Research Service,
Parliamentary Library,
Department of Parliamentary Services

Current Issues Brief No. 1, 2007

THERAPEUTIC CLONING: The Infertility Treatment Amendment Bill 2007

A discussion of issues relevant to the Infertility Treatment Amendment Bill 2007. The paper includes definitions and description of the science involved, a discussion of the bill and its legal context, a summary of ethical considerations and positions, an explanation of Victoria's science, technology and innovation industry, and developments in interstate and international jurisdictions.

Parliamentary Library Research Service
April 2007

This Current Issues Brief is part of a series of papers produced by the Library's Research Service. Current Issues Briefs see to provide an overview of a subject area for Members, and include information on key issues related to the subject.

Contents

Authors

This paper is a product of the Parliamentary Library's Research Service: Senior Research Officer Dr Greg Gardiner, Research Officer Claire Macdonald, Statistical Analyst Bella Lesman, Legal Research Officer Nathan Bunt, and Research Assistant Roshena Dutta.

Acknowledgements

The research team received information and advice from the following people whom we would like to thank: Professor Alan Trounson, Director of Monash Immunology and Stem Cell Laboratories; Professor Graham Jenkin, Associate Director of Monash Immunology and Stem Cell Laboratories; Dr Nicholas Gough, biotechnology consultant; Dr Renate Klein, biologist and social scientist, former Associate Professor in Women's Studies, Deakin University; Dr Nicholas Tonti-Filippini, medical ethicist and Senior Lecturer in Bioethics and Permanent Fellow, John Paul II Institute. Thank you also to Parliamentary Librarian Adrian Gallagher and Deborah Delahunt from the parliament's education office for their useful comments on a draft of this paper, and to Jenelle Cleary for her assistance.

Acronyms

ART	Assisted reproductive technology
ASC	Adult stem cell
ESC	Embryonic stem cell
SCNT	Somatic cell nuclear transfer (also known as therapeutic cloning)

Glossary of key terms

Adult stem cell	Stem cells found among specialised cells of tissues (such as bone marrow, skin, brain, liver), which can renew themselves and generate some other cell types
Blastocyst	A four or five to seven day old human embryo, consisting of an outer layer giving rise to the placenta and an inner cell mass, from which cells can be extracted to culture and derive stem cells
Embryonic stem cell	Cultured cell derived from inner cell mass of blastocyst, with capacity to differentiate into most other cell types
Embryonic stem cell line	Embryonic stem cells cultured in laboratory undergoing ongoing cell division
Gamete	Human sperm or egg cell
Mitotic cell division	The first cell division of the zygote, marking the first visual sign of completed fertilisation
Oocyte	An egg cell
Somatic cell	Any animal, including human, cell (except for gametes) containing full complement of chromosomes
Somatic cell nuclear transfer	Process involving insertion of somatic cell nucleus into egg cell (oocyte) from which nucleus has been removed
Stem cell	A cell with capacity to renew itself, and differentiate into other cell types
Zygote	The cell that is the result of fertilisation, that is, the fusion of male and female pronuclei

Introduction

On 13 March 2007, the Bracks government introduced the Infertility Treatment Amendment Bill into the Victorian Parliament. The main purpose of the bill is to amend the *Infertility Treatment Act 1995* ('the Principal Act') to modify the existing regulatory framework to allow for the use of somatic cell nuclear transfer (often referred to as therapeutic cloning). The bill retains the existing prohibition on human reproductive cloning. The bill also contains provisions on licensing arrangements under the authority of the National Health and Medical Research Council (NHMRC), in relation to excess assisted reproductive technology (ART) embryos, human eggs, and the creation or use of other embryos.

The bill follows upon the passage of the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* ('the Commonwealth Amendment Act 2006') through the federal parliament. This Act was introduced in response to the recommendations of the *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002* ('Lockhart Review'), produced in December 2005. The Lockhart Review was instigated in accordance with a requirement in the Commonwealth Acts of 2002 that those Acts be independently reviewed two years from the date of their assent (the end of 2005).

In her second reading speech the Minister for Health, Ms. Bronwyn Pike, stated that the amendments put forward in the bill directly correspond to the commonwealth amendments (in the Commonwealth Amendment Act 2006). The Minister stated that the bill 'retains existing prohibitions on activities such as:

- placing a human embryo clone in the human body or the body of an animal;
- importing or exporting a human embryo clone;
- creating a human embryo by fertilisation of a human egg by human sperm, for a purpose other than achieving pregnancy in a woman;
- creating or developing a human embryo by fertilisation of human egg by human sperm which contains genetic material provided by more than two persons;
- developing a human embryo outside the body of a woman for more than 14 days;
- making heritable alterations to a human genome;
- collecting a viable human embryo from the body of a woman;
- creating or developing a chimeric embryo;
- developing a hybrid embryo beyond 14 days;
- placing a human embryo in an animal, a human embryo into the body of a human other than into the female reproductive tract or an animal embryo in a human;
- importing, exporting or placing in the body of a woman, a prohibited embryo.'[1]

The Minister went on to say that the bill enables certain types of research involving embryos to be permitted under the approval of, and in accordance with, a licence issued by the NHMRC licensing committee. Ms. Pike said that in summary 'a person may apply for a licence:

- to use excess ART embryos;

[1] Victoria (2007) Legislative Assembly, *Debates*, No. 4, 14 March, p.767.

- create human embryos other than by fertilisation of a human egg by a human sperm, and use such embryos;
- create human embryos (by a process other than fertilisation of human egg by human sperm) containing genetic material provided by more than two persons, and use such embryos;
- create human embryos using precursor cells from a human embryo or a human foetus, and use such embryos;
- undertake research and training involving the fertilisation of a human egg, up to but not including the first mitotic division, outside the body of a woman for the purposes of research or training;
- creation of hybrid embryos by the fertilisation of an animal egg by human sperm, and use of such embryos up to the first mitotic division, if:
- the creation or use is for the purposes of testing sperm quality; and
- the creation or use will occur in an accredited ART centre.'[2]

The Minister noted that the use of animal eggs continues to be prohibited except for limited diagnostic use (in accredited ART centres) to test sperm quality. Ms. Pike also stated that the bill would amend the definition of a human embryo to be consistent with the NHMRC definition and the definition in the Commonwealth Amendment Act 2006.

This paper is intended to provide members with an overview and analysis of the bill, its principal provisions, and the key issues involved. Section One describes the scientific context, providing information on natural fertilisation, the ART process, adult stem cell and embryonic stem cell research, somatic cell nuclear transfer (SCNT), and recent developments in stem cell research. Section Two of the paper contains information in relation to the bill, the changes that it would provide for, the background to the bill and some information on its relationship to the Commonwealth Acts and the Lockhart Review. In Section Three, the paper presents an overview of key arguments that have been presented in recent debates on embryonic stem cell research and SCNT. Section Four provides information on the biotechnology industry, with a particular focus on Victoria and the development of stem cell research centres and companies. The final section of the paper contains an overview of developments relating to embryonic stem cell research in selected jurisdictions overseas, and relevant legislation in other states and territories.

[2] ibid.

1. The Scientific Context

1.1 Background

There have been extraordinary developments in the arenas of the genetic sciences, fertility medicine and a range of related areas in the last thirty years. The rapid development of scientific advances within secular culture has presented society at large with opportunities, choices and issues that have not previously been entertained. The Human Genome Project, the development of DNA profiling, the genetic modification of food, organ transplantation, the IVF (in vitro fertilisation) program, and stem cell research, to name a few, have each in their own way challenged received notions of the make up, and the making, of human identity and traditional human practices. They have also challenged the boundaries within which humans may act to change themselves and their environment. These transformations in science, particularly genetic science, have obvious and profound implications for the global community. Indeed, it has been argued that the scale and reach of these developments are of such potential magnitude that we could well be on the cusp of a new scientific revolution; one that could match, in its capacity to transform society, the industrial revolution of the 19th century.[3] In the face of such developments, society has at times struggled to articulate a coherent moral perspective or framework within which to deal with such scientific breakthroughs as they occur. This has been particularly the case in recent years in relation to the debate surrounding stem cell research and human cloning.

Stem cell research offers enormous potential for the treatment of long standing human disease types and the alleviation of suffering. Stem cell research scientists around the world are working on the development of therapies for such common diseases as heart disease, diabetes, spinal cord injury, Parkinson's disease, and stroke.[4] At the same time stem cell research raises important questions concerning ethical norms in a pluralist culture. While the new sciences are a global activity moving forward at rapid pace, a global 'ethics'—one that could effectively cross the divide of religion and secularism—and which could sustainably address these issues and guide the development of law-making, has yet to properly emerge.[5] Instead, each new development is addressed piecemeal and largely by jurisdictions acting on their own, with often disparate results. By the same token, individual legislators face enormously complex issues, which require them to draw on a much wider set of sources, opinions and beliefs than may be normally the case in their role as parliamentarians. That deeply held belief systems (of both religious and secular kinds) can play a central part

[3] A wealth of popular and scholarly books have appeared on the topic, see, as examples, R. Morgan (2006) *The genetics revolution: history, fears, and future of a life-altering science,* Greenwood Press, Westport; M. Boylan & K. Brown (eds) (2001) *Genetic Engineering: science and ethics on the new frontier,* Prentice Hall, New Jersey; and, H. Gee (2004) *Jacob's Ladder: The History of the Human Genome,* W.W. North and Co., New York.

[4] See Australian Government (Lockhart Review) (2005) 'Legislation Review: *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*', Reports, Canberra, December, pp.44-5.

[5] For discussion see Canadian Broadcasting Corporation (2006) 'Margaret Somerville: The Ethical Imagination', Massey Lectures 2006, viewed 2 April 2006, <http://www.cbc.ca/ideas/index.html>. On the role of ethics in science see B. Rollin (2006) *Science and Ethics,* Cambridge University Press, Cambridge.

in such deliberations for MPs is partly why "conscience" votes are often agreed to by party leaderships.

This section is designed to assist Members in their consideration of the Infertility Treatment Amendment Bill 2007 by providing a brief overview of basic scientific information and key developments in the following areas:

- the natural creation of a human embryo
- assisted reproductive technology
- stem cell research
- embryonic stem cell research
- SCNT and reproductive cloning
- recent developments in stem cell research and SCNT

1.2 The natural creation of a human embryo

The natural creation of a human embryo through sexual reproduction occurs when sperm enters and fuses with an oocyte (egg cell). As Dudley, John and Clarke show, [6] twelve to 20 hours after the sperm enters the oocyte, two pronuclei (one male and one female) are formed in the cytoplasm of the egg, each containing DNA. After 20 hours the two pronuclei fuse to form a single nucleus, one which contains a full complement of 46 chromosomes. This fusion forms the zygote, a new genetic entity, which is genetically different to its parents. Between one to three hours later the zygote will undergo the first cell division, called the first mitotic cell division, or cleavage. In days two and three following insemination the zygote continues cell division, with progeny dividing further at each stage to create a compact cell ball known as the morula. At days four to seven, the morula enlarges to create the blastocyst; the outer layer of which will give rise to the placenta, while the cells in the centre will give rise to all the other tissues and body layers of the embryo. At day 15 the "primitive streak" appears, which characterises the formation of the multi-cellular structure that will develop into the new person. At about the end of the eighth week the embryonic stage is complete, and the foetal stage begins which will continue until birth.

1.3 Assisted reproductive technology (ART)

A wide range of ART techniques have been developed by scientists over the last 30 years, beginning with the most well known technique, IVF, in the late 1970s. These techniques are designed to assist couples who experience a range of difficulties in having a baby naturally. IVF essentially involves the fertilisation of eggs by sperm outside the womb, with the process being completed in the laboratory. Ovulation is stimulated by hormones; the eggs are then removed from the ovaries, fertilised, and the resultant zygote is inserted into the uterus to develop. As the Lockhart Review reported, ART techniques available in Australia also include donor insemination, the transfer of sperm and eggs into the reproductive tract for natural fertilisation (GIFT),

[6] The scientific information in this section is derived from three principal sources: S. Dudley, T. John & J. Clarke (2006) 'Prohibition of Human Cloning for Reproduction and the Regulation of Human Research Amendment Bill 2006', *Bills Digest*, no. 59, 2006-07, Parliamentary Library, Canberra; Australian Government (2005) op. cit.; and, N. Gough (2006) 'Key Recent Advances in Human Embryonic Stem Cell Research: A Review of Scientific Literature Commissioned by the Department of Innovation, Industry and Regional Development', viewed 3 April 2007, <http://www.business.vic.gov.au/BUSVIC.590070/STANDARD//pc=PC_61985.html>. For basic definitions in biology see E. Lawrence (2000) *Henderson's Dictionary of Biological Terms*, Prentice Hall, London.

and injection of sperm directly into eggs for assisted fertilisation (ICSI). According to the Lockhart Review, achieving a successful pregnancy through ART remains difficult, with approximately only thirteen per cent of treatment cycles resulting in the birth of a live baby at term.[7] Researchers are working on developing new ART techniques, particularly for those couples who cannot produce either eggs, or sperm, or both. One of these techniques involves creating gametes from cultured embryonic stem cells, a technique that is yet to be proven. From 2002, ART embryos determined to be in excess can be used by researchers for some stem cell research.

1.4 Stem cell research

Stem cell research has been active since the 1970s, with a variety of treatments for various diseases being developed, such as the treatment of leukaemia using bone marrow containing blood stem cells. Stem cells have the capacity to regenerate damaged tissues, and their discovery has opened up a whole new potential pathway for the treatment of diseases. Adult stem cells can be found in many tissues and organs of the body, including the brain, intestines, the liver, skin, and marrow. Adult stem cells are currently being used in a wide variety of preclinical (animal) studies and clinical trials around the globe, in relation to such diseases as heart disease, Parkinson's disease, and Huntington's disease. AS cells are considered multipotent, which means they have the capacity to differentiate into a set of defined cell types, but cannot, at this stage, be manipulated into differentiating into any cell type. It is this limitation of the adult stem cell that has led stem cell researchers to consider the use of stem cells derived from embryos, which are pluripotent in nature, and thus have the potential to develop into almost any cell type.

1.5 Embryonic stem cell research

Stem cell researchers first obtained embryonic stem cells from animal embryos in the 1980s. The process involves extracting cells from the inner cell mass of the blastocyst, which are then cultured in the laboratory to form embryonic stem cells. The removal of the cells of the inner cell mass causes the destruction of the embryo. This process was not successfully applied to a human embryo until 1998, when the first culture of human embryonic stem cells was derived from an embryo. As noted above, the human blastocyst is formed at four to seven days, and it is from this point that the inner cells can be extracted. Stem cell researchers culture embryonic stem cells in laboratories where, because of their potency, they rapidly replicate themselves, creating what are known as stem cell lines. ES cells are highly productive in the laboratory with an infinite capacity for replication. A stem cell line represents thousands of genetically identical stem cells (of one stem cell type) which have been multiplied from a single source—essentially a collection of containers holding stem cells, maintained in a stable environment for future use. The maintenance of the genetic integrity of stem cell lines is a challenge for researchers.[8] Such lines can be used for research on disease therapies, disease studies and for drug testing. Stem cells can be stimulated by researchers via a range of means to differentiate into a variety of cells types, with ES cells having the potential for differentiation across nearly all cell types.[9] One of the key challenges of stem cell research is understanding, controlling

[7] Australian Government (2005) op. cit., p.26.

[8] Genetic instability occurs in some stem cell lines more than others, and is probably related to the number of times that they are 'passaged', i.e., multiplied.

[9] ES cells cannot develop into placental and placental related tissue cells.

and directing the differentiation process. A further issue is ensuring that any cells for transplant have assumed the correct structure and don't develop into tumours.[10]

Since 2002 domestic embryonic stem cell lines in Australia have been developed from stem cells extracted from excess ART embryos—i.e. fertilised eggs that are surplus to the needs of couples—under strict licensing conditions, and requiring the informed consent of the ART program couples involved. Stem cell lines have also been obtained from overseas. The 2002 legislation permitted the use of excess ART embryos for stem cell research, prohibited the development of human embryos for research purposes only, by any means (including by therapeutic cloning), and banned human reproductive cloning. The last few years has seen a significant increase in embryonic stem cell research both here and internationally. Two Australian developed stem cell lines have been lodged with the UK Stem Cell Bank, and are thus now available to researchers internationally, indicative of the global nature of this activity.

1.6 SCNT (therapeutic cloning) and reproductive cloning

Cloning is essentially a process of asexual reproduction that results in an organism that is the genetic copy of another. There are currently two main types of cloning processes which are distinguished, therapeutic cloning (SCNT) and reproductive cloning. Both of these processes are currently banned in relation to humans under Victorian state law, while the federal law since 2006 permits therapeutic cloning under conditions. Since the late 1990s cloning technology has been used in relation to animals to produce live offspring in some species (such as "Dolly" the sheep). However, a principal focus of research has been the development of embryonic stem cells derived from a cloned embryo.

SCNT is the process leading to the creation of an embryo (animal or human) which is the genetic double, or clone, of the animal or person from whom a somatic cell has been obtained. There are a number of steps:

- A female egg is obtained and its nucleus removed
- A somatic cell (any "body" cell such as a skin cell) is obtained from a donor/patient
- The nucleus of the somatic cell is removed and inserted into the egg cell
- The egg cell is stimulated to activate embryonic development.

At the blastocyst phase, cells from the inner cell mass can be removed from the created embryo (and, as with excess ART embryos, causing the destruction of the embryo) and cultured to produce embryonic stem cells.

Embryonic stem cells derived from SCNT are especially significant for researchers due to the fact that they allow for potential disease treatments using the genetic material of the patient. Patient derived stem cells are important in terms of the prevention of immune rejection that can occur with the introduction of another animal or person's genetic material. The SCNT process is also significant for stem cell researchers because of its potential to unlock the molecular processes underpinning the reprogramming of adult cell nuclei within egg cells. Such an understanding may lead in the future to the reprogramming of adult cells to produce embryonic stem cells

[10] Australian Government (2005) op. cit., p.40.

without the need for oocytes.[11] However, on current understandings human SCNT research will be dependent on the supply of donated human oocytes. At present, there are no substantiated reports of the successful establishment of an ES cell line derived from a human embryo clone using the SCNT method.[12]

Reproductive cloning involves the same process outlined above, with the exception that (in mammals) the cloned embryo is transferred into the uterus of a female where it may undergo the full development and birth cycle. Human reproductive cloning is banned in many countries around the world. There are other more recent techniques for the creation of embryo clones, which have been deployed with animals, including parthenogenesis, where the egg is stimulated to divide without fertilisation, and embryo splitting, which involves splitting the embryo at the cleavage, morula or blastocyst stages.

1.7 Recent developments in stem cell research and SCNT

The Lockhart Review reported a rapid increase in the level of research activity in the area of stem cell research since 2001, with most work focused on rodent, nonhuman primate and human embryonic stem cells and adult stem cells.[13] A significant number of studies and trials are occurring in relation to stem cell treatments for major diseases. Many of these are preclinical studies employing animal models, but there are also clinical trials on potential therapies using AS cells, such as heart cells, neural cells, and brain cells. Gough reports on a number of recent studies investigating ES cell-derived cells transplanted into animal models, including transfer of neural cells derived from human ES cells into a rat Parkinsonian model, and human ES cell-derived heart cells grafted into a pig malfunctioning model.[14] Stem cells are also being deployed as models to study the development of disease, with some stem cell lines developed to mimic certain disease states. ES cells in particular are regarded by researchers as providing good models for basic disease research and the understanding of disease progression. Stem cells, including ES cells, are being used as well to test for the chemical toxicity of chemical agents, a precursor process for developing drug testing systems using stem cells. The Lockhart Review reported a high level of research activity in ES cell research since 2002, with a significant focus on developing culture conditions for maintaining well-characterised ES cells and for differentiating them into cell types.[15]

Recent work on AS cells indicates that some AS cells may have the potential for a higher degree of potency, called 'plasticity', than previously thought. This means that certain AS cells may be able to be cultured and stimulated to produce a wider range of cell types. Of particular interest to researchers have been haematopoietic stem cells, bone marrow stromal cells, and neural stem cells. Proponents of AS cell research as an alternative to ES cell research also suggest other sources of AS cells as having potential plasticity, including the umbilical cord, the placenta, human cord blood, and olfactory ensheathing cells. However, according to the Lockhart Review, the area is controversial, and while there is some suggestion that some AS cells may be

[11] Standing Committee on Community Affairs (2006) *Legislative responses to recommendations of the Lockhart Review*, The Senate, Canberra, p.29.
[12] N. Gough (2006) op. cit., p.19.
[13] Australian Government (2005) op. cit., p.40.
[14] N. Gough (2006) op. cit., p.13.
[15] Australian Government (2005) op. cit., p.53.

pluripotent, this research is not conclusive and research in the area is ongoing.[16] Many scientists working in the areas of AS cell research and ES cell research appear to concur that their work in the two main areas of stem cell research is both complementary and necessary, and will remain so for many years.

Other areas of recent interest for stem cell researchers have included: the apparent multipotency of amnion and amnion fluid derived stem cells, which have shown a capacity to differentiate into a range of cell types; and, human embryonic germ cells derived from ectopic foetuses.[17] Germ cells give rise to gametes and are thus potentially capable of producing pluripotent stem cells.

There has also been some research internationally on the use of mammalian non-human oocytes in nuclear transfers with human nuclei.[18] The production of "hybrid" embryos, which could be used to derive human ES cells, would obviate the need to obtain large numbers of human oocytes, which will be necessary for SCNT research, particularly in relation to gaining insights into some of the basic reprogramming factors which may be common to most eggs, and for research into disease specific stem cells. However, the conditions surrounding hybrid embryo research in the new federal law of 2006 limit hybrid embryo research to ART research and the testing of sperm to be conducted up to, but not including the first mitotic cell division (see section two below), thus preventing the use of non-human oocytes for human SCNT.

There have also been developments in both animal cloning and human SCNT in recent years. Researchers have been examining techniques and methods within animal SCNT in order to improve animal cloning and the SCNT process; outcomes have been improved in relation to research with a range of animals, with implications for human SCNT. According to Gough, key developments include the following: the demonstration that the molecular and developmental parameters of murine (rodent) ES cells generated by the SCNT process were indistinguishable from ES cells derived from a blastocyst created by natural fertilisation; the demonstration that different cell types derived from SCNT stem cells were not rejected in a bovine model; and, research showing that SCNT derived stem cells could restore function to damaged tissue in some animal models.[19] As Gough notes, several groups across the globe are pursuing SCNT to generate human embryonic cell lines, but as yet there has been no successful development of human SCNT-derived embryonic cell lines.[20]

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[16] ibid., p.42. For discussion of the adult stem cell vs. embryonic stem cell debate see also E. Finkel (2005) *Stem Cells: Controversy at the frontiers of science*, ABC Books, Sydney, pp.75-86. The Lockhart Review also reported one submission on research being conducted on a technology known as "altered nuclear transfer-oocyte assisted re-programming", a process that would involve, if successful, the conversion of AS cells into ES cells by genetic reprogramming. However, while there are reports of such research being undertaken, there is no evidence to date that the process is, or will be successful, see Australian Government (2005) op. cit., p.52.

[17] Australian Government (2005) op. cit., p.52.

[18] ibid., p.58.

[19] N. Gough (2006) op. cit., p.6.

[20] ibid., p.19.

2. The Legislation

2.1 The Infertility Treatment Amendment Bill 2007

The Infertility Treatment Amendment Bill 2007 was introduced into the Legislative Assembly of the Parliament of Victoria on 13 March 2007 and received its second reading speech on 14 March 2007. If passed, the Act would commence on 12 June 2007. The bill proposes to amend Victoria's *Infertility Treatment Act 1995* ('the Principal Act') to mirror recent amendments made to corresponding Commonwealth legislation. In her second reading speech on the bill, the Minister for Health, Ms. Bronwyn Pike, explained the purpose of the proposed amendments as follows:

> Societies worldwide are grappling with the speed of research developments and new emerging technologies. In the area of stem cell research, the potential to alleviate significant human pain and suffering is great; however, we also need to closely consider the mechanisms and safeguards to allow the progress of this research in a responsible manner.
>
> This bill provides the opportunity to explore the potential benefits of stem cell research in Victoria within a strictly regulated and ethical framework.[21]

The main changes proposed by the bill are to permit specific types of research involving embryos, under a licence issued by the NHMRC Licensing Committee, and subject to legislative criteria. Nearly all of the substantive changes proposed by the bill would be made by amendments to Parts 2A and 4A of the Principal Act ('Regulation of Certain Uses Involving Excess Art Embryos' and 'Prohibited Practices', respectively).[22] For convenience, the proposed changes are considered under the following headings.

Circumstances in which a person may apply for a licence

A person would be able to apply for a licence to:

- use excess ART embryos;
- create human embryos other than by fertilisation of a human egg by a human sperm, and use such embyros;
- create human embryos, by a process other than the fertilisation of a human egg by human sperm, which contain genetic material from more than 2 persons, and use such embyros;
- create human embryos using precursor cells from a human embryo or a human fetus, and use such embyros;
- carry out research and training involving the fertilisation of a human egg, up to but not including the first mitotic division, outside the body of a woman for the purposes of research or training; and
- create hybrid embryos by the fertilisation of an animal egg by human sperm, and develop such embryos up to, but not including, the first mitotic division provided that the creation or use is for the purposes of testing sperm quality and occurs in an accredited ART centre.

[21] Victoria (2007) Legislative Assembly, *Debates*, no. 4, 14 March, pp.766-777.
[22] The titles to both Parts would also be amended accordingly.

Offence Provisions
In addition to making each of the above activities an offence if conducted without a licence, the Bill would increase the penalties for a number of existing offences under the Principal Act from a maximum of 10 to 15 years imprisonment (this issue is discussed further below).

Existing prohibitions retained
The bill would retain the existing prohibitions on:
- placing a human embryo clone in a human body or in the body of an animal;
- importing or exporting a human embryo clone;
- creating a human embryo by fertilisation of a human egg by human sperm, for a purpose other than achieving pregnancy in a woman;
- creating or developing a human embryo by fertilisation of a human egg by human sperm which contains genetic material provided by more than 2 persons;
- developing a human embryo outside the body of a woman for more than 14 days;
- making heritable alterations to a human genome;
- collecting a viable human embryo from the body of a woman;
- creating or developing a chimeric embryo;
- developing a hybrid embryo beyond 14 days;
- placing a human embryo in an animal, a human embryo into the body of a human other than into the female reproductive tract or an animal embryo in a human; and
- importing, exporting or placing in the body of a woman, a prohibited embryo.

Other Amendments
The bill would also make a number of related amendments to the Principal Act, including:
- amended conditions for licences issued by the NHMRC Licensing Committee regarding excess ART embryos, human eggs, and the creation or use of other embryos (s. 21L);
- providing inspectors with the power to apply for a 'monitoring warrant' under which they would be authorised to enter premises for the purposes of monitoring compliance with the amended Act (proposed sections 21WA to 21WD).

2.2 Background to the current bill

The bill follows amendments made to the Principal Act in 2003 by the Victorian *Health Legislation (Research Involving Human Embryos and Prohibition of Human Cloning) Act 2003*. At the time the Minister outlined some of the anticipated benefits of embryonic stem cell research and the legislative challenge involved:

> One of the greatest potential applications of embryonic stem cell research is the generation of cells and tissues for therapeutic purposes. This may lead to the replacement of diseased or damaged tissue in a range of conditions, which may include Parkinson's disease, diabetes, liver and other organ failure, a variety of cancers, spinal cord injury and genetic conditions such as cystic fibrosis. These potential benefits will take some time to be realised.
>
> The challenge for government is to find a way to provide legislative parameters that will guide the work of the biotechnology field which is rapidly changing and developing.[23]

[23] ibid., p.235.

The *Health Legislation (Research Involving Human Embryos and Prohibition of Human Cloning) Act 2003* amended the Principal Act by the insertion of Parts 2A and 4A. The insertion of Parts 2A and 4A achieved consistency between the Principal Act and the Commonwealth legislation passed the previous year. Those Acts were:

- the *Research Involving Human Embryos Act 2002* (Cth) ('the RIHE Act'); and
- the *Prohibition of Human Cloning Act 2002* (Cth) ('the PHC Act')

(collectively: 'the Commonwealth Acts').

The Commonwealth Acts were the result of a Council of Australian Governments (COAG) agreement, which was preceded by two years of consultation throughout Australia. Victoria, together with each of the Australian States and Territories, committed at the COAG in April 2002 to implementing nationally consistent legislation which would prohibit human reproductive cloning and regulate assisted reproductive and related emerging technologies.

The COAG agreement included a requirement that the Commonwealth Acts be independently reviewed two years from the date of their assent. This review commenced in June 2005 with the appointment of a six-member Legislative Review Committee, by the then Commonwealth Minister for Ageing, the Hon. Julie Bishop MP. The Committee was chaired by the late John S Lockhart AO QC, a former Justice of the Federal Court of Australia. The Committee reported to the Minister in December 2005 following a period of extensive community consultation.

The Committee's final report, the Lockhart Review, made 54 recommendations. In summary, the Committee recommended the continuation of nationally consistent legislation prohibiting human reproductive cloning and some other ART practices. The Committee also recommended that certain human embryo research practices should be allowed, under licence, and subject to strict control and monitoring. The *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth) ('Commonwealth Amendment Act 2006') implemented the majority of those Lockhart Review recommendations. The current bill mirrors the provisions of the Commonwealth Amendment Act 2006. The following sections discuss some of the more significant changes which would be introduced if the bill is passed.

2.3 Removal of certain prohibitions and amended offence provisions

The Lockhart Review made a series of recommendations regarding activities that had been prohibited under the Commonwealth Acts before the passage of the Commonwealth Amendment Act 2006.[24] The Committee recommended that the following should now be allowed, provided that in each instance the work is authorised by a licence from the NHMRC Licensing Committee:

1. creation of a human embryo by a process other than the fertilisation of a human egg by a human sperm or the development of such an embryo (Lockhart Review recommendations 23 & 25);

[24] These activities will remain prohibited by the Commonwealth Acts until the main provisions of the Commonwealth Amendment Act 2006 commence on 12 June 2007.

2. creation or development of a human embryo containing genetic material provided by more than 2 persons (recommendation 26);
3. creation of human embryos from human embryo or human fetus precursor cells and the use of such embryos (recommendation 27); and
4. creation of hybrid embryos in defined circumstances (recommendations 17 & 24 – this issue is discussed below).[25]

If the current Bill is passed, a person would be able to apply to the NHMRC Licensing Committee for authorisation to carry out each of the above – see proposed sections 21H(1)(b); 21H(1)(c); 21H(1)(d); and 21(H)(1)(f) respectively.

As with the Commonwealth legislation, the current bill provides that in giving permission to conduct any of the activities listed at 1 to 3 above, the NHMRC Licensing Committee would not be permitted to authorise the use of an embryo that would result in development of more than 14 days (exclusive of any period when the development of the embryo is suspended).

Each of the activities listed at 1 to 4 above would remain an offence if conducted without a licence, see proposed sections 38OA, 38OB, 38OC and 38OD respectively. The maximum penalty for each of the above offences proposed by the current bill would be 10 years imprisonment. It would also be an offence, punishable by imprisonment for a maximum of 5 years, to 'use' such an embryo (s.21CA).

In addition, the bill proposes an increase in the maximum penalty for a range of existing offences from 10 to 15 years imprisonment.[26] By way of example, the existing offence of creating a human embryo for a purpose other than achieving pregnancy in a woman (s.38F) would carry a maximum sentence of 15 years (consistent with the changes discussed above, the provision would also be amended to make the 'fertilisation of a human egg by a human sperm' a necessary element of the offence).

2.4 Embryos created by human SCNT and other means

A key recommendation of the Lockhart Review was that human SCNT should be allowed, under licence, to create and use human embryo clones 'for research, training and clinical application, including the production of human embryonic stem cells', provided such activity satisfies all the legislative criteria and that such embryos are not implanted in the body of a woman or allowed to develop for more than 14 days (Lockhart Review recommendation 23)

This recommendation would be implemented by proposed s.21H(1)(b) (noted above). According to the Explanatory Memorandum to the Commonwealth Amendment Act 2006 the intentionally general terms in which this section is drafted (as opposed to

[25] Consistent with these changes, the bill proposes the repeal or amendment of some existing offence provisions. It would no longer be an offence to create a human embryo clone, provided this occurs under licence (repeal of s.38A); nor would it be an offence to create a human embryo by a process other than the fertilisation of a human egg by human sperm, or to develop such an embryo (repeal of s.38E).

[26] See the proposed amendments to sections 38F(2), 38G92), 38H(2), 38J(3), 38K(2), 38M(4), 38N(5) and 38O(4); the substitution of new s.38L(2); and the insertion of new s.38LA in the Principal Act.

explicitly permitting human SCNT under licence) could allow it to apply to human embryos created by new means as technology changes.[27]

2.5 Excess ART embryos

The Principal Act currently provides that a person commits an offence (punishable by a maximum of five years imprisonment) if she or he intentionally uses an excess ART embryo unless authorised to do so by a licence or the use is an 'exempt use' (s.21C).[28] Proposed new subsection 21L(8) would provide that a licence in relation to excess ART embryos that are unsuitable for implantation may allow for the NHMRC guidelines to apply in a modified form in relation to the use of such embryos.

The Principal Act does not currently prohibit the licensing, for use in training and research, of fresh ART embryos that are unsuitable for implantation. However, it is a statutory condition of such licence that the responsible people in relation to an excess ART embryo give proper consent to any research, in accordance with NHMRC guidelines.[29] Those guidelines require a 14 day cooling off period before a person's consent becomes effective. The Lockhart Review found that researchers and the NHMRC Licensing Committee had apparently been interpreting this requirement in a way which prevented the use for research of embryos that are unsuitable for implantation and which are not frozen.

New section 24(8) is intended to address this issue by clarifying that where the NHMRC Licensing Committee considers it appropriate, it may approve the use of embryos that are unsuitable for implantation and amend the cooling-off period. According to the Explanatory Memorandum, this would allow the use of excess ART embryos that are unsuitable for implantation while ensuring that appropriate consent is obtained.

2.6 Hybrid embryos

The creation of human–animal hybrid or chimeric embryos[30] is banned under the Principal Act (s.38L). The Lockhart Review made two recommendations regarding hybrid embryos:

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[27] See the Explanatory Memorandum to the Commonwealth Amendment Act 2006 regarding the equivalent Commonwealth provision (new s.20(1)(b) of the RIHE Act).

[28] An 'exempt use' is currently defined in the Principal Act as:

- a use that consists only of: the storage; the removal from storage; or the transport of, an excess ART embryo;
- a use that consists only of the observation of the excess ART embryo;
- a use that consists only of allowing the excess ART embryo to succumb;
- a use that forms part of diagnostic investigations conducted in connection with the ART treatment of a woman for whom the excess ART embryo was created, where the excess ART embryo is unsuitable for placement in the body of that woman, (where such suitability is determined solely on the basis of its biological fitness for implantation) and provided the use is carried out by an accredited ART centre (see also the new definition of 'unsuitable for implantation' proposed for insertion into s.21A); or
- a use that is for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created, provided the use is carried out by an accredited ART centre.

The Principal Act also allows for an 'exempt use' to be prescribed by regulation.

[29] The relevant guidelines are the Australian Health Ethics Committee Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2004.

[30] A 'chimeric embryo' is defined in s.3 of the Principal Act as a human embryo into which a cell, or any component part of a cell, of an animal has been introduced.

1. to allow particular types of 'interspecies fertilisation and development' (up to but not including the first cell division) for the purposes of testing human sperm and egg cells for 'ART training and practice' (recommendation 17); and
2. to allow the creation of hybrid embryos by introducing the nucleus of a human cell into an animal egg (i.e. SCNT) and the use of such human embryo clones, under licence, for 'research, training and clinical applications', including the production of human embryonic stem cells (recommendation 24).

The rationale given for recommendation 17 was the desirability of reversing one effect of the Commonwealth Acts, which had been to stop ART researchers from testing the viability of human sperm on animal eggs, a practice described as routine in other countries.[31]

The rationale given for recommendation 24 was the desirability of reducing the use of human egg cells in 'preliminary investigations of nuclear transfer technologies' and to advance 'embryonic stem cell research'.[32] The Lockhart Review also recommended that no hybrid embryo should be allowed to be implanted into the body of a woman or to develop for more than 14 days.

The Commonwealth Amendment Act 2006 originally contained provisions which would have given effect to recommendations 17 and 24. However, the clause that would have implemented recommendation 24 (clause 20(1)(g)) was omitted in the Senate, on the motion of Democrat Senator Andrew Bartlett.[33] A central argument given by Senator Bartlett for the amendment was the view that while the ethical issues involved in the use of animal eggs for SCNT research were worthy of 'specific consideration' this had apparently not occurred prior to the introduction of the federal bill.[34]

Since the current state bill is consistent with the Commonwealth Amendment Act 2006 it would therefore implement recommendation 17 (proposed s21H(1)(f)) but not recommendation 24.[35] Proposed s.21H(1)(f) would allow a person to apply to the NHMRC Licensing Committee for a licence authorising the creation of hybrid

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A 'hybrid embryo' is defined in s3 as:

- an embryo created by the fertilisation of a human egg by animal sperm; or
- an embryo created by the fertilisation of an animal egg by human sperm; or
- a human egg into which the nucleus of an animal cell has been introduced; or
- an animal egg into which the nucleus of a human cell has been introduced.

Both hybrid and chimeric embryos may also be declared by regulations (made under the Principal Act) and both currently fall within the definition of a 'prohibited embryo' in the Principal Act (s.38N(4)).

[31] See Australian Government (2005) op. cit., pp.xv, 153.

[32] ibid., pp.xviii, 58, 164 and 176.

[33] Australia (2006) Senate, *Debates*, No. 13, 7 November, pp.44, 58.

[34] ibid., p.116.

[35] Note (b) to proposed s.38OD of the current Bill refers to the creation of a 'hybrid embryo…by introducing the nucleus of a human cell into an animal egg' as an activity that may be allowed under licence by the NHMRC Licensing Committee (under s.21I). However, the note, which also appears in the Commonwealth Amendment Act, is probably redundant as notes in legislation do not generally form part of an Act. (The retention of note (b) in the Commonwealth Act is explained by the fact that such notes – which form part of the 'drafting process' – cannot be amended during the passage of an Act.)

embryos by the fertilisation of an animal egg by a human sperm, and the use of such embryos up to, but not including, the first mitotic division, provided:

> (i) the creation or use is for the purposes of testing sperm quality; and
> (ii) the creation or use will occur in an accredited ART centre.

In summary, the current bill would allow the creation of hybrid embryos by one of the methods currently prohibited under s.3 of the Principal Act – i.e. the fertilisation of an animal egg by a human sperm (but only in the circumstances and for the ART-related purposes set out in proposed s.21H(1)(f)). As Senator Bartlett noted, one consequence of passing legislation that does not implement recommendation 24 of the Lockhart Review is that it 'create[s] a situation where the only eggs that could be used for this research are the eggs of women'.[36]

2.7 Human embryos

The current definition of a human embryo, introduced by the *Health Legislation (Research Involving Human Embryos and Prohibition of Human Cloning) Act 2003*, is as follows:

> "human embryo" means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means;

The bill would introduce a new definition of a 'human embryo' into s.3(1) of the Principal Act:

> *human embryo* means a discrete entity that has arisen from either:
> (a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
> (b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;
> and has not yet reached 8 weeks of development since the first mitotic division.[37]

The new definition is a response to recommendation 28 of the Lockhart Review. The Legislative Review Committee heard from ART providers and researchers that the definition was one of the changes that had deterred ART research.[38] As noted in the Lockhart Review, the appearance of the two pro-nuclei provides the earliest "biological marker" for ART research.[39] Therefore, by taking this as the moment when an embryo begins, the current definition (together with the prohibition against the creation of a human embryo for research under s.14 of the PHC Act), currently prohibits any research that requires experimental fertilisation of an egg by sperm.[40] The Lockhart Review found that this has impeded IVF research in a range of areas,

[36] Australia (2006) Senate, *Debates*, No. 13, 7 November, p.119.
[37] See the PHC and RIHE Acts at sections 8(1) and 7(1) respectively.
[38] Australian Government (2005) op. cit, pp.29-31.
[39] ibid.
[40] ibid., p.30.

including the maturation of oocytes, testing of sperm quality and fertilisation research.[41]

[41] ibid.

3. Debate on Embryonic Stem Cell Research and SCNT

Research involving human embryos is certainly a complex issue, and one on which members of the community hold a variety of views. Below is a summary of some of the contentious aspects, with various arguments for and against the science. It is not a definitive list, and certainly not all perspectives are covered; rather, it is intended to present some of the opinions given by those who have contributed to the debate thus far.[42]

3.1 The use of human embryos for research and therapeutic purposes

The potential for adult and embryonic stem cells to be used as a treatment for a variety of severely debilitating and/or life-threatening diseases has excited scientists worldwide. Researchers are hopeful that therapies will be produced to treat conditions which are currently incurable, such as diabetes, Parkinson's disease, spinal cord injury and Huntington's disease.

Adult stem cells can be derived from particular structures such as the heart, eye, liver, bone marrow and skin. As explained in section one, they are multipotent, which means they can differentiate to form a limited number of cell types. Embryonic stem cells, on the other hand, are derived from embryos which are four to seven days old. These stem cells are pluripotent, which means they have the ability to create almost any cell type. It is for this reason that they are particularly attractive to scientists, as they have the potential to develop into a host of different tissues for cell-based therapies. However, the removal of these cells from the embryo inevitably results in the embryo's destruction. This practice was legislated for in the *Health Legislation (Research Involving Human Embryos and Prohibition of Human Cloning) Act 2003*, so that in Victoria, excess ART embryos are able to be used for research, with the donor's consent. Unsurprisingly, this is controversial science; it raises moral and ethical questions about what life is, when it begins, and whether it is right to harm embryos in any circumstance, even if potentially life-saving therapies may be derived.

The bill currently before the Victorian Parliament proposes that SCNT be permitted in Victoria. As detailed in section one of this paper, SCNT means that an embryo will be created in order to obtain stem cells. This adds a new ethical dimension to be considered; while ART embryos are created with the intention of producing a child, the approval of SCNT would mean that embryos will be created purely for research purposes. As was the case with initial embryonic stem cell research, interested parties have strong views on this issue.

Views against SCNT

Those opposed to SCNT largely argue that the embryo, as a human life, is sacred; as such it is morally wrong to destroy this life, as is the creation of life solely for the purposes of experimentation. Nicholas Tonti-Filippini, an independent consultant

[42] On the debates surrounding stem cell research see E. Finkel (2005) *Stem Cells: Controversy at the frontiers of science*, ABC Books, Sydney; N. Snow (2003) *Stem Cell Research: New Frontiers in Science and Ethics*, University of Notre Dame Press, Notre Dame and J. Humber & R. Almeder (eds) (2004) *Stem Cell Research - Biomemedical Ethics Reviews*, Humana Press, Totowa NJ.

ethicist, is one who views the creation of 'embryonic members of the human family for destructive use' as fundamentally unethical. He writes that:

> No matter what putative benefits might be claimed for the future by such experiments, the social significance is to undermine a cornerstone of who we are as a human society. In a democratic society each individual member possesses a worth and dignity that is not based on how well we function, our attributes, our contribution, but on the simple fact that we belong to the human family. Each of us carries an inheritance of human genes containing the inherent radical capacity for reason, for enquiry, for wonderment and for love that is so distinctive of our species. By manufacturing embryonic members of the human family for disposal we are all diminished.[43]

Catholic Archbishop Denis Hart, urging Victorian parliamentarians to vote against the bill, has stated that 'To allow embryos to be deliberately created and then destroyed for scientific research is always unethical and would be an assault on the dignity of the human person at its most vulnerable'.[44] Others have argued about the importance of intent in creating the embryo. As stated by the Liberals' Senator Fifield, 'Excess ART embryos were created with the intent of giving life. The embryos proposed to be created for embryonic stem cell research would be created in all cases with the intention of destruction… And I must confess to being troubled by the creation of an embryo specifically for experimentation and destruction rather than as a by-product of a process designed to bring life'.[45]

This view was echoed by the Anglican Church of Australia, Sydney Diocese, in their submission to the Lockhart Review: 'Although some would wish to make a distinction between therapeutic and reproductive cloning, this distinction is not biological and only has a sociological basis, not a scientific basis…As there is no developmental difference, the only possible difference is that of intended use, and intention is not always a robust or objective enough category upon which to legitimate a practice'.[46]

The debate in the federal parliament revealed that the issue certainly crossed party lines. The Liberal Party's Kevin Andrews argued against the federal bill, stating that:

> "Do no harm" is a principle which has enlightened 2,500 years of Western medical and scientific practice. It is the bedrock upon which ethical medical science is founded. It has been restated in various declarations over the past 60 years, beginning with the 1948 Declaration of Geneva. This enlightened tradition has always placed great emphasis on the intrinsic worth and equal value of every human life regardless of its stage or condition. We should not depart from it.[47]

Along with Prime Minister John Howard, Labor leader Kevin Rudd also voted against the bill. In his speech to parliament he said:

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[43] N. Tonti-Filippini (2004) 'The creation of disposable human beings diminishes us all', *On Line Opinion*, viewed 27 March 2007, <http://www.onlineopinion.com.au/view.asp?article=2061>.
[44] D. Rood (2007) 'Cloning an assault on human dignity, says Catholic Archbishop', *The Age*, 12 April, p.9.
[45] Australia (2006) Senate, *Debates*, No. 13, 6 November, p.27.
[46] Australian Government (2005) op. cit., p.59.
[47] Australia (2006) House of Representatives, *Debates*, No. 18, 6 December, p.47.

> I find it very difficult to support a legal regime that results in the creation of a form of human life for the single and explicit purpose of conducting experimentation on that form or human life. Furthermore, I am concerned about the crossing of such an ethical threshold and where that may lead in the long term. For these reasons I will not be supporting the legislation, based on the information that is currently available to me.[48]

Another argument against SCNT is that it is another step down the "slippery slope", which will eventually lead to reproductive cloning, presently regarded as morally reprehensible by most of the community, including scientists.[49] The Southern Cross Bioethics Institute, for example, expressed this fear in their submission:

> Research on cloning human embryos is inextricably connected to bringing clones to birth. Regardless of the legislative restrictions on "reproductive cloning", the groundwork will be laid for those in other settings who will implant cloned embryos for development to birth. If this legislation is passed, government funded research that results in the refinement of procedures for producing cloned human embryos will be taken up by others who are intent on producing born human clones. This needs to be acknowledged as a real consequence of such legislative permission.[50]

The fact that therapeutic cloning was banned in the 2002 legislation but is now being considered, and indeed sanctioned by the federal parliament, is evidence for some commentators that this slippery slope does exist.

Views supportive of SCNT

Many others in the community, however, hold quite different views, which sees the use of embryos for research and therapeutic purposes as permissible, and indeed to be encouraged, if performed for the "greater good". Supporters of SCNT point to the fact that a cloned embryo, at less than seven days old, is a "senseless" clump of cells, which does not actually have the capacity to become a human life as it will never be implanted in a womb. They argue that the potential of SCNT is so important that we have a responsibility to explore the science and give scientists the best possible chance at developing cures and therapies for presently untreatable and terminal conditions.

Professor Peter Singer, associated with Princeton and Melbourne Universities, has written that it is in fact incumbent on us to utilise our scientific knowledge in this way: 'There is an ethical obligation to carry out research with stem cells in the manner that gives us the best prospects of success. If that means destroying human embryos in order to create embryonic stem cells, that should not hold us back'.[51] A similar view was presented by Professor Julian Savelescu during the Lockhart Review hearings. He argued that 'a better ethical starting point should be to question why we are not supporting this research…if we cause a delay in this research, we may thereby be responsible for the premature deaths of many people'.[52] This perception aligns with the Orthodox Jewish faith, as described by Elizabeth Finkel: 'Orthodox Judaism

[48] Australia (2006) House of Representatives, *Debates*, No. 18, 6 December, p.120.
[49] Australian Government (2005) op. cit., p.60.
[50] Standing Committee on Community Affairs (2006) op. cit., p.63.
[51] P. Singer & A. Sagan (2006) 'Choose Life', *The Bulletin*, 5 September, p.40.
[52] Australian Government (2005) op. cit., p.63.

holds that the imperative to ease human suffering outweighs the rights of a senseless embryo, and makes it justifiable to create and destroy such a cloned embryo'.[53]

Responding to the claim that SCNT is a step on the way to cloning humans for reproduction, Professor Rudolph Jaenisch of the Massechusetts Institute of Technology argues that a therapeutically cloned embryo is quite different to a "normal" embryo: 'In contrast to an embryo derived by *in vitro* fertilisation, a cloned embryo has little if any potential to ever develop into a normal human being because of faulty reprogramming. Therefore, from a biologist's point of view, the cloned human embryo used to make embryonic stem cells has little if any potential to create a normal human life'.[54]

Federal parliamentarians presented a range of views as to why SCNT is valuable and should be permitted. Democrats Senator Lyn Allison pointed to the fact that as a society we sanction IVF, where embryos are created with the knowledge that not all will be used. 'If it is acceptable that we create embryos for IVF with the knowledge that many will be destroyed, I can not see why it is less acceptable to create them for the purposes of research which has the potential to benefit so many people'.[55] Liberal MP Brendan Nelson claimed it is customary for new treatments to be regarded with suspicion, yet the benefits they have provided society have been immeasurable:

> When insulin was introduced into Australia, one critic reported in the *Medical Journal of Australia*: "Public propaganda has been used to build false expectations and no doubt hundreds of diabetics would be hastened to their graves." It is a matter of record that, today, 130,000 Australian juvenile diabetics owe their lives to insulin. Smallpox vaccination, blood transfusion, organ transplantation, analgesics and oral medicines have all, at various times, evoked religious and moral opposition.[56]

Victorian Liberal Senator Judith Troeth raised the issue of Victoria's leadership in this particular scientific field, and the risk of scientists moving overseas if Australia does not permit research allowable in other jurisdictions: 'I am aware that my home state of Victoria has a particular level of excellence in this field of science, and I am very keen to see Victoria maintain this expertise. So often our scientists have to leave Australia to pursue their area of research, and I would want my country and state to be a leader in this research'.[57]

3.2 Adult and embryonic stem cells

The debate surrounding stem cell research often takes the course that therapies using one type of stem cell (adult or embryonic) should be pursued at the expense of the other. It must be noted that within the scientific community there appears to be a general consensus that ES cell research and AS cell research should be pursued concurrently, in order to realise the full potential of the technology. As explained in Stem Cell Sciences Ltd's submission to the Lockhart Review, '…embryonic stem cell research should be viewed as complementary to adult stem cell research. Both

[53] E. Finkel (2005) 'Time for a serious debate on cloning', *Australasian Science*, October, pp.39-40.
[54] S. Luntz (2006) 'Therapeutic cloning gains state support', *Australasian Science*, Jan/Feb, pp.24-25.
[55] Australia (2006) Senate, *Debates*, No. 13, 6 November, p.178.
[56] Australia (2006), House of Representatives, *Debates*, No. 18, 6 December, p.29.
[57] Australia (2006) Senate, *Debates*, No. 13, 6 November, p.24.

avenues of investigation hold promise which when explored together will lead to a better understanding and development of stem cell-based human therapeutics'.[58]

A specific advantage, however, of embryonic stem cells derived through SCNT is the fact that the tissue generated would be the patient's own, and thus the patient is less likely to encounter transplantation rejection issues. As stated by Dr Nicholas Gough, 'At present SCNT is the only way to create "tailored" stem cell lines that would be specific for a particular patient or disease condition'[59], thus the risk or rejection by the body is drastically reduced. This argument was also used by Liberal MP Malcolm Turnbull during the federal debate:

> Why do scientists want to create embryos by SCNT?...[because] there is one profound challenge that can only be surmounted by SCNT. An embryonic stem cell therapy is essentially a transplant and, like any transplant, the embryonic stem cells could be rejected. SCNT provides the hope of making embryonic stem cells that will be genetically identical to the person who is being treated. This has the potential to overcome the risk that the embryonic stem cells will be rejected by the immune system…We therefore stand on the brink of a revolution in medicine—an offer of hope to those currently living; an offer of hope to people suffering from devastating disease for which there is currently no hope.[60]

Another unique potential of SCNT is the opportunity it would afford researchers to investigate disease development, and gain a better understanding of the specificities of various conditions. As explained by Senator Allison, 'It was pointed out during the inquiry that because stem cells developed from Somatic Cell Nuclear Transfer processes could be developed from people with identified diseases they would allow for a unique opportunity to look into disease formation—something which is not possible through harvesting stem cells from excess IVF blastocysts'.[61] The Australian Stem Cell Centre reports that scientists may be able to understand why cells become cancerous or develop other abnormalities, and what causes some birth defects, by studying embryonic stem cells, and that 'this may give scientists clues as to how such abnormalities and diseases may be prevented'.[62]

Some commentators have been critical of the lack of developments in embryonic stem cell research thus far, and claim that we are not yet ready, and nor is it necessary, to take the next step in allowing SCNT. Countering this argument, Senator Natasha Stott-Despoja stated that research on adult stem cells has been going for 50 years, while embryonic stem cell research is in its infancy (eight years). Thus 'to claim that we have not seen enough development to justify legally regulating somatic cell nuclear transfer is disingenuous. This is not a field of rapidly realised cures and quick fixes. It takes time; it takes investment'.[63] Additionally, as Nicholas Gough has pointed out, 'with licenses to conduct (SCNT) research few in number and only

[58] Australian Government (2005) op. cit., p.50.
[59] N. Gough (2006) op. cit., p.15.
[60] Australia (2006) House of Representatives, *Debates*, No. 18, 5 December, p.130.
[61] Australia (2006) Senate, *Debates*, No. 13, 6 November, p.178.
[62] The Australian Stem Cell Centre (2006) 'What are stem cells?', viewed 5 April 2007, <http://www.stemcellcentre.edu.au/public-education_what-cells_potential.aspx>.
[63] Australia (2006) Senate, *Debates*, No. 13, 6 November, p.7.

recently issued (and with such research currently prohibited in Australia) there has of course as yet been no successful development of human SCNT-derived ES lines'.[64]

Other stakeholders and interest groups, however, argue that progression in and possibilities with adult stem cell technology render embryonic stem cell research unnecessary, and thus the complex ethical boundary does not need to be crossed. Particular adult stem cells, such as haematopoitic stem cells, bone marrow stromal cells and neural stem cells[65], have shown substantial plasticity, which has led some researchers to believe that 'adult stem cells may, in the future, be as useful as are embryonic stem cells in generating tissue for transplants'.[66] Thus a lot of work is currently being done to understand adult stem cell differentiation. Some interest groups therefore claim that funding and research effort should be concentrated on adult stem cells. In their submission to the Lockhart Review, the Christian Adult Social Institute Inc stated that 'the evidence indicates that embryo stem cell research…has been a choice for a science which is not ethical…and…is winning funding disproportionate to its promises and in a way that wastes time and money that could be going towards science which is ethical and is paying real dividends in human health today, ie. adult stem cell research…'.[67]

It has also been argued that the risk of tumour formation is a drawback to transplanting tissue generated from ES cells. As explained by Emeritus Professor Jack Martin from the University of Melbourne, 'Malignant tumour formation is a major complication of ES cell transplantation. The propensity to develop teratomas has been a feature of all the animal studies so far with ES cells…The tumour complication has not to the present time been a feature of the use of adult stem cells'.[68] Professor Alan Mackay-Sim, a molecular biologist from Griffith University, concurred with this opinion in his submission to the Lockhart Review, when he provided an overall summary of the advantages of adult stem cells:

> Adult stem cells from numerous sources (e.g. bone marrow, olfactory mucosa, skin, hair follicles, muscle, fat) have been shown in numerous independent laboratories to develop into cells not normally found in the originating tissues and, despite the rhetoric to the contrary, some develop into most cell types of the body. Adult stem cells are currently used in human therapies and there are numerous animal studies demonstrating their efficacy in a variety of animal models of disease and injury such as spinal cord injury, stroke, Parkinson's disease and cardiac ischemia.[69]

3.3 Women's health issues

The framing of the therapeutic cloning debate as a choice between science and religion is of frustration to many (mainly female) commentators, who claim that the female/feminist position has largely been ignored, as has women's role in the process.

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[64] N. Gough (2006) op. cit., p.19.
[65] Australian Government (2005) op. cit., p.42.
[66] The Australian Stem Cell Centre (2006) 'Adult stem cells?', viewed 10 April 2007, <http://www.stemcellcentre.edu.au/public-education_what-cells_adult.aspx>.
[67] Australian Government (2005) op. cit., p.47.
[68] ibid., p.48.
[69] A. Mackay-Sim (2006), 'Submission to the Inquiry into legislative responses to recommendations of the Lockhart Review', viewed 5 April 2007, <http://www.aph.gov.au/Senate/committee/clac_ctte/leg_response_lockhart_review/submissions/sublist.htm>.

This is despite the fact that the technology relies on a ready supply of female eggs. A criticism has been that the eggs are discussed in the context of SCNT as if they just magically appear, and the actual egg harvesting procedure, with its accompanying complications, are glossed over. As Melinda Tankard Reist has argued,

> Without the bodies of women, the dreams of scientists would never come true. There would be no ova to harvest, no embryos—surplus or manufactured—to experiment on or plunder for stem cells. Yet despite the widespread appropriation of women's bodies for these experiments, they remain faceless and nameless. They are divided into component parts, mined for their ova, viewed as experimental test sites.[70]

The process of donating eggs for SCNT is envisaged to be the same as that which many women currently undergo as part of IVF treatment. First a drug is administered to halt normal egg cell growth and hormone production. Follicle stimulating hormones are then introduced to encourage hyperstimulation, the production of numerous eggs. Surgery is required to capture the eggs; this is done by inserting a needle into the ovary under anaesthetic.

Every day, in many countries all over the world, women undergo this process without complication; however, there is the potential for various problems to occur. Ovarian Hyperstimulation Syndrome (OHSS) affects some women who undergo the IVF procedure, and is an exaggerated response to ovulation induction. Clinical manifestations range from mild (including abdominal discomfort and mild nausea) to severe (including vomiting, rapid weight gain, respiratory difficulty, severe abdominal pain and excessive fluid collection in the abdomen). Dr Renate Klein writes that five to ten per cent of women undergoing ovarian hyperstimulation suffer OHSS,[71] while the Royal Women's Hospital reports that in 2004, 15 patients out of 2,731 at the hospital (0.5 per cent) suffered severe OHSS, including one patient who was transferred to an intensive care unit at another hospital.[72] The latest figures released in a report by the European Society of Human Reproduction and Embryology show that in 2002 in 22 surveyed European countries, 2,148 cases of OHSS were reported from a total of 224,327 IVF and Intracytoplasmic Sperm Injection (ICSI) cycles. The report also shows that in the same year, two women undergoing IVF treatment died.[73] Comprehensive national data on the side-effects of women undergoing IVF treatment is not kept in Australia.

While women receiving IVF treatment might be willing to risk these side-effects if the end result is the possibility of producing a child, questions have been raised about the likelihood of women wanting to go through this procedure for purely altruistic reasons. The potential for exploitation has been well documented, especially the possible inducement for women to permit embryo extraction in return for financial

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[70] M. Tankard Reist (2004) 'Do the cloning experiment egg donors appreciate their place in history?, *On Line Opinion*, viewed 27 March 2007, <http://www.onlineopinion.com.au/view.asp?article=2063>.
[71] Dr Renate Klein, address to Victorian MPs, 15 March 2007.
[72] The Royal Women's Hospital (date unknown) 'Ovarian Hyerstimulation Syndrome', viewed 12 April 2007, <http://www.thewomens.org.au/OvarianHyperstimulationSyndromeManagementofSevereOHSSinHDU>.
[73] A. Nyboe Andersen et al (2006) *Assisted reproductive technology in Europe, 2002*, European Society of Human Reproduction and Embryology, Belgium, viewed 12 April 2007, <http://www.eshre.com/emc.asp?pageId=496>.

gain. The Victorian Bill explicitly bans the selling of eggs in order to prevent the commercialisation of egg donation. Additionally, the NHMRC's Australian Health Ethics Committee has recently released for consultation an amended version of the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*, which 'aim[s] to protect women from being exploited'.[74] Specifically, the guidelines state that 'There should be no payment for gametes, gonadal tissue or cells donated for research…The reimbursement of reasonable out-of-pocket expenses associated with the procedures is acceptable'.[75] The guidelines also state that 'It is unethical to coerce potential research participants in any way into taking part in the research. Consent must be freely given and be explicit for the proposed research'.[76]

SCNT opponents, however, point to the UK where the selling of embryos was also prohibited until it became apparent that limited eggs were being donated. Women in the UK undergoing IVF treatment now receive a discount on treatment costs if they agree to donate eggs for research, in a process described as 'egg sharing'.[77]

In 2004, the now-discredited researcher Dr Woo Suk Hwang from Seoul University, South Korea, claimed that his research team had extracted stem cells from cloned human embryos. Not only were his results proved to be false, but it was revealed that he had obtained eggs from female laboratory members—this is deemed highly unethical 'because of the potential for them to feel coerced'.[78] According to an article in the *Asia News*, a coalition of 35 women's groups have now 'filed a suit for compensation against the South Korean government on behalf of women suffering from side-effects after making uninformed ova donations to Prof Hwang Woo-suk for his research on stem cell embryos'.[79]

In their submission to the Lockhart Review, the Victorian Government articulated its concern about the potential for exploitation, stating that:

> If SCNT is to be permitted under revised legislation, a supply of human eggs will be sought. Egg donors are exposed to significant medical, physical, psychological and social dangers. It will be mandatory to prevent exploitation of women under such circumstances…The donation of eggs for SCNT research purposes should be voluntary, with no financial inducements permitted, with donors thoroughly informed of the risks associated with donation.[80]

During the debate in the federal parliament, Liberal Senator Jeannie Ferris expressed her anger at the suggestion that women will be taken advantage of:

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[74] C. Nader (2007) 'New guidelines to protect egg donors', *The Age*, 12 April, p.9.
[75] National Health and Medical Research Council (2007) *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research: Consultation draft April 2007*, NHMRC, Canberra, viewed 12 April, <http://www.nhmrc.gov.au/consult/art.htm>.
[76] ibid., p.49.
[77] Newcastle University (2006) *'Egg-sharing' go-ahead for stem cell researchers*, media release, 27 July, viewed 3 April 2007, <http://www.ncl.ac.uk/press.office/press.release/content.phtml?ref=1154008083>.
[78] S. Sexton (2005) 'Transforming "waste" into "resource": from women's eggs to economics for women', viewed 3 April 2007, <http://www.thecornerhouse.org.uk/subject/genetics/>.
[79] T. Kim Hwa-young (2006) 'Ova donors demand compensation from government', *Asia News* (on-line), 7 February, viewed 3 April 2007, <http://www.asianews.it/view.php?l=en&art=5322>.
[80] Australian Government (2005) op. cit., p.65.

> Finally, let me briefly canvass the utterly abhorrent suggestion that women will "sell their fresh eggs" or the even more objectionable suggestion that "female cadavers will have their eggs removed". These arguments are as patronising as they are specious. They suggest that a woman has no control over her body, is driven by money and greed, will willingly take medication to stimulate egg production in return for payment and will jeopardise her health and potentially endanger her life. There will be no opportunity for this. The law will prevent it in this country and those opponents well know it. Moreover, these accusations are deeply offensive to women—indeed, they should be to men too—and it is particularly unfortunate that they were put to some of our most eminent research teams to try to substantiate a very offensive argument. Surely we think more of the intellectual capacity of our scientists and of our female population.[81]

Greens Senator Christine Milne, on the other hand, conveyed her feelings that the exploitation of women was inevitable if therapeutic cloning were permitted to proceed:

> The cloning research that is proposed can go nowhere without women. Women's bodies are required to provide ova…Altruism will be encouraged on the basis of an imminent cure for a relative or friend playing on woman's compassion. Women are not commodities. Women's body parts are not for sale. Women are not selfish walking repositories of eggs that are being wasted because women will not donate them. The fact that we are having this debate about finding ways to encourage women to undergo invasive procedures that have no benefit to themselves and give up body parts demonstrates of itself how far down the road we are to arguing that the advancement of science justifies harming women. No women can give informed consent because we do not know what the health risks and impact of the hormonal stimulating drugs involved will have years down the track. The end does not justify the means.[82]

Labor MP Peter Garrett also expressed his opposition to the bill on the grounds that demand will ultimately outstrip supply of eggs:

> I want to make brief mention of the issue of the supply of eggs…It is here that I find the arguments of those who served on the Lockhart committee least convincing. Why is that? Because the research and economic imperative to access a large number of eggs for cloning will in my view inevitably lead to calls to amend legislation and guidelines to facilitate and encourage a greater supply. If in its initial phase there is a requirement for a number of eggs, numbering many hundreds towards thousands, necessary to create a single living clone then there is a calculation here which for me lacks proportion.[83]

Aware of issues surrounding the limited supply of eggs, scientists are investigating processes which may reduce, or even eliminate, the need for eggs. For example, in the Senate Community Affairs Committee's *Inquiry into the Legislative responses to Recommendations of the Lockhart Review*, it was noted that 'Other research has recently shown that it is possible to re-program specialised cells to behave like pluripotent cells. This is promising new research, as if proven it could remove the need to use human ova'.[84] However, 'scientists point out that SCNT research is vital in advancing this new research as de-differentiation of the adult cell is an intrinsic part

[81] Australia (2006) Senate, *Debates*, No. 13, 6 November, p.46.
[82] ibid., pp.181-182.
[83] Australia (2006) House of Representatives, *Debates*, No. 18, 5 December, p.145.
[84] Standing Committee on Community Affairs (2006) op. cit., p.17.

of the SCNT process',[85] thus the initial requirement for eggs remains. The Australian Stem Cell Centre also described this potential process in their submission to the Lockhart Review on the value of SCNT:

> Understanding the reprogramming of an adult cell nucleus to achieve a more flexible or plastic state would have far-reaching beneficial implications for biology and medicine. Ultimately, SCNT may deliver an understanding of those unidentified factors within an egg cell that can reprogram the behaviour of a mature cell, these findings might eventually obviate the need to use eggs or produce embryos at all, because it could be applied directly to the reprogramming of adult cells.[86]

Another potential alternative, as canvassed in section one, is to use animal ova and human cells to create hybrid embryo clones, enabling stem cells to be harvested for research and clinical application. Human ova would therefore not need to be used in such numbers. Such an approach was recommended by the Lockhart Review, however it was not included in the federal Act. The Victorian bill, through the licensing guidelines, effectively prohibits the creation of hybrid embryos for SCNT purposes.

[85] ibid., p.24.
[86] ibid., p.29.

4. Science, Technology and Innovation

4.1 Investment in science, technology and innovation

In the latter part of the 1990s, state and federal governments in Australia established a number of agencies to explore pathways to improve science, technology and innovation. Federally, for example, there was the formation of the Prime Minister's Science, Engineering and Innovation Council (PMSEIC) in 1997, the same year that the then Premier of Victoria established a Science, Engineering and Technology Taskforce in this state. The resulting reports highlighted concern at the country's "brain drain" and the manifest underperformance of government investment in research and development, in comparison to competitor economies.[87] Recognising the importance of science and innovation as a driver of economic growth, governments around the country started to accelerate their funding. This commenced with the Federal Government's *Backing Australia's Ability* package in 2001 and the Victorian Government's *Investing in Innovation* program brought down in the May 1999 budget.

Federal Funding

- 2001 *Backing Australia's Ability* - $3 billion over five years: $193 million in 2001-02, $419 million in 2002-03, $634 million for 2003-04 , and $1 billion for 2005-06
- 2004 *Backing Australia's Ability - Building Our Future Through Science and Innovation* - $5.3 billion over seven years

Together they constitute a ten year, $8.3 billion funding commitment by the Australian Government from 2001-02 to 2010-11.[88]

Investment in Science, Technology and Innovation in Victoria

The Kennett Government's *Investing in Innovation* program brought down in the May 1999 budget pledged a hitherto unparalleled funding of $310 million over five years to science, technology and innovation projects. The incoming Bracks Government took up the mantle in the form of its *First Generation STI Initiative* ($310 million) and put forward its vision for Victoria to become one of the world's top five biotechnology locations. The Victorian Government followed the *2001 STI initiative* with a further $310 million in 2004.

Victorian Government Funding

- STI Initiative $620 million
- Medical Research Institute support $330 million
- Biotechnology Strategic Development Plan $34.5 million
- Other ICT & Innovation Projects $618 million

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[87] Department of Health and Aging (1998) 'The Virtuous Cycle: working together for health and medical research, Health and Medical Research Strategic Review (Summary)', December, viewed 28 March 2007, <http://www.health.gov.au/internet/wcms/publishing.nsf/content/hmrsr.htm>.

[88] Further details on funding are set out in the funding table at the following site: Department of Education, Science and Training (2007) 'Backing Australia's Ability – Building Our Future Through Science and Innovation', viewed 29 March 2007, <http://backingaus.innovation.gov.au/>.

- National Biosecurity Centre $6 million
- TOTAL $1.6085 billion [89]

In its report prepared for the Australian Society for Medical Research in 2003, Access Economics determined that historically, every dollar spent on health research and development was worth five dollars in returns. [90]

4.2 The Biotechnology Industry

Definition of Biotechnology

The OECD definition of biotechnology is 'the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services'.[91] Biotechnology applications are used in agriculture, medicine, food processing, manufacturing and environmental management.

National Biotechnology Strategy

The National Biotechnology Strategy was launched in July 2000 to provide a 'framework for Government and key stakeholders to work together to ensure that developments in biotechnology are captured for the benefit of the Australian community, industry and the environment, while safeguarding human health and ensuring environmental protection'.[92] The strategy consisted of:

- Initial funding of $30.5 million 2001-04.
- Further $66.5 million funding allocated in 2001 from the *Innovation Statement, Backing Australia's Ability*, with funding for the establishment of a new "Biotechnology Centre of Excellence". This was awarded to the Centre for Stem Cells and Tissue Repair in May of 2002, and was renamed the National Stem Cell Centre and established in May 2003. It was later renamed the Australian Stem Cell Centre in August 2004.
- Further $20 million in 2004 from *Backing Australia's Ability – Building Our Future through Science and Innovation*.
- Further funding to extend support for the Australian Stem Centre until 2010-11.

The Victorian Biotechnology Strategic Development Plan

In 2001, the Victorian Government launched its Biotechnology Strategic Development Plan, which committed funding to a range of projects including biotechnology, ICT, new manufacturing technologies and design and environment technologies. Its aim was to position Victoria as one of the world's five leading

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[89] Department of Innovation, Industry and Regional Development (2006) *Healthy Futures: Delivering better health, research and jobs for Victorians*: *The Victorian Life Sciences Statement*, Department of Innovation, Industry and Regional Development, Melbourne, p.13.

[90] Access Economics (2003) *Exceptional Returns: the Value of Investing in Health R&D in Australia*, Access Economics, Canberra, viewed 28 March 2007, <http://www.accesseconomics.com.au/publicationsreports/search.php?searchby=year&searchfor=2003>, p.1.

[91] Department of Industry, Tourism and Resources (2004) *Global Partners Australian Biotechnology 2004*, Department of Industry, Tourism and Resources, Canberra, p.7. and
Victorian Government Health Information (2007) 'Biotechnology', viewed 23 March 2007, <http://www.health.vic.gov.au/biotechnology/index.htm>.

[92] Biotechnology Australia (2000) 'National Biotechnology Strategy', viewed 29 March 2007, <http://www.biotechnology.gov.au/index.cfm?event=object.showContent&objectID=538B635B-BCD6-81AC-1E1B66BB24EA3184>.

locations for biotechnology research and development, commercialisation, production and marketing. The Strategic Plan identified five key areas for action:

- Developing a biotechnology skill base;
- Developing Victoria's research base;
- Commercialising Victoria's biotechnology;
- Building Victoria's corporate base and marketing its capabilities;
- Providing Government leadership and support.

In 2004, the Victorian Government released an updated Biotechnology Strategic Development Plan for 2004-2007. The 2004 strategy emphasises connectivity between the education, research and industry sectors and focuses on 'ensuring that the products of Victoria's biotechnology research make it to the vital pre-market stage—and beyond'.[93]

The Victorian Biotechnology Industry at a Glance

- In 2005, estimated sales from Victoria's biotech and pharmaceutical companies totalled $5.9 billion, driven by Victoria's established pharmaceutical groups (Australia's three largest listed pharmaceutical companies are based in Victoria: CSL, Mayne Pharma and Sigma Pharmaceuticals);
- Around $200 million in funds was raised in 2005 by Victorian biotech companies;
- Employment numbers exceed 6,000;
- As of February 2006, Victorian biotech firms were conducting 38 clinical trials, either managed directly or in conjunction with development partners;
- Victorian biotech companies signed international deals worth in excess of $678 million over the last 14 months;
- Victorian companies secured 41 percent of the US biotech patents granted to Australian companies in 2004; and
- Victorian biomedical research institutes and universities dominate in National Health and Medical Research Council (NHMRC) grants, with an increase from 37% in 1999 to 46% in 2006.[94]

Biotechnology Precincts

Victoria has six key biotech research precincts encompassing universities, research institutes, hospitals and companies.

- Parkville Precinct: medical and bioscientific research, education, clinical practice, production of pharmaceuticals and biotechnology products. The Bio21 Molecular Science and Biotechnology Institute: genetics, bioinformatics, molecular diagnostics, proteomics, biomolecular science, medical research and clinical informatics;
- Alfred Medical Research and Education Precinct: biomedical research and development;
- Monash Health Research Precinct: biomedical and other biotechnology research;

[93] Business Victoria (2004) 'Biotechnology', viewed 29 March 2007, <http://www.business.vic.gov.au/BUSVIC/STANDARD/PC_50848.html>.

[94] Business Victoria (2006) '2006 Victorian Life Sciences Industry Update', viewed 29 March 2007, <http://www.business.vic.gov.au/BUSVIC.9896242/STANDARD//PC_50855.html>; Business Victoria (2005) 'Competitive Advantages', viewed 29 March 2007, <http://www.business.vic.gov.au/BUSVIC/STANDARD/1001/PC_60142.html> and Department of Innovation, Industry and Regional Development (2006) op. cit., p.17.

- Werribee: animal and food research, including veterinary applications, agribusiness and environmental sustainability;
- Bundoora: plant bioscience and medical research; and
- Austin Biomedical Alliance Precinct: biomedical research.[95]

4.3 Stem Cell Research at the Monash Science, Technology, Research and Innovation Precinct (STRIP)

The Monash STRIP includes the stem cell research hub in Australia. In addition to the Australian Stem Cell Centre, there is the Monash Immunology and Stem Cell Laboratories, Stem Cell Sciences and Norwood Immunology.

The Australian Stem Cell Centre

The Australian Stem Cell Centre (ASCC) is the first 'biotechnology centre of excellence' established by the Federal Government in 2003, funded through the 2001 *Innovation Statement, Backing Australia's Ability.* It receives funding from both the Federal and Victorian Governments, with Federal Government Funding of $104.05 million (up to the year 2010) and Victorian Government Funding of $11.3 million. Its principal objective is 'to integrate a national multi-institution research and discovery program to develop treatments for serious diseases through the application of stem cells and related technologies'.[96] Its core role is to facilitate the commercialisation of treatments.

Although the ASCC is based at the Monash Health Research Precinct in Melbourne, it has additional nodes in New South Wales, Queensland and South Australia. There are 'stakeholder' university and research institutes in addition to collaborative arrangements with commercial partners. Founding stakeholder universities are: the University of Adelaide, Monash University; University of NSW; University of Queensland; Peter MacCallum Cancer Centre; Victor Chang Cardiac Research Institute and the Howard Florey Institute. Additional stakeholders are: the Murdoch Childrens Research Institute and the Baker Heart Research Institute. Commercial Partners are:

- Stem Cell Sciences Ltd (SCS), to derive, characterise and distribute new human embryonic stem cell lines as a tool for academic researchers;
- Singapore-based ES Cell International Ltd (ESI), for commercialisation of research relevant to diabetes;
- Australian biotechnology company Nephrogenix Pty Ltd, for expertise relevant to the development of kidneys, blood and cardiac tissue; and
- US-based company LifeCell Corp, to collaborate in the area of tissue repair.

Main areas of research:

- regeneration of damaged cardiac (heart) tissue,
- investigating stem cell technologies for blood and bone marrow regeneration to improve bone marrow transplantation techniques and to generate safer blood cell products for patients needing transfusion,

[95] Business Victoria (date unknown) 'Biotechnology Precincts', viewed 30 March 2007, <http://www.business.vic.gov.au/BUSVIC.11993298/STANDARD//PC_50856.html#intNav1>.
[96] Australian Stem Cell Centre (2007) 'The Centre', viewed 10 April 2007, <http://www.stemcellcentre.edu.au/>.

- the use of stem cell therapies in lung diseases, such as Cystic Fibrosis.[97]

Monash Immunology and Stem Cell Laboratories (MISCL)

The Monash Immunology and Stem Cell Laboratories (MISCL) is a centre of research excellence within the School of Biomedical Sciences, Faculty of Medicine at Monash University. One of the world's largest stem cell research facilities, it is closely allied to the Australian Stem Cell Centre and other Monash departments focusing on development, genomic and epigenetic science, reproduction, immunology and transplantation medicine. Its focus is embryonic stem cell research and its 'potential applications in repair and regeneration of blood, pancreatic, respiratory renal and neural tissues.'[98]

Stem Cell Sciences Limited

Established in Melbourne in 1994, Stem Cell Sciences Limited is a global biotechnology company with partnerships with Monash University, the Australian Stem Cell Centre, the Institute of Stem Cell Research (ISCR), Edinburgh University, Sosei Co. Ltd Japan and the RIKEN Centre for Developmental Biology, Kobe Japan. Its research focus is 'on technologies to grow, differentiate, select and purify mouse and human embryonic stem cells for use in genetic, pharmacological and toxicological screens.' [99] In November 2004, Stem Cell Sciences Limited, the Australian Stem Cell Centre and Melbourne IVF announced MEL-1, the first of six human embryonic stem cell lines to be made available to scientists around the world free of intellectual property or commercial restraint. It was accepted for deposit into the UK Stem Cell Bank. MEL-2 was released in 2005.

Norwood Immunology Limited

Norwood Immunology Limited is a Victorian based company, which 'develops technologies and therapies to rejuvenate activity of the immune system, through re-growth of the thymus, improvements in bone marrow function and enhancement of T cell functionality'.[100] In March 2006 it entered a tripartite agreement with Monash University and the Australian Stem Cell Centre to combine research of stem cell technology with the immune system, to minimise rejection of stem cell therapies introduced into the body. It is currently involved in a suite of cancer-based clinical trials in the United States.[101]

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[97] Australian Stem Cell Centre (2007) 'Centre Funding, Partnerships', viewed 10 April 2007, <http://www.stemcellcentre.edu.au/>.

[98] Business Victoria (2007) 'Biotechnology Snapshot, 2005', viewed 10 April 2007, <http://www.business.vic.gov.au/BUSVIC.983260/STANDARD//PC_50855.html>, p.3.

[99] ibid.

[100] Monash University (2006) 'Norwood Immunology Partners with Australian Stem Cell Centre and Monash University', viewed 10 April 2007, <http://www.monash.edu.au/news/newsline/story/798>.

[101] Norwood Immunology (2007) 'Clinical Trials', viewed 10 April 2007, <http://www.norwoodimmunology.com/companyProfile.html>.

5. Approaches to Human Embryonic Stem Cell Research in Other Jurisdictions

5.1 Other Australian states and territories

Queensland

The *Research Involving Human Embryos and Prohibition of Human Cloning Act 2003* complements the previous Commonwealth legislation; the *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002*. Accordingly the Queensland Act prohibits SCNT and reproductive cloning while allowing licensed use of excess ART embryos. In s.7 the Queensland Act makes it an offence to intentionally create a human embryo clone. A human embryo clone is a genetic copy of a living or dead human according to s.5(2). It is also an offence to place a human embryo clone in the body of a human or animal according to s.8. Both offences are punishable by 15 years imprisonment. Furthermore s.10 provides it is an offence to create a human embryo other than by fertilisation or to develop such an embryo. It is also an offence to create a human embryo for a purpose other than achieving pregnancy in a woman under s.11. Hybrid embryos are also prohibited under s.17. The use of excess ART embryos is only permitted where the use is an exempt use, such as storage, removal or transport, or it is licensed under s.23.

South Australia

The *Prohibition of Human Cloning Act 2003* has similar provisions. It makes it an offence to create a human embryo clone in s.5, to place the clone in a human or animal in s.6 or to import or export a human embryo clone under s.7, punishable by 15 years imprisonment. It is also an offence to create a human embryo other than by fertilisation under s.9 or to create a human embryo for a purpose other than achieving pregnancy in a woman under s.10. Hybrid embryos are also prohibited under s.16. The *Research Involving Human Embryos Act 2003* permits the use of excess ART embryos only if licensed or an exempt use under s.5.

Western Australia

The *Human Reproductive Technology Act 1991* similarly makes it an offence to create a human embryo clone in s.53C or to place a human embryo clone in a human or animal s.53D. It is also an offence to import or export a human embryo clone s.53E. The offences are punishable by 900 penalty units or 15 years imprisonment or both. Like the Queensland legislation it is an offence to create a human embryo other than by fertilisation, to allow such an embryo to develop s.53G or to create an embryo for a purpose other than achieving pregnancy in a woman s.53H so SCNT would be prohibited. Hybrid embryos are prohibited in s.53N and embryos cannot be placed in animals or in humans other than in a woman's reproductive tract under s.53O. Use of excess ART embryos is allowed only if licensed or an exempt use under s.53W.

Australian Capital Territory

The *Human Embryo (Research) Act 2004* sets out similar offences in relation to creating embryos, placing them in humans or animals and importing and exporting them under sections 8-10, punishable by 15 years imprisonment. Embryos cannot be created other than by fertilisation or for purposes other than pregnancy, sections 12-

13. Use of excess ART embryos is only permissible if licensed or an exempt use under s.25.

New South Wales
The *Research Involving Human Embryos (New South Wales) Act 2003* does not identify specific offences but aims to follow the approach adopted by the Commonwealth in relation to using ART embryos in the *Research Involving Human Embryos Act 2002*. The *Human Cloning and Other Prohibited Practices Act 2003* mirrors the offences of the Commonwealth *Prohibition of Human Cloning Act 2002* similarly to other states as above.

Tasmania
The *Human Embryonic Research Regulation Act 2003* similarly does not specify offences but adopts an approach uniform to the Commonwealth *Research Involving Human Embryos Act 2002*. The Tasmanian *Human Cloning and Other Prohibited Practices Act 2003* identifies prohibited practices such as creating a human embryo clone (s.5) placing such a clone in a human or animal (s.6) or importing or exporting such clones in s.7, punishable by imprisonment of up to 15 years. It is also an offence to create embryos other than by fertilisation under s.9 or for purposes other than achieving pregnancy in a woman under s.10.

Northern Territory
There is currently no relevant legislation in the Northern Territory.

5.2 International

Individual countries have taken varied approaches to regulating human embryonic stem cell research. Most countries take an intermediate policy approach. This generally involves modest government intervention and permitted research on supernumerary ART embryos while prohibiting therapeutic and reproductive cloning. Countries in this category include Australia (although the national law has now changed), Brazil, Canada, France, Spain, The Netherlands, Taiwan and many others. A group of countries takes a more permissive approach, allowing in various ways for human SCNT. Countries in this group include Belgium, Japan, Singapore, South Korea, Sweden, the UK, Israel, India, and China. At the other end of the spectrum, various countries take a restrictive approach, either prohibiting human embryo research, or allowing research on imported stem cell lines, or on existing stem cell lines only. Countries prohibiting human embryo research include Austria, Ireland, and Poland, while those that allow research on stem cell lines include Italy, Germany and the US.[102]

The European Union decided in July 2006 to allow EU funding for human embryonic research under conditions.[103] A significant number of countries world-wide have no explicit policy on human embryonic stem cell research, while nearly all countries that have passed legislation on the subject have banned human reproductive cloning.

[102] See Centre de Recherche en droit Public (2006) *StemGem,* Universite de Montreal, viewed 12 April 2006, <http://www.stemgen.org/>; University of Minnesota (2006) *MBBnet-World Stem Cell Map,* University of Minnesota Medical School, viewed 12 April 2006, <http://mbbnet.umn.edu/index.html>.
[103] See S. Laitner & C. Cookson (2006) 'EU to fund human embryonic research', *FT.com Financial Times,* viewed 12 April 2006, <http://www.ft.com/cms/s/1d419f90-1b47-11db-b164-0000779e2340.html>.

There appears to be a general trend towards liberalisation of policies across the spectrum of approaches, but some countries have passed or have retained restrictive laws. In addition, the above information relates to public funding and policy—the private sector is highly active in this area, particularly in the US. The following is a brief survey of selected countries and their different approaches.

United Kingdom

The United Kingdom has a licensing system pursuant to the *Human Fertilisation and Embryology Act 1990* (UK). In 1991 the stem cell research regulator, the Human Fertilisation and Embryology Authority (HFEA), was established by the *HFEA Act 1990*. The introduction of the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 widened the scope of research to permit therapeutic cloning. Only embryos under 14 days may be used. In August 2004 the HFEA granted the first licence to allow scientists to create human embryos for research using somatic cell nuclear transfer.[104] The UK regime allows UK scientists to maintain a competitive advantage globally due to the restrictive regimes implemented in some other countries.[105]

The issues of animal/human hybrids and egg donation are currently areas of contention. The HFEA has announced that women can donate eggs for research, widening the pool of potential donors. Previously women could only donate spare eggs produced through ART or gynaecological treatment. Donors will be entitled to claim up to £250 in expenses. Opponents argue that this area of research is too "young" to justify encouraging donations. Supporters argue women are already paid to donate eggs for other types of research such as drug trials. The HFEA also advised that women should be allowed to participate in egg-sharing schemes where they will receive reduced prices for IVF in return for their eggs.[106] The HFEA's guidelines aim to allow women to make informed choices.[107] The United Kingdom is not a signatory to the European Convention of Human Rights and Biomedicine and accordingly is not constrained by Art 18 (2) which prohibits producing human embryos for research.[108]

South Korea

South Korea will long be remembered for the Woo Suk Hwang fiasco, which emerged at the beginning of 2006. The greatest advances in stem cell research were attributed to Hwang but were later found to be fraudulent. Hwang claimed to have derived cell lines by therapeutic cloning and created 11 stem cell lines tailored to individual patients.[109] Hwang was also alleged to have used donor eggs from his own researchers, a practice prohibited under national laws.

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[104] S-N. Then (2004) 'Stem cell technologies: Regulation, patents and problems', *Journal of Law and Medicine*, vol. 12, iss. 2, p.188.
[105] ibid., p.195.
[106] BBC News (2007), 'Altruistic egg donation "allowed"', 21 February, viewed 2 April 2007, <http://news.bbc.co.uk/1/hi/health/6379827.stm>.
[107] See N. Gough (2006) op. cit., p.18; and NewScientist.com (2006) 'UK stem cell scientists to recruit egg donors', viewed 2 April 2007, <http://www.newscientist.com/article.ns?id=dn8719>
[108] S-N. Then (2004) op.cit, p.193.
[109] S. Bhattacharya (2006) 'Hwang faked all research on human stem cells', *NewScientist.com*, viewed 2 April 2007, <http://www.newscientist.com/article.ns?id=dn8557>; D. Cyranoski (2006) 'South Korean scandal rocks stem cell community', *Nature Medicine*, vol.12, iss.1, p.4.

India

India is regulated by guidelines, although the possibility of legislation has been raised. The guidelines are not enforceable but have been developed by the Indian Council of Medical Research and the Department of Biotechnology.[110] In 2001 the national bioethics panel recommended that researchers share commercial benefits emerging from embryonic stem cell lines with donors,[111] but it is unclear if this has happened in practice. Both public and private clinics claim to use stem cells to treat a wide variety of conditions but it is unclear what clinical studies are being undertaken.[112] In 2006 an Indian physician claimed to be using embryonic stem cells to treat 100 patients without ethical oversight from regulatory agencies.[113] There is some religious opposition from Hindu groups but the research has not received the level of outcry from religious groups as in the United States. This may be due, in part, to widespread use of adult stem cells and a lack of media attention. Government funding is modest as such research is a low priority in comparison to the lack of access to basic health care for millions of Indians.[114] SBS news has reported that an Australian woman has undergone embryonic stem cell treatment in New Dehli for paralysis caused by a car accident. The report states that the woman is now walking.[115]

China

China allows therapeutic cloning under guidelines requiring informed consent and informed choice. Compliance is monitored by institutions,[116] and the Ministry of Health acts as the regulating agency. However, according to one report, regulations are sometimes not followed and some studies are conducted with little or no institutional review.[117] It is difficult to determine the extent of China's research as the government does not release statistics but it may be the largest stem cell program in Asia. It is estimated to have 300 to 400 researchers in the area and seven laboratories.[118] As opposed to Singapore where there is a coordinated national plan, China has a range of overlapping initiatives developed by the central government, cities and provinces, private enterprise and semiprivate venture capital funds.[119] There is a lack of collaboration with researchers within and outside China.[120] Although President Hu Jintao has repeatedly stressed the importance of scientific development it appears government funding is limited with about US$38 million spent since 2000. This is in contrast to the state of California which has already earmarked US$3 billion to fund research in the next decade. It is likely funding in China will increase

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[110] T. V. Padma (2006) 'Unchecked by guidelines, Indian stem cell scientists rush ahead', *Nature Medicine*, vol. 12, iss. 1, p.4.

[111] G. Mudur (2001) 'India to tighten rules on human embryonic stem cell research', *British Medical Journal*, vol. 323, iss. 7312, p.530.

[112] K. Jayaraman (2005) 'Indian regulations fail to monitor growing stem-cell use in clinics', *Nature*, vol. 434, iss. 7031, p.259 .

[113] T.V. Padma (2006) op. cit., p.4.

[114] R. Lakshmi (2001) 'Scientists Say Restrictions in U.S. May Give Them Advantage in Development', *The Washington Post*, 28 August, p. AO7.

[115] AAP (2007) 'UK: Australian woman says stem cells helped her walk again', *AAP NewsWire*, 14 April.

[116] D. Normile & C. Mann (2005) 'Asia Jockeys for Stem Cell Lead', *Science*, vol. 307, iss. 5710, p.663.

[117] X. Yang (2004) 'An Embryonic Nation', *Nature*, vol. 428, iss. 6979, p.212.

[118] F. Murray & D. Spar (2006) 'Bit Player or Powerhouse? China and Stem-Cell Research', *The New England Journal of Medicine*, vol. 355, iss. 12, p.1191.

[119] D. Normile & C. Mann (2005) op. cit., pp.663-4.

[120] X. Yang (2004) op. cit., p.212.

drastically in the coming five years.[121] There have been reports suggesting China has made progress in the area. A team has allegedly cloned human embryos to the multicellular blastocyst stage and there has also been progress in successfully extracting embryonic stem cells.[122] In 2003 Chinese scientists claimed to have made human embryonic stem cells by injecting a human skin cell nucleus into a rabbit egg. The validity of the findings was queried in the United States.[123]

Japan

In 2001 Japan passed legislation allowing research on stem cells derived from surplus ART embryos. In 2004 the government's advisory panel approved the creation of embryos for research if specific requirements were met. The government has created the Centre for Development Biology to serve as a site to advance stem cell research.[124] Debate over the ethics of the research has not been heated compared to other nations because biotechnology is held in high esteem and considered to be a source of economic growth in Japan.[125] Scientists from Kyoto University claim to have created "reprogrammed" cells in mice that may be equivalent to embryonic stem cells but do not require the use of an embryo or destruction of the blastocyst, claims not yet substantiated. Previously researchers in the United States claimed they could generate embryonic stem cells without destroying the embryo but the research was challenged.[126]

Canada

Canadian legislation prohibits therapeutic and reproductive cloning, and consequently they are criminalised. The maximum penalty is $500,000 or ten years imprisonment. Stem cell research using surplus ART embryos is permitted and the Assisted Human Reproduction Agency, partly modelled on the UK HFEA, acts as a regulator. In addition to the legislation, there are guidelines limiting research to surplus ART embryos. Canada's position is interesting given it is a pluralistic society. Arguments leading to the ban on therapeutic cloning included the moral status of the embryo, the moral harm outweighing potential benefits, adult stem cells being a better alternative, respect for human dignity and concern that a permissive approach may lead to reproductive cloning in the future.[127]

United States

There is limited federal regulation of stem cell research in the United States and inconsistent approaches are taken by the states. Congress has banned federal funding of research resulting in the destruction of embryos since 1995. In 2001 President Bush

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[121] F. Murray & D. Spar (2006) op. cit., pp.1191-2.
[122] X. Yang (2004) op. cit., p.211.
[123] A. Regalado (2003) 'Chinese Scientists Report Advance in Stem-Cell Work', *Wall Street Journal*, 14 August 2003, p.D.5.
[124] A. Campbell (2005) 'Ethos and Economics: Examining the Rationale Underlying Stem Cell and Cloning Research Policies in the United States, Germany and Japan', *American Journal of Law and Medicine*, vol.31. iss.1. p.55.
[125] ibid., p.63.
[126] P. Aldhous (2006) 'Review 2006: No embryos were harmed…', *New Scientist*, viewed 2 April 2007, <http://www.newscientist.com/channel/sex/mg19225834.900-review-2006-no-embryos-were-harmed.html>.
[127] T. Bubela & T. Caufield (2006) 'When Human Dignity is Not Enough: Embryonic Stem Cell Research and Human Cloning in Canada', viewed 2 April 2007, Conference paper, <http://ica.stanford.edu/francestanford/conferences/workingpapersseries/bioethics>.

announced his administration would allow federal funding only for research on the existing 60 stem cell lines, so no federal funding would result in the destruction of blastocysts. This appears to have been a compromise to appease the most prominent groups; religious activists, the anti-abortion lobby and the scientific community.[128] To be eligible, stem cell lines must have existed before August 2001 and have been derived from excess ART embryos, with informed donor consent and no financial inducement. Since then many of these lines have been found to be contaminated and unusable.[129] Consequently scientists in the United States who are reliant on government funding are comparatively limited in their capacity to undertake research. In 2006 President Bush used his veto for the first time in relation to a bill on federal funding for embryonic stem cell research. Votes for the bill fell short of the two-thirds majority required to overcome the veto. Opponents of the research argue that taxes should not be used to fund research which results in the destruction of embryos, while supporters argue that the embryos could be sourced from excess ART embryos that would otherwise be discarded.[130]

As already noted, state laws are inconsistent: with nine states banning human reproductive cloning and several also banning therapeutic cloning. California and New Jersey are two states that specifically permit SCNT. California has voted US$3 billion worth of funding for stem cell research, while New Jersey has allocated US$380 million. Scientists operating in the private sector are virtually unregulated if no relevant state laws apply. The private sector is vigorously pursuing stem cell research.

In April 2007 the US Senate voted by a majority of 63 to 24 to ease restrictions on federal funding for stem cell research, by passing a similar bill to that of 2006 (just short of a two-thirds majority required to override a presidential veto).[131] President Bush responded by saying he would use his power of veto to overturn the Senate vote.

Germany

Germany's comparatively restrictive approach to therapeutic cloning appears to have been influenced by the history of Nazi eugenics. In 1990 the Embryo Protection Law was enacted, which criminalized reproductive cloning and prohibited embryonic research not intended to benefit the embryo concerned. German scientists deriving stem cells from human embryos in other countries may be violating the law. The importation of stem lines from surplus embryos is allowed if researchers can demonstrate the research cannot be carried out by other means.132 Importation occurs under strict conditions set out in the Act Ensuring the Protection of Embryos in Connection with the Importation and Utilization of Human Embryonic Stem Cells 2002. There has been a push to liberalise the laws from the country's main funding agency, the DFG (Deutsche Forschungsgemeinschaft, the German Research Foundation). The DFG is seeking better access to stem cell lines in other countries, the importation of human embryonic stem cell lines for clinical and research purposes

[128] A. Campbell (2005) op. cit., p.53.
[129] S-N. Then (2004) op. cit., pp. 194-5.
[130] BBC News (2007) 'US House backs stem cell research', viewed 2 April 2007, <http://news.bbc.co.uk/1/hi/world/americas/6254039.stm>.
[131] BBC News (2007) 'Senate defies Bush on stem cells', viewed 12 April 2007, <http://news.bbc.co.uk/2/hi/americas/6547259.stm>.
[132] A. Campbell (2005) op. cit., pp.53-4.

and the lifting of threats to punish German researchers working overseas. Politicians are generally supportive of decriminalising research by German scientists in countries where it is permitted.[133]

[133] A. Abbott (2006) 'German stem-cell law under fire', *Nature*, viewed 2 April 2007, <http://www.nature.com/news/2006/061113/full/444253a.html>.

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Enquiries

Enquiries should be addressed to:
Dr Greg Gardiner
Senior Research Officer
Victorian Parliamentary Library
Parliament House
Spring St, Melbourne
Victoria 3002

T: (03) 9651 8640
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