The tension between harnessing the potential of stem cell research and the protection of human embryos is also evident in the more cautious approach of the European Group on Ethics.

10.103 The approach taken by the United Kingdom is similar to that in Victoria, South Australia and Western Australia. The advantages of such a regulatory approach are that it is clear and consistent, applies throughout the country and the requirements and procedures for any research involving the use of embryos are plain to researchers, practitioners and the general public. The general principles are well established and have been debated extensively. The regulatory framework in the United Kingdom has not inhibited the conduct of research in that country since the United Kingdom is a world leader in this research and the regulatory mechanism has proved flexible enough to accommodate developments in the science. The United Kingdom framework also covers both the public and private sectors. The Committee regards the distinction drawn on this basis at the federal level within the United States regulatory framework and the lack of consistent national coverage as the greatest weaknesses of the United States system.

10.104 Some of the international developments outlined in this chapter have been drawn on by the Committee in developing its recommended regulatory framework for Australia. This is outlined in Chapter 12.

11

AHEC's recommendations and other options for regulation of human cloning

INTRODUCTION

11.1 This chapter outlines the responses of those who gave evidence on the recommendations contained in the AHEC report. The Committee will outline its suggested framework for the appropriate regulation of human cloning and related research in Chapter 12.

COMMENTS ON THE AHEC RECOMMENDATIONS

11.2 The AHEC recommendations and resolutions are set out in full at Appendix D. In summary, AHEC recommended that the Commonwealth Government reaffirm its support for the UNESCO *Universal Declaration on the Human Genome and Human Rights* (in particular Article 11) (Recommendation 1) and that the Minister for Health and Aged Care should urge those states and territories without legislation regulating research on human embryos (Recommendation 2) or without statutory authorities with power to regulate research on human embryos (Recommendation 3) to legislate to achieve these ends. The legislation and statutory authorities should accord with the principles set out in Guidelines 6 and 11 of the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (set out at Appendix F). AHEC also recommended that informed community debate on potential risks and benefits of the development of cloning techniques be encouraged (Recommendation 4).

11.3 In its submission to this inquiry, AHEC stated that its reasons for making Recommendations 2 and 3 (see Appendix D**)** were:

- there are social and ethical issues attendant on these research programs and these are appropriately the subject of legislation rather than review by IECs whose responsibility is for the welfare of participants in research;
- it is undesirable that approval of research using cloning techniques especially the cloning of human embryonic stem cells, be dependant on geography—a national regulatory framework would ensure that no one State or Territory is perceived as a 'safe harbour' for the conduct of research which is not permitted elsewhere;
- mandatory monitoring procedures should be instituted and researchers subjected to compulsory record keeping;
- the auditing of research on embryos should be done by statutory authorities such as already exist in three states;
- an authority should issue licences to competent professionals and thereby prohibit others from undertaking such research;
- the legislation could bring about consistency between existing state legislation and the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* and the Reproductive Technology Accreditation Committee Code of Practice and establish limits on research involving embryos;[1]
- research will be facilitated by clarifying the kind of research on embryos which is permitted and which requires approval, thus assisting researchers.[2]

11.4 Very little evidence to this inquiry responded to the AHEC recommendations in detail. Perhaps this is because some felt that the debate and scientific developments had moved beyond the recommendations. The more common approach adopted by most was to outline the kind of regulation they thought most appropriate.

11.5 AHEC's recommendations drew little unqualified support. The Australian Medical Association generally supported the recommendations[3] and the Royal College of Pathologists of Australasia also indicated its support.[4]

1 The NHMRC *Ethical Guidelines on Assisted Reproductive Technology* and the Reproductive Technology Accreditation Committee Code of Practice are discussed in Chapter 9

2 AHEC, *Submissions*, pp.S351-352

3 AMA, *Submissions*, p.S26

4 Royal College of Pathologists, *Submissions*, p.S161. The Consumers Health Forum also indicated its support for Recommendations 1 and 2, *Submissions*, p.S792

11.6 As might be expected, the views expressed in relation to ethical issues (discussed in Chapters 6 and 7) flowed through people's comments on AHEC's recommendations.

11.7 Hence, while the Human Genetics Society of Australasia[5] and Queensland Right to Life[6] supported Recommendation 1, some, such as the Catholic Archdiocese of Melbourne were more restrained. The Archdiocese argued that 'reproductive cloning', mentioned in Article 11 of the UNESCO *Universal Declaration on the Human Genome and Human Rights* also included the creation of embryos. Before the Archdiocese could fully support Recommendation 1, it argued, it was necessary to clarify the Australian Government's interpretation of Article 11.[7] It argued that if its view of the correct interpretation of Article 11 was adopted then AHEC's Resolutions 1 and 2 were inconsistent with Recommendation 1.[8] In a similar vein, the Queensland Bioethics Centre supported Recommendation 1 so long as it was understood to refer also to cloned embryos.[9] The Caroline Chisholm Centre for Health Ethics was prepared to agree with the recommendation, but argued that it should be more specific and include a legislative provision that detailed what was meant by 'reproductive cloning'. The Centre understood reproductive cloning to mean cloning human embryos, human foetuses, children and adults.[10]

11.8 The effect of previously expressed ethical views on the assessment of AHEC's recommendations was most apparent in the case of Recommendations 2 and 3 and Resolutions 1 and 2.

11.9 The Council on Marriage and the Family rejected Recommendations 2 and 3 'on principle' because they would permit destructive embryo research in some instances and enable institutional ethics committees (IECs) to permit such research.[11] The Caroline Chisholm Centre for Health Ethics

5 Human Genetics Society of Australasia, *Submissions*, p.S506

6 Queensland Right to Life, *Submissions*, p.S263

7 Catholic Archdiocese of Melbourne, Submissions, p.S521. Paragraphs 10.15-10.27 discuss the interpretation of Article 11 of the UNESCO Declaration

8 Catholic Archdiocese of Melbourne, *Submissions*, p.S521. The Archdiocese argues that the two resolutions would seem to enable cloning for 'therapeutic purposes'. See also Queensland Bioethics Centre, *Submissions*, p.S707

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

10 Caroline Chisholm Centre for Health Ethics, *Submissions*, p.S490

11 Council on Marriage and the Family, *Submissions*, p.S494. This consequence arises because recommendations 2 and 3 of the AHEC report urge States and Territories without current legislation or statutory authorities regulating embryo research to establish them based on the principles set out in sections 6 and 11 of the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (set out at Appendix F). Guideline 6.4 enables non-therapeutic research using embryos to be approved in certain exceptional circumstances. The Catholic Women's League Bioethics Working Party, *Submissions*, p.S104. Queensland Right to Life, *Submissions*, p.S263

supported Recommendation 2 but thought it should have gone further to review Guidelines 6.2 and 6.4 of the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* because these sections of the Guidelines permit destructive research on embryos in some circumstances which the Centre believes is ethically unacceptable. The Centre supported both resolutions.[12]

11.10 The Catholic Archdiocese of Melbourne regarded the two resolutions in the AHEC report as 'a wholly inadequate response to the Australian Government's moral and legal obligations'.[13] While the General Synod of the Anglican Church of Australia welcomed the notion of an expert advisory committee to assist IECs in relation to scientific issues in human cloning, it stated that 'much more is needed'.[14]

11.11 AHEC's Recommendation 4 (see Appendix D) drew little comment. The Australian Research Council supported the recommendation[15] as did the Australian Academy of Science and the Caroline Chisholm Centre for Health Ethics.[16]

OPTIONS FOR REGULATION

11.12 There was virtually unanimous support for any regulatory framework adopted being nationally uniform.[17] The Australian Catholic Bishops Conference preferred uniform regulation to unenforceable guidelines or self-regulation and accreditation.[18] The Consumer's Health Forum argued that human cloning is a national issue and Commonwealth leadership is required.[19]

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and the Coalition for the Defence of Human Life, *Submissions*, p.S270-271 also expressed the same view

12 Caroline Chisholm Centre for Health Ethics, *Submissions*, pp.S490-491

13 Catholic Archdiocese of Melbourne, *Submissions*, p.S522

14 General Synod of the Anglican Church of Australia, *Submissions*, p.S344

15 Australian Research Council, *Submissions*, p.S226

16 AAS, *Submissions*, p.S245 and Caroline Chisholm Centre for Health Ethics, *Submissions*, p.S490

17 Those articulating this view included- AMA, *Submissions*, p.S27; Mr / Ms Hartwig, *Submissions*, p.S22; Mr / Ms Murrell, *Submissions*, p.S42; Country Women's Association of NSW, *Transcript*, p.95; Catholic Women's League of Australia Bioethics Working Party, *Submissions*, p.S102; Mr Latchford, *Submissions*, p.S111; Dr David Gawler, *Submissions*, p.S628; Queensland Bioethics Centre, *Submissions*, p.S708

18 Australian Catholic Bishops Conference, *Submissions*, p.S733

19 Consumers Heath Forum, *Submissions*, p.S792

11.13 Members of the public who urged uniform national regulation included Dr David Elder [20] and Mr Richard Dewis who considered the AHEC recommendations to be 'redundant' and urged national legislation 'so that the entire nation is operating at the same level and by the same definitions'.[21]

11.14 Youth Concerned with Cloning considered that:

> …cloning technology is not, in principle, policeable. However, we believe that legislation is a better option than self-regulation through institutional ethics committees.[22]

11.15 Regulation that applies consistently to both private and public sectors was also supported. Dr David Elder commented that the sort of 'double standard' that operates in the United States in the regulation of public and private research was 'highly unacceptable'.[23]

11.16 The Australian Academy of Science noted that in the United States the private sector is virtually unregulated. In the Academy's view this has resulted in an element of secrecy whereby the information being gained as the result of research is not in the public domain. In its view regulation must be binding on both private and public sectors and the right regulatory tool is not the withholding of funds from research (as is currently the case in relation to the NHMRC).[24]

What Should Be Regulated?

11.17 The evidence suggested strong support for several specific aspects of human cloning and related research to be strictly regulated. The first and clearest of these specific aspects was the overwhelming support for cloning for reproductive purposes to be prohibited.[25]

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20 Dr David Elder, *Submissions*, p.S202

21 Richard Dewis, *Submissions*, p.S12

22 Youth Concerned with Cloning, *Submissions*, p.S547

23 Dr David Elder, *Submissions*, p.S194. See Chapter 10 for a discussion of regulation of human cloning and its related research in the United States. Others to stress the importance of covering both the public and private sectors included—Country Women's Association of NSW, *Submissions*, p.S160 and *Transcript* p.95; Consumers Health Forum, *Submissions*, p.S792; Human Genetics Society of Australasia, *Submissions*, p.S509; AAS, *Submissions*, p.S250 and the Anglican Diocese of Melbourne, *Submissions*, pp.S308-310

24 AAS, *Transcript*, p.78

25 This was supported by, for example - Human Genetics Society of Australasia, *Submissions*, p.S509; Catholic Archdiocese of Melbourne, *Submissions*, p.S522; AAS, *Submissions*, p.S251; Law Society of NSW, *Submissions* p.S280. See also submission numbers 69, 70, 72, 76, 81, 82, 89, 92, 99, 110, 111, 112, 144, 146, 160, 164, 166, 171, 175, 196, 204, 216, 224, 239, 244, 253, 257,

11.18 There were arguments both in favour of and against banning research and experimentation involving the use of embryos.[26] There were also views expressed both in favour of and against the import and export of embryos and embryonic material.[27]

11.19 Other matters regarded as requiring inclusion in any regulatory framework were the protection of genetic privacy[28] and measures to ensure that consent to the donation of eggs or embryos for research was not the result of pressure or coercion.[29]

How Should These Matters Be Regulated?

A national licensing system

11.20 The most common suggestion for an appropriate regulatory framework to govern human cloning and associated research was the institution of a national licensing system. The Social Responsibilities Committee of the Anglican Diocese of Melbourne regarded the present control mechanisms using local ethics committees with different approaches operating under NHMRC guidelines as insufficiently accountable to society. It argued that:

> For questions such as cloning national legislation and a national control and licensing structure must be introduced[30]…The Government must develop mechanisms whereby the ongoing research, development, introduction and patenting of the technology to reproduce human materials and cell lines of human origin will be made publicly accountable and responsive to the needs of the community by regulation and licensing.[31]

11.21 The Social Responsibilities Committee also argued that the existing controls and regulation are the product of conditions developed for assisted reproductive technology. The current model of NHMRC

260, 272, 302, and 316. Dr Russell Blackford, *Submissions*, pp.S1-2 and Dr David Swanton, *Submissions*, p.S121 did not support a ban on reproductive cloning

26 See submission numbers – 47, 54, 69, 70, 72, 76, 81, 82, 92, 94, 97, 99, 110, 111, 112, 142, 144, 146, 149, 160, 164, 166, 171, 175, 196, 204, 216, 224, 239, 244, 253, 254, 257, 260, 272,.295, 302, 316

27 Youth Concerned with Cloning, *Submissions*, p.S547; Federation of Right to Life Associations, *Submissions*, p.S323 and the Festival of Light SA, *Submissions*, p.S336, Professor Robert Norman, *Transcript*. pp.82 and 115-116. See also Submission numbers – 69, 70, 72, 239, 244, 257, 295

28 Dr David Elder, *Submissions*, p.S205

29 Ridley College, *Submissions*, p.S35

30 Social Responsibilities Committee, Anglican Diocese of Melbourne, *Submissions*, p.S299

31 Social Responsibilities Committee, Anglican Diocese of Melbourne, *Submissions*, p.S302

guidelines and local ethics committees is inadequate, in the view of the Social Responsibilities Committee, to deal with such a 'fast moving, wide-ranging and complex issue with its implications for the whole of society'.[32] It argued that as well as:

> … establishing Statutory authorities, in all States the Commonwealth should implement a national Authority to licence, approve and regulate all work in the area of cloning and embryo research.[33]

11.22 The General Synod of the Anglican Church of Australia considered that this is 'a matter which requires explicit regulation as opposed to just guidelines'.[34] It sought a prohibition on the cloning of human beings and embryos and stated that the clear intent of NHMRC Guidelines and current legislation had been 'circumscribed by the well-known practice of border-hopping'.[35]

> … it is apparent that this is an area that cannot be left merely to self-regulation or NHMRC guidelines…it is quite clear that privately financed interests are quite capable of undertaking research in Australia, including States/Territories where there is not legislative prohibition.[36]

11.23 The Humanist Society of Victoria advocated a licensing model based on that used in the United Kingdom. Such a system would regulate:

> … all creation, research and treatment of human embryos *in vitro*… Were such a model to be used here, on a Federal scale, it would remove the problem of legislative differences between States.[37]

11.24 The Royal Australian and New Zealand College of Obstetricians and Gynaecologists also supported licensed and accountable facilities undertaking:

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32 Social Responsibilities Committee, Anglican Diocese of Melbourne, *Submissions*, p.S308

33 Social Responsibilities Committee, Anglican Diocese of Melbourne, *Submissions*, p.S308

34 General Synod of the Anglican Church of Australia, *Submissions*, p.S342

35 General Synod of the Anglican Church of Australia, *Submissions*, p.S342

36 General Synod of the Anglican Church of Australia, *Submissions*, p.S343

37 Humanist Society of Victoria, *Submissions*, p.S150. The Human Genetics Society of Australasia also supported the creation of a national statutory body to review all proposals and policies relating to the use of new reproductive technologies for human cell or tissue cloning in any context, *Submissions*, p.S509

> Non-reproduction cloning, and stem cell research where the primary focus is on transplant and tissue graft potential, from bone marrow to full organs….[38]

11.25 The Royal College of Nursing cited an urgent need for 'strengthened regulation and community debate', as well as a separate body, accountable to the people, to review, monitor and regulate the scientific, ethical and social impact of human genetics.[39]

11.26 The Murdoch Institute for Research into Birth Defects also made a similar suggestion and recommended a National Regulatory Committee for Reproductive and Genetic Technology (NRC) be established to which all groups, public or private, should be legally bound to submit any proposals for research with human material in this field. The NRC should determine that no reproductive cloning procedures that could lead to a viable human being or foetus of more than 28 days be permitted. The NRC should be directed to permit a limited number of procedures on embryos that are surplus to assisted reproductive technology programs provided that consent procedures were followed. The recommendations of such a NRC should be in force throughout all States and Territories.[40]

11.27 The Caroline Chisholm Centre for Health Ethics agreed with the view that if the Commonwealth, States or Territories were to make new laws, the legislation should only contain basic ethical principles and provisions that would not become outdated quickly. Regulatory authorities should interpret the legislation and control new developments.[41]

Two-tier regulatory process

11.28 The other principal suggestion for an appropriate regulatory framework was that proposed by the Australian Academy of Science (AAS). The AAS suggested a two tier regulatory process which would involve approval to undertake research involving human embryos and human ES cell lines being sought from IECs first. Then those research proposals could be assessed for their scientific merits, safety and ethical acceptability by a national panel of experts established by the NHMRC.[42]

11.29 The AAS argued that both the Academy and AHEC recognise the:

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38 Royal Australian and New Zealand College of Obstetricians and Gynaecologists, *Submissions*, p.S190

39 Royal College of Nursing, *Submissions*, p.S283

40 Murdoch Institute for Research into Birth Defects, *Submissions*, p.S348

41 Caroline Chisholm Centre for Health Ethics, *Submissions*, pp.S491-492

42 Australian Academy of Science, *Submissions*, p.S250

> …need for regulation …so that the public can be assured that only responsible research, properly assessed on its scientific merit, on safety issues and on its ethical acceptability, will be undertaken in Australia.[43]

11.30 The AAS suggested that the only real difference between the position taken by the AAS and that of AHEC, is that in the view of the AAS, human cells, whether derived from cloning techniques or embryonic stem cell lines, should not be precluded from use in approved research activities.[44] On the other hand the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* would only allow the production of embryonic stem cell lines in exceptional circumstances.[45] In the AAS' view these restrictive provisions should be amended.

11.31 Under the AAS proposal legislation would limit research practice by, for example, legislatively prohibiting the cloning of human foetuses. The national panel of experts would then regulate research practice under the legislation.

11.32 The AAS argued that national regulation:

> …provides more consistent application of national standards and would ensure greater accountability than individual IECs operating within varying State laws. The need for national oversight of therapeutic cloning, rather than local oversight, is crucial if the public is to be assured that any work in human stem cell research is of the highest scientific standard, is safe and is ethically acceptable.[46]

11.33 AHEC did not support the AAS two tier model and argued that it has the following problems:

- it would have no jurisdiction over private facilities;
- it could be ignored by the existing regulatory bodies in Victoria, Western Australia and South Australia;

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43 Australian Academy of Science, *Submissions*, p.S250

44 Australian Academy of Science, *Submissions*, p.S250

45 Australian Academy of Science, *Submissions*, p.S250. The Coalition for the Defence of Human Life argued that, in their view, the AAS would achieve the desired uniformity in regulation by relaxing restrictions in the three states with existing legislation and relaxing restrictions in the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* which have no force but which may affect research funding. The Coalition urged legislation to ban destructive embryo research and allow only research that was therapeutic for the individual embryo, *Submissions*, p.S271

46 Australian Academy of Science, *Submissions*, p.S251

- it would have no enforcement powers; and
- reporting to such a body could not be made mandatory.[47]

11.34 The Human Genetics Society of Australasia offered a similar proposal to that of the AAS. It suggested a national regulatory committee for reproductive and genetic technology with appropriate legislation mandating that any group undertaking such research in Australia would first submit its proposal for research using human material in this field to such a committee. That committee could then determine the extent of research that could be undertaken on human embryos.[48]

Other proposals

11.35 The Catholic Archdiocese of Melbourne suggested two options whereby the Commonwealth could achieve regulation. These were first, a uniform legislative ban by the Commonwealth, States and Territories or, second, failing this, Commonwealth legislation to fill the lacuna in those States and Territories where no legislative ban has so far been enacted or where the current legislation is inadequate or ineffective.[49]

11.36 The Australian Research Council suggested that it was highly desirable in order to ensure consistent legislation that the Commonwealth develop model legislation for the States or for the States to refer their power over this area to the Commonwealth under section 51 (xxxvii) of the Constitution.[50]

11.37 The Law Society of NSW supported uniformity in the laws regulating human cloning amongst the States and Territories but argued that a sunset clause should be included to ensure the issue was reviewed and a decision made as to whether a prohibition on cloning for reproductive purposes was still needed.[51]

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47 Letter from AHEC to AAS, 23 April 1999, *Exhibit* 10

48 Human Genetics Society of Australasia, *Submissions*, p.S507

49 Catholic Archdiocese of Melbourne, *Submissions*, p.S523. The Archdiocese suggested that the Commonwealth should rely on its constitutional powers over family law, corporations, finance, external affairs and customs, excise and patenting

50 Australian Research Council, *Submissions*, p.S225. The referral of the relevant constitutional powers by the States to the Commonwealth is regarded as unlikely and has not been pursued by the Committee

51 Law Society of NSW, *Submissions*, p.S280

Australian Health Ministers' Agreement

11.38 A further initiative for the regulation of human cloning was announced in a media release on 31 July 2000. The Commonwealth Minister for Health, the Hon. Dr Michael Wooldridge MP, announced that Australian Health Ministers had agreed to 'the development of a national framework to prevent the exploitation of human cloning'. The announcement stated the Ministers acknowledged that:

> The development of complementary legislation across the states and territories was essential to ensure a consistent national approach to the cloning of humans … each jurisdiction will need to work cooperatively to ensure consistency in banning the cloning of human beings.

11.39 Submissions from State and Territory Health Ministers advising on their progress in implementing this decision and their proposed time frame for doing so provided little information on either of these matters.[52]

11.40 The Committee has also noted the decision of the Council of Australian Governments (COAG) on 8 June 2001 to develop nationally consistent provisions in legislation to prohibit human cloning. COAG agreed that jurisdictions would work towards nationally consistent approaches to the regulation of assisted reproductive technology and related emerging human technologies. Health Ministers are expected to report back to COAG by the end of the year on technical issues arising from this decision with the aim of a nationally consistent approach being in place in all jurisdictions by June 2002.

11.41 The Committee is concerned at the delays that have occurred since July 2000 in implementing the earlier decision of the Australian Health Ministers and the lack of progress on this matter in some States and Territories. The Committee urges the Commonwealth to take the lead in ensuring that the proposed timetable for the implementation of the decision of the Council of Australian Governments is adhered to.

11.42 This raises the issue of the extent of the Commonwealth's constitutional power to enact legislation that would regulate human cloning and its related research.

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52 Minister for Human Services in South Australia, *Submissions*, pp.S857-858; Minister for Health in Western Australia, *Submissions*, p.S859-860; Minister for Health in Victoria, *Submissions*, p.S861; Minister for Health in Queensland, *Submissions*, p.S862; Minister for Health and Human Services in Tasmania, *Submissions*, p.S864; Minister for Health in NSW, *Submissions*, p.S866; Minister for Health and Community Care in the ACT, *Submissions*, p.S863

11.43 In relation to the Commonwealth's constitutional power to legislate, the Attorney-General's Department submitted:

> … it may be possible to legislate in a piecemeal fashion using a number of Commonwealth heads of power such as the trade and commerce power and the corporations power, ultimately it is probably the case that the Commonwealth Parliament does not have the power to enact legislation that would provide a comprehensive basis for prohibiting scientific research aimed at achieving reproductive human cloning or cloning research that involves the use of embryonic tissue.[53]

11.44 The Department also made the point that:

> … Commonwealth powers to legislate is one part of the issue, but, even assuming the Commonwealth parliament does have power to legislate, it would be doing so because there was a perceived gap in state and territory legislation, or in order to override state and territory legislation… even if the Commonwealth parliament were to legislate on these issues, … it would … be necessary to consult quite heavily with the states and territories and ideally to have agreement … So … there are some other political dimensions as well.[54]

11.45 The Committee agrees. It also notes Associate Professor Skene's comment:

> …Federal Parliament could legislate to establish a federal body to oversee developments in cloning and like technology (cf the regulatory scheme in the [*Gene Technology Act 2000*]). This could be achieved under the External Affairs power.[55]

11.46 The Committee considers the Commonwealth has the constitutional power to enact legislation regulating most aspects of research involving the use of cloning technologies. The legislation could be enacted relying on the Commonwealth's constitutional power over areas such as corporations, trade and commerce, quarantine, territories, import and

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53 Attorney-General's Department, *Submission*s, p.S537. In a further submission the Attorney-General's Department stated that reproductive cloning is not yet a matter of sufficient 'international concern' to support Commonwealth legislation based on the external affairs power although it considers that it is 'arguable that an international expectation is evolving that human cloning for reproductive purposes should be prohibited, but evidence of this international expectation is still emerging', Submissions, pp.S874 and S885

54 Attorney-General's Department, *Transcript*, pp.137-138

55 Associate Professor Loane Skene, *Submissions*, p.S689. Associate Professor Skene later clarified her view: only Article 11 of the UNESCO *Universal Declaration on the Human Genome and Human Rights* 'is clearly adequate to found legislation under the external affairs power', *Transcript*, p.45

export, patents, statistics, external affairs, actions by the Commonwealth or Commonwealth authorities as well as its power to attach conditions to its funding of projects and institutions.

DISCUSSION

11.47 The Committee outlined what it saw as the flaws in the current regulatory framework applicable to human cloning and its related research at the conclusion of Chapter 9.

11.48 In the light of the evidence presented throughout this inquiry it is clear that AHEC's recommendations have been overtaken by the developments that have occurred since the AHEC report was concluded. However, the Committee supports the general approach taken by AHEC and seeks to build on its recommendations.

11.49 Reaffirming the UNESCO Declaration (particularly Article 11), as recommended by AHEC, does not go far enough in the light of regular press reports of attempts to clone a human being (however unrealistic and distant in reality). These continuing reports simply serve to heighten public concern.

11.50 Considerable frustration was plain in much of the evidence to the inquiry at the lack of regulatory activity by some State and Territory governments over matters of embryo research and assisted reproductive technology and the continual postponement of action into the future. The aftermath of the Australian Health Ministers' Agreement appeared to be following the same pattern.

11.51 Professor Norman made the point that people have been struggling with national regulation of *in vitro* fertilisation for many years and it still appears a long way from actually happening. He commented: 'I am not aware that it has progressed in any way at all.'[56]

11.52 The AHEC report and its recommendations need to be placed in the larger context of the rapid pace of the research and the continuing announcements of scientific discoveries that have occurred since the AHEC report was completed.

11.53 It is clear (as was demonstrated in Chapter 3) that this research activity cannot be ignored. It proceeds and public concern and interest will not diminish. The issue of the appropriate regulation of this research will

56 Professor Robert Norman, *Transcript*, p.80

become more and more pressing. The current lack of action at Commonwealth, State and Territory level is increasingly likely to lead to the research taking place altogether outside public scrutiny.

11.54 What is so different about this research that makes the mechanism of unenforceable guidelines and institutional ethics committees that regulate most general research involving humans so inappropriate? Research into human cloning, like assisted reproductive technology, evokes continuing calls for tighter regulation.

11.55 The reason may be found in the discussion of the ethical issues in Chapters 6 and 7. Most research involving humans is generally relatively non-controversial. Research that involves the creation or use of embryos, or involves the possible development of human life is, of its nature, controversial and always has been.

11.56 The evidence presented throughout this inquiry demonstrated a high level of concern about the ethical issues raised by the use of embryos in research in particular. There was no consensus in favour of prohibiting such research, as was the case with cloning for reproductive purposes, although strong support was evident for such a move. Indeed, to prohibit research involving the use of embryos would be contrary to most current practice in Australia which permits research involving the use of embryos within carefully defined parameters.

11.57 The Committee agrees with Professor Chalmers that:

> … the legislation in the various states and the principles embodied in a number of national reports suggested and led to no other conclusion than the fact that this country has a view about the integrity and dignity of the human embryo and that research should not be conducted on the human embryo, except according to prescribed legislation.[57]

11.58 It appears that there is a consensus in favour of the need to regulate embryo experimentation, even if the consensus does not extend to the specific limits that should be imposed. The imperative to regulate in a clear and transparent way arises out of the need to maintain public confidence that decisions about the use of embryos are being made by qualified, accountable people in an open way.

11.59 Those who advocate research involving the use of embryos also acknowledge the sensitivity surrounding the issue and the need for greater scrutiny and care in dealing with this kind of research.

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57 Professor Donald Chalmers, *Transcript*, p.3

11.60 The Committee also agrees with Professor Chalmers that:

> … if the science is to proceed, as a community we owe it to the scientists to try and clarify, through legislation, those circumstances in which procedures may be acceptable after consideration and those cases in which a line may be drawn and where this country might prefer not to follow those particular procedures.[58]

11.61 Hence regulatory mechanisms that may be sufficient in their application to other research are not appropriate for research involving human cloning technologies because the issues raised are so much more fundamental and sensitive.

11.62 It is absolutely essential that public confidence be developed in the system of regulation applicable to research involving human cloning and related technologies. The public must be assured that all research in this area is properly considered and soundly based, that it is being conducted in the interests of benefiting the community and that governments are exercising a firm oversight to ensure that it accords with community standards. Only if these conditions are met will the public develop confidence that this research is appropriate.

CONCLUSIONS

11.63 The Committee favours consistent national regulation of cloning research that applies equally to both public and private sectors. The principles on which the regulation of this research should be based are transparency, accountability, enforceability, responsiveness, flexibility, practicality and consistency.

11.64 With this in mind the Committee has developed a suggested regulatory framework for a national licensing scheme to regulate research involving human cloning and related technologies. The suggested regulatory framework responds appropriately to the concerns raised in the evidence, is achievable, realistic and flexible.

11.65 The Committee's suggested regulatory framework for the regulation of human cloning and its related research in Australia is outlined in the next chapter.

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58 Professor Donald Chalmers, *Transcript*, p.3

12

Proposed regulation of human cloning

INTRODUCTION

12.1 This chapter outlines the Committee's proposed framework for the regulation of human cloning and related research in Australia. The Committee has drawn on the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* and the existing legislative regulation of these matters in Victoria, South Australia, Western Australia and the United Kingdom in developing its proposal.

12.2 As reported in Chapter 7, Committee members recognise the potential benefits of human cloning, but they have differing views about using stem cells, depending on the source of the material. Whilst the majority of members believe that it should be permissible for surplus embryos from assisted reproductive technology programs to be used in clearly defined, limited circumstances,[1] other members believe that procedures that involve the destruction of embryos are unethical and should be rejected.[2]

12.3 All members recognise, however, that the final decision about cloning in Australia will be made by Commonwealth, State and Territory Parliaments.[3] If Australian Governments and Parliaments decide to

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1 See Chapter 7, paragraphs 7.110-7.111

2 See Chapter 7, paragraph 7.112-7.115

3 The Council of Australian Governments (COAG) decided (on 8 June 2001) to develop nationally consistent provisions in legislation to prohibit human cloning. COAG agreed that jurisdictions would work towards nationally consistent approaches to the regulation of assisted reproductive technology and related emerging human technologies. Health Ministers are expected to report back to COAG by the end of the year on technical issues arising from this decision with the aim of a nationally consistent approach being in place in all jurisdictions by June 2002. Council of Australian Governments' Meeting, *Communique*, 8 June 2001

regulate human cloning involving stem cells derived from embryos surplus to assisted reproductive technology programs, all Committee members agree upon the proposed system of regulation outlined in this chapter. Those members of the Committee who believe the use of embryos in research is unethical, nevertheless agree that if such research is permitted it should be regulated in the way outlined in this chapter.

A SYSTEM OF REGULATION

12.4 The Committee proposes the following features of a regulatory framework:

- a national uniform legislative approach;
- a ban on cloning for reproductive purposes;
- one system of regulation for privately and publicly funded research;
- legislation regulating human cloning and stem cell research to be separate from that governing artificial reproductive technologies (ART);
- any attempt to undertake cloning for reproductive purposes to be subject to criminal penalty and the withdrawal of a licence to undertake research in this area;
- research using cloning techniques be subject to clear legislative parameters, including (subject to the moratorium referred to in paragraph 12.42) a complete ban on the deliberate creation of embryos for research purposes;
- a national licensing body be established to regulate human cloning and research using cloning techniques;
- individual researchers be licensed for each research project that involves the use of an embryo;
- the import and export of embryonic stem cells should be permitted within the framework of principles outlined in this report, that is, it should be permissible to import or export embryonic stem cell lines that are already in existence or have been created using embryos that are surplus to the requirements of assisted reproductive technology programs. The import or export of embryos for the purposes of cloning related research need not occur. As there is no evidence to suggest that this is required, the Committee is not convinced that it is appropriate or necessary; and

- the regulatory framework must be transparent, accountable and responsive.

12.5 These features are discussed in detail below.

12.6 The Committee supports the continued development of adult stem cell research but does not believe it should be subject to the regulatory framework outlined in this report. Such research should be governed by existing regulatory schemes.

12.7 The clinical application of the results of research involving cloning technologies will not occur for some time. The Committee did not examine the regulatory framework that should govern such clinical application in detail. The regulatory issues arising from the clinical application of the results of cloning related research should be considered if and when the research yields results that may be applicable in the clinical context.

A National Approach

12.8 As was noted in the previous chapter, the evidence overwhelmingly supported national uniform regulation covering both public and private sectors.

12.9 The AHEC report recommended that the way to achieve this would be for those States and Territories without specific legislation governing this area to proceed to enact such legislation. This recommendation was premised on the view that the Commonwealth did not have sufficient constitutional power to legislate on its own.

12.10 These recommendations by AHEC found little support among those giving evidence to the inquiry. In the Committee's view simply following AHEC's recommendations would not do justice to the fundamental importance of the issues. Past experience inspires little confidence that AHEC's recommendations would be implemented expeditiously if left to individual states and the end result of such an approach would be likely to be further jurisdictional inconsistency.

12.11 Other alternatives for regulation include the:

- passage of uniform legislation by the Commonwealth, States and Territories;
- use of available constitutional powers to support Commonwealth legislation; or
- Australian Academy of Science proposal which builds on the existing system.

12.12 In the Committee's view the Commonwealth must take the lead in regulating this area of research because:

- of its inherent importance, involving as it does fundamental and sensitive issues concerning the possible development of human life and the creation and use of embryos. This is a matter so significant as to require a national response;
- the international as well as national dimension of the research requires consistent national regulation within Australia;
- the Commonwealth has legislative power in many areas that impinge upon the conduct of research involving the use of cloning techniques such as the import and export of human material, patenting, trade and commerce, corporations, external affairs and higher education;
- Commonwealth leadership is required to ensure the necessary uniformity; and
- some of the States and Territories have been tardy in developing legislation.

12.13 The Committee considers it would be preferable for the Commonwealth to take the lead in developing national legislation. The legislation, developed in cooperation with the States and Territories, would establish a national licensing body to regulate research involving human cloning and related technologies.

12.14 This matter requires urgent action. It is the Committee's view that if the will for immediate action on the part of the States and Territories is not apparent the Commonwealth should develop and enact legislation in reliance on the full extent of its constitutional powers and work with the States and Territories to seek to ensure that they enact legislation consistent with that of the Commonwealth in order to fill any gaps in coverage that remain.[4]

12.15 In the Committee's view the Commonwealth has the constitutional power to legislate to regulate human cloning and its related research.

12.16 The clear preference of the Committee is for the Commonwealth Government to enact legislation to regulate cloning and its related research. It should rely on the full range of its constitutional powers in relation to matters such as corporations, trade and commerce, quarantine, territories, import and export, patents, statistics, external affairs, actions by

4 See discussion in Chapter 11 at paragraphs 11.42-11.46

the Commonwealth or Commonwealth authorities and its capacity to attach conditions to its funding of activities or institutions.[5]

Recommendation 1

12.17 **The Committee recommends the enactment of legislation by the Commonwealth to regulate human cloning and stem cell research.**

12.18 The Committee has noted the Council of Australian Governments' (COAG) decision of 8 June 2001 to develop a consistent national approach to the regulation of these issues.[6] Should the enactment of legislation by the Commonwealth not prove to be feasible, the Committee recommends, in light of the decision by COAG**,** the enactment of national uniform legislation at both the Commonwealth and the State / Territory level to achieve a cooperative uniform national scheme to regulate these matters. The Committee considers it is crucial that the national regulation of these issues be uniform across jurisdictions. While the alternative regulatory proposal of COAG is not the Committee's preferred approach, it has the potential to appropriately regulate human cloning and its related research if the Committee's proposals in the rest of this chapter are incorporated in its national scheme.

Public And Private

12.19 The Committee proposes that the legislation cover both privately and publicly funded research involving cloning techniques.

12.20 The AHEC report expressed concern that privately funded organisations in those States and Territories without legislation governing cloning might consider cloning a human being or human parts without the approval of an institutional ethics committee (IEC) under National Health and Medical Council (NHMRC) guidelines. The AHEC report noted that ' … [w]ithout

5 See Constitution; section 51(i)–trade and commerce; section 51(ix)– quarantine; section 51(xx) – corporations; section 51(xi)–statistics; section 51(xviii)–patents; section 51(xxix)–external affairs; section 122-Territories. Commonwealth legislation in reliance on these powers would lead to significant Commonwealth control particularly in relation to research conducted by corporations and Commonwealth funded institutions as well as over the import and export of research material

6 Council of Australian Governments' Meeting, *Communique*, 8 June 2001

legislation the NHMRC cannot stop private institutions conducting such work'.[7]

12.21 The evidence to the Committee overwhelmingly supported one regulatory framework for both privately and publicly funded cloning related research.

12.22 Professor Chalmers, then Chairman of AHEC, reiterated that AHEC's '…feeling is that much of this work could be done in the private sector'[8] and that the private sector needs to be regulated.[9]

12.23 Dr Mayo, of the Australian Academy of Science, sought uniform national legislation that 'would apply equally to both the public and private sector'.[10] In the Academy's view the right regulatory tool is not the withholding of funds from research (as is currently the case in relation to the NHMRC).[11]

12.24 The view that any regulatory framework must apply to both the public and private sectors was supported by the Human Genetics Society of Australasia which supported the creation of a national statutory body to review:

> … all proposals and policies relating to the use of new reproductive technologies for human cell or tissue cloning in any context …[and] ensure that this policy applies both to the public and private sectors.[12]

12.25 Professor Williamson also took the view that any regulation must cover both publicly and privately funded research.[13] Dr Nicholas Tonti-Filippini argued that the lack of regulation of private sector cloning related research in many of the States and Territories is '… really creating a pressure for this work to go into the private institutions and private companies' and urged that private sector research in this field be regulated.[14]

12.26 The Committee agrees with these concerns. It also agrees with the comment of a private citizen, Dr David Elder, who argued that the sort of

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7 AHEC report, Chapter 4, paragraph 4.34
8 Professor Donald Chalmers, *Transcript*, p.3
9 Professor Donald Chalmers, *Transcript*, p.52
10 Dr Oliver Mayo, *Transcript*, p.78
11 AAS, *Transcript*, p.78
12 Human Genetics Society of Australasia, *Submissions*, p.S509
13 Professor Robert Williamson, *Transcript*, p.9
14 Dr Nicholas Tonti-Filippini, *Transcript*, p.46

'double standard' that operates in the United States in the regulation of public and private research was 'highly unacceptable'.[15]

12.27 As was noted in Chapter 10 research that occurs in the private sector in the United States is virtually unregulated. The Australian Academy of Science also made this point. In the Academy's view this has resulted in an element of secrecy whereby the information being gained as the result of research is not in the public domain.[16]

Recommendation 2

12.28 **The Committee recommends that legislation regulating human cloning and stem cell research cover all research in this area, both publicly and privately funded.**

Separate From Legislation Governing Assisted Reproductive Technologies (ART) and Other Legislation

12.29 The Committee proposes that legislation governing human cloning and stem cell research be separate from legislation pertaining to artificial reproductive technologies (ART).

12.30 Current regulation of cloning and research involving the use of embryos was developed in the context of assisted reproductive technology and fertility treatment. While aspects of research involving the use of cloning technologies (such as for reproductive purposes) may still have some connection with these areas, the focus of the research is currently in areas that potentially will be applicable to all in society and involve fundamental changes in medical and social practices.

12.31 Further, while at present reproductive medicine is a comparatively discrete area, the future development of research involving cloning technologies will involve large biotechnology interests and major research projects. The products of the research could potentially be applicable in broad areas of clinical and medical practice that go a long way beyond reproductive technologies. Hence it is important that the regulation of this research be separated from the regulation of assisted reproductive technologies.

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15 Dr David Elder, *Submissions*, p.S194. See Chapter 10 for a discussion of regulation of human cloning and its related research in the United States. Others to stress the importance of covering both the public and private sectors included the Country Women's Association of NSW, *Submissions*, p.S160 and *Transcript* p.95; Consumers Health Forum, *Submissions*, p.S792

16 Australian Academy of Science, *Transcript*, p.78

12.32 The Committee reiterates that its proposed regulatory framework applies only to the conduct of research and not its clinical application.

Recommendation 3

12.33 **The Committee recommends that the regulation of research involving the use of cloning technologies should be separate from that governing assisted reproductive technologies.**

12.34 The Committee also emphasises that only research involving humans should be regulated under this proposed new system. Research and commercial applications involving plants and animals should continue to be subject to current regulation. In the Committee's view it is both inappropriate and inadequate to include provisions concerning human cloning in the *Gene Technology Act 2000*.[17]

THE CONTENT OF THE LEGISLATION

Ban On Cloning for Reproductive Purposes

12.35 For the reasons set out in Chapter 6, the Committee proposes that any legislation contain a ban on cloning for reproductive purposes.

12.36 The Committee further proposes that any attempt to undertake cloning for reproductive purposes should be subject to criminal penalty and the withdrawal of a licence to undertake research by the individual concerned.

Recommendation 4

12.37 **The Committee recommends that the legislation regulating human cloning and stem cell research contain a ban on cloning for reproductive purposes. Any attempt to undertake cloning for reproductive purposes should result in a criminal penalty and the withdrawal of a licence to undertake research in this area for the individual concerned.**

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17 The *Gene Technology Act 2000* was discussed in Chapter 8 at paragraphs 8.21-8.22, 8.37- 8.38 and 8.76

Provisions Relating To Research

12.38 The Committee emphasises that the following discussion concerning the regulation of research involving the use of embryos is not intended to affect the existing regulation applicable to assisted reproductive technology programs.

12.39 Hence a person may produce a human embryo by achieving the fertilisation of a genetically unaltered human ovum by genetically unaltered human sperm through natural conception or artificial conception (by means of, for example, IVF, GIFT etc).

12.40 The Committee proposes that research involving the use of cloning technologies and requiring the use of embryos should be subject to clear parameters.

12.41 The Committee proposes that, with the exception of embryos created by means of somatic cell nuclear transfer, which is dealt with specifically in paragraph 12.42, the legislation should ban the deliberate creation of an embryo for research purposes as well as any selling or trading in embryos, sperm or eggs. The term 'embryo' should include an entity with a genome that is human or substantially human and that has a capacity for development similar to a human zygote or embryo normally produced by the fertilisation of a human ovum by human sperm.

12.42 There should be a moratorium on the creation of embryos by means of somatic cell nuclear transfer techniques for three years, at which point the issue should be re-examined. During the next three years the progress of research should be continually monitored by AHEC and it should provide regular reports to the Council of Australian Governments through the Commonwealth Minister for Health and Aged Care. If, at any time, AHEC forms the view that research has progressed to a point which necessitates that the moratorium be lifted it should report to the Council of Australian Governments. The creation of embryos by means of somatic cell nuclear transfer should not be permitted at this stage although this need not necessarily form part of the legislative ban on the deliberate creation of embryos. Currently, there is no therapeutic purpose to be served by the creation of such embryos as research has identified no specific opportunities that require the deliberate formation of embryos.

12.43 The legislation should permit the licensing body to issue a licence for a person to use a surplus embryo from an assisted reproductive technology program for research or therapy that damages or destroys the embryo where that project has the approval of both an institutional ethics committee (IEC) established, composed and conducted in accordance with

NHMRC guidelines and the national licensing body proposed in this report, and that the approval is given on the 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;[18]
- the procedure involves a restricted number of embryos and a separate account of the use of each embryo is provided to the IEC and the national licensing body (as is the case with animal research);
- all tissue and gamete providers involved and their spouses or domestic partners, if any, have consented to the specific form of research for each embryo used;
- no animal tissue or animal gametes are used to form a human-animal hybrid embryo;
- no embryo that has been the subject of cloning technology, or produced other than by fertilisation of a human ovum by a human sperm is ever transferred to the body of a woman or otherwise allowed to survive beyond the stage at which a blastocyst forms or the age by which a blastocyst would normally have formed;
- no human embryo is ever allowed to be transferred to the body of an animal or to be artificially gestated;
- no attempt is made to form embryos using stem cells or stem cell cultures; and
- a licence has been granted for the use of the embryo (see below).

18 The inclusion of such a criterion should not be able to be used as a means of reopening the issue of embryonic stem cell research. It would simply require, in the case of an individual application to conduct research involving a surplus embryo gained from assisted reproductive technology programs, that the applicant demonstrate that the individual project for which approval is sought could not be conducted without the use of a surplus embryo. This is similar to the requirements established under legislation in the United Kingdom. Paragraph 3 (6) of Schedule 2 of the *Human Fertilisation and Embryology Act 1990 (*UK) provides that research licences for research involving the use of embryos may only be granted if the Human Fertilisation and Embryology Authority is satisfied that any proposed use of embryos is necessary for the purposes of the research. See Chapter 10, paragraphs 10.76-10.85 and 10.92-10.96 for a more detailed discussion of the United Kingdom regulatory regime

Recommendation 5

12.44 **The Committee recommends that the Commonwealth regulate human cloning and stem cell research within the strict parameters outlined in paragraphs 12.41-12.43.**

National Licensing Body

12.45 The legislation should also establish a national body to license research involving the use of cloning and associated technologies.

Recommendation 6

12.46 **The Committee recommends that a national licensing body be established to regulate any research involving the isolation, creation and use of embryonic stem cells.**

A Licensing Scheme

12.47 The Committee proposes a national licensing body to regulate human cloning and stem cell research. This would be comparable to the regulatory approach used in the United Kingdom.

12.48 A licensing approach to the conduct of this research would enable decisions to be made in an open and transparent way that is easily understood by all. It would apply consistent rules across the country and serve to reassure the community that fundamental values are being protected. It would also provide certainty to researchers and to industry.

12.49 Regulation in this form should also ensure effective access to knowledge of scientific and clinical developments with a view to protecting the public interest. The legislation should provide sufficient discretion to the licensing body to enable it to respond to developments and implement changes in response to discoveries in the areas of science and medicine and the growth in community understanding.

12.50 The legislation should incorporate a sunset clause to enable its operation to be reviewed in five years.

12.51 The legislation could also incorporate a mechanism similar to the Ministerial Council used in the *Gene Technology Act 2000* to engage the

States / Territories in the regulation of the issues.[19]

Recommendation 7

12.52 **The Committee recommends that a licence issued by the national licensing body should be required to undertake any research involving the isolation, creation and use of embryonic stem cells.**

Structure Of The Licensing Body

12.53 The legislation should provide that a licence from this body is required to undertake any research involving the use of cloning technologies. It should be an offence to conduct such research without a licence. Furthermore, only a holder of a current licence should be eligible to receive Commonwealth research funding to undertake research involving the use of the listed technologies.

12.54 The licensing body should be established by the legislation. In the Committee's view the licensing body should have a good balance of membership across relevant sectors such as science, medicine, law, ethics and the social sciences. Its membership should include a scientist with knowledge of human cloning technologies.

Powers Of The Licensing Body

12.55 The licensing body would:

- grant research licences in accordance with the legislation as set out in paragraphs 12.35-12.37 and 12.40-12.43;
- develop and issue guidelines concerning various aspects of the conduct of research. Such guidelines could be used by States and Territories;
- ensure transparency and accountability by reporting annually to Parliament outlining all licences granted, the purposes for which they were granted and the outcome of such research;
- conduct inspections;
- monitor compliance with the conditions of the licence;

19 The Ministerial Council is established under the Gene Technology Agreement made between the Commonwealth and the States and Territories in relation to the regulation of gene technology. The *Gene Technology Act 2000* (sections 21-24) enables the Ministerial Council to issue policy principles or guidelines or codes of practice

- impose sanctions for the breach of licence conditions. These sanctions should include withdrawal or non-renewal of a licence or fines;
- consult with scientists, researchers, other regulatory bodies, industry and the general public; and
- consult regularly with AHEC on ethical, scientific and other issues arising from research applications.

Recommendation 8

12.56 **The Committee recommends that the national licensing body have the responsibilities listed in paragraph 12.55.**

Role of AHEC

12.57 AHEC should have a continuing role. It should monitor scientific developments in this area in Australia and overseas, analyse their potential impact and provide advice to Commonwealth, State and Territory governments on future directions in research, anticipated challenges, strategic priorities for research and the potential implications of research. Such a role would provide an integrated advisory and policy capacity that is currently lacking. In order to carry out this function AHEC would need to involve a person(s) with direct scientific experience in this area of research.

12.58 AHEC should also be responsible for developing and implementing a strategy to consult and involve the public in consideration of the issues arising from this research and encourage debate on the potential and implications of the research.

Recommendation 9

12.59 **The Committee recommends that the Australian Health Ethics Committee (AHEC) be responsible for monitoring scientific developments in this area, analysing their potential impact and providing advice to Commonwealth, State and Territory governments on these matters.**

Type Of Licence

12.60 The Committee proposes that individuals and organisations be licensed to undertake cloning related research. Individuals should also be licensed for each research activity involving cloning related research they intend to undertake. Issuing general licences to organisations to undertake research of this kind should increase the efficiency, speed and responsiveness of the licensing process for research activities.

12.61 The *Human Fertilisation and Embryology Act 1990* (UK) establishes a similar system in the United Kingdom. The Human Fertilisation and Embryology Authority has comprehensive authority and jurisdiction over all laboratories dealing with gametes or embryos whether those laboratories are in the public or the private sector. All centres and individuals in the United Kingdom that carry out research involving the use of human embryos must be licensed by the Authority and individual research projects must also be licensed. Premises to which a licence relates may be subject to an annual inspection. *The Human Fertilisation and Embryology Act 1990* (UK) makes it a criminal offence to bring about the creation of an embryo outside the human body or to keep or use an embryo without a licence from the Authority. The parameters within which the Authority may issue licences are provided for in the *Human Fertilisation and Embryology Act 1990 (*UK).[20]

Recommendation 10

12.62 **The Committee recommends that individuals and organisations be licensed for each research activity involving the isolation, creation and use of embryonic stem cells they intend to undertake.**

Parameters Of A Licence

12.63 The legislation should prohibit the issue of a licence to do any of the following:

- engage in cloning for reproductive purposes;
- manipulate the germ line;

20 For further information concerning the regulatory framework in the United Kingdom see Chapter 10 at paragraphs 10.75-10.85 and 10.92-10.96

- insert a human somatic nucleus into the cytoplasm of a non-human mammal, or fuse cells (adult and eggs or other) from humans and animals;
- purchase or sell human embryos, sperm or eggs;
- harvest human material or cells for cloning without express permission in writing from the person from whom such material originates (not the family); or
- create an embryo outside the body of a woman by means of somatic cell nuclear transfer for any reason (noting the moratorium set out in paragraph 12.42).[21]

Recommendation 11

12.64 **The Committee recommends that the matters listed in paragraph 12.63 be prohibited. Such a prohibition would mean that the licensing body would not have the authority to issue a licence for research involving any of the items listed in paragraph 12.63.**

Issuing A Licence

12.65 The licensing body would be able to issue licences for research involving the use of embryos within the parameters outlined in this chapter. The legislation should provide that the following may only be undertaken in pursuance of a licence:

- the extraction of embryonic stem cells from any embryo; and
- the use of embryos surplus to fertility treatments for the purposes of research.[22]

Recommendation 12

12.66 **The Committee recommends that research using cloning technologies and involving the use of embryos may only be undertaken pursuant to a licence.**

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21 The deliberate creation of embryos for research is not permitted under the Western Australian, South Australian and Victorian legislation. It is also not permitted under the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*

22 The regulation of assisted reproductive technology practice would remain with the States and Territories. The licensing body would need to liaise with State and Territory authorities where these exist

12.67 In order to grant a licence for one of the above the licensing body must be satisfied of the matters listed in paragraph 12.43.

Recommendation 13

12.68 **The Committee recommends that a licence for research using cloning technologies and involving the use of embryos only be granted if the licensing body is satisfied of the matters listed in paragraph 12.43 and that informed consent has been granted by all relevant persons.**

Consent

12.69 The licensing body must be satisfied that proper arrangements are in place to ensure that all relevant persons have given the consent necessary for embryos to be used in the course of research. The licensing body must also issue guidelines outlining the steps licensees must follow to ensure that consent is properly informed. Suggestions for matters to be included in such guidelines are outlined below.

12.70 The number of persons from whom it may be necessary to obtain consent may be quite large. For example, stored embryos may be formed for a couple:

- using their own genetic material;
- using the woman's ovum and donor sperm;
- using a donated ovum and the man's sperm;
- using donated ovum and donated sperm; or
- in any of the above scenarios and donated to another couple.[23]

12.71 In relation to the use of embryos for the extraction of embryonic stem cells, the licensing body should consider the use of the United States National Institutes of Health (NIH) *Guidelines for Research Using Human Pluripotent Stem Cells.*[24] The application of those guidelines in this context would require: only using stem cells from frozen embryos created for the purpose of fertility treatment and in excess of clinical need; prohibiting the use of inducements (monetary or otherwise) for the donation of the embryo and a clear separation between the fertility treatment and the decision to

23 NSW Government Discussion Paper, *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies*, p.6.4

24 See discussion of these guidelines in Chapter 10 at paragraphs 10.61-10.69

donate; that the informed consent specify whether or not information that could identify the donor(s) will be retained; the donation must be made without any restriction as to the individual(s) who may be the recipient of any derived cells and informed consent must have been obtained (see below).[25]

12.72 Establishing suitable guidelines for adequate disclosure of information and properly informed consent and ensuring that these are implemented conscientiously is a primary safeguard against pressure, coercion or undue influence being placed upon women to donate eggs or for couples to donate embryos for research purposes.

12.73 The potential for pressure to be applied to women to agree to the donation of eggs or for people to be pressured to agree to the formation of additional embryos and to donate them for research is a matter of great concern to the Committee and will require intensive monitoring by the licensing body. Further legislation on this matter may be necessary.

12.74 The licensing body should develop guidelines in relation to the disclosure of information and the gaining of informed consent. Compliance with these guidelines should be a condition of a licence to undertake any research involving cloning technologies. Because of the number of people potentially involved in decisions to donate material for research involving cloning techniques certain consents need to be mandated.

12.75 Current provisions[26] relating to disclosure and consent specify that consent must be in writing and not withdrawn or varied. The consent may specify conditions subject to which an embryo may be used. Consent must be given by the gamete providers whose gametes constitute the embryo and the consent must be to the use of the embryo in a particular procedure. Prior to giving consent a person or couple must have been given a suitable opportunity to receive proper counselling and detailed information about the proposed research.

12.76 Consent should also be given by the spouses and partners of donors of embryos or gametes in accordance with the current requirements of the *Infertility Treatment Act 1995* (Vic).[27] As is currently the case in South

25 See paragraph 12.77

26 See generally the *Infertility Treatment Act 1995* (Vic), the Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 (SA) and the *Human Fertilisation and Embryology Act 1990* (UK)

27 The *Infertility Treatment Act 1995* contains detailed requirements relating to consent (see sections 27-30 and sections 34-38). These sections contain provisions relating to consent by spouses and partners of donors and matters such as withdrawal of consent or objections by a later spouse

Australia, consent provisions should also specify that a woman must consent not only to the donation of ova (eggs) but also to the use of drugs to stimulate their production and the medical or surgical procedure associated with their removal.[28]

12.77 The Committee also suggests that, in relation to the donation of embryos for embryonic stem cell research, the following informed consent requirements of the NIH *Guidelines for Research Using Human Pluripotent Stem Cells* should form the basis of guidelines issued by the licensing body. The Guidelines state that the informed consent process should include discussion of the following information with potential donors:

- a statement that the embryos will be used to derive human pluripotent stem cells for research that may include human transplantation research;
- a statement that the donation is made without any restriction or direction regarding the individual(s) who may be the recipient(s) of transplantation of the cells derived from the embryo;
- a statement as to whether or not information that could identify the donors of the embryos, directly or through identifiers linked to the donors, will be removed prior to the derivation or the use of human pluripotent stem cells;
- a statement that derived cells and / or cell lines may be kept for many years;
- disclosure of the possibility that results of research on the human pluripotent stem cells may have commercial potential and a statement that the donor will not receive financial or any other benefits from any such future commercial development;
- a statement that the research is not intended to provide direct medical benefit to the donor; and
- a statement that embryos donated will not be transferred to a woman's uterus and will not survive the cell derivation process.

Recommendation 14

12.78 **The Committee recommends that the licensing body develop detailed guidelines specifying the requirements for informed consent and take**

28 This is currently provided for in Regulation 15 of the Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 in South Australia

into account the matters discussed in paragraphs 12.69-12.77 in developing these guidelines.

Role Of Institutional Ethics Committees

12.79 The criticisms that were made of institutional ethics committees (IECs) during the course of the inquiry were outlined in Chapter 9.[29] Associate Professor Thomson, the Deputy Chair of AHEC, accepted that there are inadequacies in the transparency and accountability of IECs. He also stated that there:

> … is presently some extensive work on the notion of compliance and better methodology in seeing that the processes of [IECs] do conform and that there is some way of assuring that quality happens.[30]

12.80 A review of the structure and operation of IECs is beyond the scope of this inquiry but the Committee is concerned about their operation and believes that there should be greater transparency and accountability in relation to IECs.[31]

Recommendation 15

12.81 **The Committee recommends that the Government establish an independent review of the institutional ethics committee system in Australia.**

Other Matters

12.82 The licensing body should also have regard to the potential commercialisation of the products of cloning related research and issue guidelines to other Commonwealth agencies, such as the Australian Quarantine and Inspection Service (AQIS), concerning material that should be permitted to be imported or exported.

12.83 All Commonwealth Departments should refer to the licensing body for guidance where a matter arises that involves the use of human reproductive material, embryonic stem cell research or cloning research.

29 See Chapter 9 at paragraphs 9.24-9.36

30 Associate Professor Colin Thomson, *Transcript*, p.199

31 In March 1996, the *Report of the Review of the Role and Functioning of Institutional Ethics Committees* to the Minister for Health and Family Services was released.That review was undertaken some time ago and for present purposes is not adequate

Examples of occasions on which such guidance would need to be sought include the granting of funds for research or the consideration of research and development grant applications.

Recommendation 16

12.84 **The Committee recommends that all Commonwealth Departments refer to the licensing body for guidance where a matter arises that involves the use of human reproductive material, embryonic stem cell research or cloning research.**

Kevin Andrews MP
Chairman