The Lockhart Review: Where now for Australia?

Donna Cooper*

In 2005 a Legislation Review Committee, known as the Lockhart Review, undertook a review of the Commonwealth legislation regulating human embryo research. The report that emanated from the review was released in December 2005. If the report recommendations are implemented by the Federal Government, Australian scientists will be permitted to create human embryo entities currently known as "human embryo clones" by the process known as somatic cell nuclear transfer to develop stem cell lines for research purposes. Many argue that stem cells have the potential to be developed into valuable medical therapies that could assist with, or cure, serious diseases such as Type 1 diabetes and Parkinson's disease. This article analyses the evidence presented to the Lockhart Review and the report recommendations. It assesses where the Lockhart recommendations would place Australia in terms of worldwide embryo research. It is argued that the Federal Government should fully embrace the recommendations so that Australia can progress stem cell research to its fullest potential.

INTRODUCTION

Sweeping reforms to liberalise the present regulatory climate in relation to human embryo research have been recommended by a Commonwealth Legislation Review Committee which undertook a review of the *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition of Human Cloning Act 2002* (Cth).[1] If the recommendations of the Review Committee, known as the Lockhart Review, are implemented by the Commonwealth Government, scientists will be permitted to create an embryo entity currently known as a "human embryo clone"[2] for research purposes by the process of somatic cell nuclear transfer (SCNT), also known as "therapeutic cloning".[3] Scientists use these entities to extract embryonic stem cells and, in the process, the embryos are destroyed. The creation of embryos via SCNT is currently illegal in Australia; however, it is permitted in such countries as the United Kingdom, Singapore and South Korea.[4]

* LLB (QIT), LLM (QUT); Lecturer, Member of Health Law Program, PhD Candidate, Faculty of Law, Queensland University of Technology. The author would like to thank Professor Derek Morgan for his comments on an earlier version of this article.

Correspondence to: d.cooper@qut.edu.au.

[1] Each Act had provided that it was required to be independently reviewed by 19 December 2005. The review was commissioned by the Commonwealth Minister for Aging, the Hon Julie Bishop MP, who at that time had portfolio responsibility for human cloning and stem cell research. The Committee was made up of six members with backgrounds in law, medicine, science and ethics and was chaired by the late Hon John S Lockhart AO, QC. Details of the Committee are available at http://www.lockhartreview.com.au/public/content/ViewCategory.aspx?id=2 viewed 22 January 2006. The Committee was required to report to the Council of Australian Governments (COAG) by 19 December 2005. At a COAG meeting on 10 February 2006 it was agreed that Senior Officials would report to the next COAG meeting in June 2006. See http://www.coag.gov.au/meetings/100206/index.htm viewed 12 June 2006.

[2] "Human embryo clone" is defined in the *Prohibition of Human Cloning Act 2002* (Cth), s 8(1), as "a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by human sperm".

[3] "Somatic cell nuclear transfer", also referred to in this article as "nuclear transfer", is defined as "moving the nucleus and its genetic material from a somatic cell to another cell (usually an egg cell from which the genetic material has been removed)": Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002: Reports* (December 2005) (Legislation Review Committee Report), Glossary, p 252: see http://www.lockhartreview.com.au viewed 7 February 2006.

[4] Legislation Review Committee, *Legislation Review of Australia's Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002, Issues Paper* (August 2005) (Issues Paper) p 25.

The Lockhart recommendations do not extend as far as the current United Kingdom position which permits the creation of human embryos, either by fertilisation or by SCNT, for research purposes.[5] The Review Committee was of the view that the in vitro creation of embryos by fertilisation should remain restricted to assisted reproductive technology (ART) treatment[6] for family creation.[7] However, ART embryos left over when a couple have completed their family would continue to be eligible for donation to research, providing that the creating couple give informed consent.[8] In addition, a new legislative definition of "embryo" was suggested, which would place it at a slightly later stage in the fertilisation process.[9] This would enable much valuable research into the improvement of ART procedures to occur, which has previously been illegal. Scientists would be permitted to study the fertilisation of human eggs by human sperm up to, but not including, the first cell division for the purposes of research, training and improvements in the clinical practice of ART.[10]

Other practices which the Lockhart Review recommended be legalised in Australia and currently permitted in the United Kingdom include the process of cytoplasmic transfer[11] and the creation of embryos through parthenogenesis.[12] The Lockhart recommendations also encompass some of the issues being contemplated in a current review of the United Kingdom legislation, the *Human Fertilisation and Embryology Act 1990* (UK), such as human nuclear transfer into animal egg cytoplasm, purely for research purposes.[13] The Review Committee also suggested that, as is the case in the United Kingdom, a national stem cell bank should be established and suggested that the Australian Stem Cell Centre at Monash University would be an appropriate forum.[14] The Committee was confident that legislative prohibitions on developing SCNT embryos for more than 14 days and on their implantation into a human would alleviate community concern that the legalisation of nuclear transfer would lead to such embryos being used for reproductive cloning.[15]

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[5] *Human Fertilisation and Embryology Act 1990* (UK); *Human Fertilisation and Embryology (Research Purposes) Regulations 2001* (UK).

[6] "Assisted reproductive technology" is defined as "the application of laboratory or clinical techniques to gametes or embryos for the purposes of reproduction": Legislation Review Committee Report, n 3, Glossary, p 247. The primary methods of ART procedures used in Australia which result in human embryos are in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI): Bryant J, Sullivan EA and Dean JH, "Assisted Reproductive Technology in Australia and New Zealand 2002", *Assisted Reproductive Series*, No 8 (Australian Institute of Health and Welfare, National Perinatal Statistics Unit and the Fertility Society of Australia, 2004) p 1.

[7] Legislation Review Committee Report, n 3, Recommendation 12, p 166.

[8] Legislation Review Committee Report, n 3, Recommendation 14, p 167.

[9] Legislation Review Committee Report, n 3, Recommendation 28, p 174.

[10] Legislation Review Committee Report, n 3, Recommendation 15, p 168.

[11] Legislation Review Committee Report, n 3, Recommendation 19, p 168. "Cytoplasmic transfer" is defined as "injecting cytoplasm from the egg of a healthy woman into the egg of another woman to assist conception or to correct defects": Legislation Review Committee Report, n 3, Glossary, p 248.

[12] Legislation Review Committee Report, n 3, Recommendation 25, p 172. "Parthenogenesis" is defined as "the development of an organism from an unfertilised egg cell ... Since a female parent is, in essence, cloning herself, parthenogenesis always produces female offspring": Legislation Review Committee Report, n 3, Glossary, p 251. On 10 June 2003 the Human Fertilisation and Embryology Authority (HFEA) of the United Kingdom granted a licence to the Roslin Institute to enable researchers to create human embryos through parthenogenesis from donated human eggs.

[13] Legislation Review Committee Report, n 3, Recommendation 24, p 172. Currently in the United Kingdom animal eggs are permitted to be fertilised with human sperm and the process is "only allowed under licence for testing the fertility or normality of sperm and the result must be destroyed when the test is complete and no later than the two cell phase". See *Human Fertilisation and Embryology Act 1990* (UK), Sch 2, s 1(1)(f); United Kingdom Department of Health, *Review of the Human Fertilisation and Embryology Act, A Public Consultation* (Department of Health, 2005) at [9.31]: see http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4123863&chk=zy5dcI viewed 7 February 2006. The public consultation process of the review closed on 25 November 2005.

[14] Legislation Review Committee Report, n 3, Recommendations 47, 48, p 181.

[15] Legislation Review Committee Report, n 3, Recommendations 2-11, pp 163-165.

The Lockhart Review conducted an extensive consultation process throughout Australia.[16] The Review Committee concluded that Australians hold a variety of views about the status of pre-implantation embryos. Submissions revealed that some groups strongly objected to destructive embryo research on the grounds that an embryo is human life and that such research interferes with the sanctity of such life. Other sectors of the community clearly supported stem cell research due to its potential to assist with, or cure, many serious medical conditions. The Review Committee found it impossible to reconcile these conflicting views. It found common ground, however, in general community support for medical research, such as stem cell research, that has the potential to assist many Australians suffering from serious diseases and infertile couples wanting to have children.

This article critically analyses the key recommendations of the Lockhart Report and examines the implications for Australian research. It first addresses the background to the Review and the existing legislation. The evidence presented to the Lockhart Review, summarising some of the primary policy arguments, is then analysed and the relevant recommendations discussed. It is suggested that the recommendations should be fully implemented to enable Australian researchers to realise the potential of stem cell research. Such an approach would also place Australia in a competitive position in terms of worldwide human embryo research. An overview of the position in liberal jurisdictions such as the United Kingdom is discussed to assist in determining how the Lockhart Report recommendations could now be implemented.

THE BACKGROUND TO THE LOCKHART REVIEW

The Lockhart Review Committee was charged with investigating whether developments in ART and stem cell research since 2002 justified amendments to update the Commonwealth legislation and the relevant customs regulations.[17] It was also required to assess the potential benefits of stem cell research in the treatment of diseases and whether research developments could justify legalising the nuclear transfer process. In conducting the review, the Review Committee was directed to take into account economic implications and current community standards, together with investigating the need for and viability of a national stem cell bank.[18]

To put this review in perspective, it is instructive to briefly discuss the background to the *Prohibition of Human Cloning Act 2002* (Cth) and the *Research Involving Human Embryos Act 2002* (Cth). This legislation currently permits research to be performed on embryos left over from ART procedures, termed "excess ART embryos".[19] The legislation originally prescribed that only excess ART embryos created prior to 5 April 2002 could become the subject of medical research.[20] However, the legislation also provided that the provisions containing this time restriction would be automatically repealed on 5 April 2005.[21]

In 2001, prior to the drafting of this legislation, the issues surrounding human embryo research, including the creation of embryos by nuclear transfer, were investigated by the House of

[16] The Committee considered 1,035 written submissions and heard oral evidence from 109 people around Australia: Legislation Review Committee Review of the Human Cloning Act 2002 and the Research Involving Embryos Act 2002, "Lockhart Review Supports Strong Regulation of Research Involving Human Embryos", Press release, 19 December 2005, p 1.

[17] *Customs (Prohibited Exports) Regulations 1958* (Cth) and *Customs (Prohibited Imports) Regulations 1956* (Cth).

[18] *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (Cth), Pt 6, Div 1, Revised Explanatory Memorandum.

[19] *Research Involving Human Embryos Act 2002* (Cth), s 9.

[20] It had been considered more ethically sound to permit research on existing embryos that would be likely to be disposed of at the end of the permissible storage period: *Research Involving Human Embryos Act 2002* (Cth), s 24(3)(b), 24(1)(c) and 24(3). Clinics can store embryos for five years, and couples then have the option to renew their consent to storage for a further five years: National Health and Medical Research Council, Australian Health Ethics Committee, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (September 2004) at [8.8] (NHMRC Ethical Guidelines): see http://www.nhmrc.gov.au/publications/synopses/e56syn.htm viewed 7 February 2006. Victorian legislation allows embryos to be stored for five years, but longer on application to the Infertility Treatment Authority: *Infertility Treatment Act 1995* (Vic), s 52(4).

[21] *Research Involving Human Embryos Act 2002* (Cth), s 46.

Representatives Standing Committee on Legal and Constitutional Affairs. As a result, a report was presented to Commonwealth Parliament making various recommendations.[22] This report was known as "the Andrews Report".[23]

The Andrews Report revealed that its Standing Committee members were divided on the issue of whether the creation of embryos via the SCNT process should be permitted in Australia. It noted that a majority of the Standing Committee supported this process being legalised, primarily on the basis of the potential for such research to develop stem cell therapies to treat various diseases.[24] A minority of the Committee were opposed to such research due to concerns about the ethics of the destruction of human embryos for research, particularly as, at that time, the potential benefits of such research were highly speculative. These Committee members considered that it was unnecessary to perform research on embryonic stem cells as there had been considerable progress made towards developing adult stem cell therapies, but no reported success with embryonic stem cell therapies. Such adult stem cell therapies also had the advantage of being compatible with the patient and did not involve the ethically controversial destruction of human embryos.[25]

As the potential of embryonic stem cell research was unclear and there appeared to be a sufficient supply of stem cells being derived from excess ART embryos, the Standing Committee reached a consensus to recommend a three-year moratorium on the legalisation of nuclear transfer, with the issue to be reviewed at the conclusion of that period. The Committee reasoned that there was simply no need for further embryos to be created through the SCNT process, particularly considering the ethical objections of many Australians presented in the many submissions it had considered.[26] It was thought that a future committee could assess whether Australian research needs had changed and whether embryonic stem cell research had progressed to such a point that the creation of embryos through the SCNT process could be justified.[27] Pursuant to the Standing Committee Report, in 2002 the Council of Australian Governments (COAG) agreed to introduce consistent legislation throughout Australia. The *Prohibition of Human Cloning Act 2002* (Cth) and the *Research Involving Human Embryos Act 2002* (Cth) ensured a more consistent national approach.[28] The States and Territories subsequently passed legislation which mirrored these Commonwealth provisions.[29]

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[22] Parliament of the Commonwealth of Australia, House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (August 2001) (the Andrews Report).

[23] For a discussion of the Andrews Report in the context of human reproductive cloning, see Little K, "Human Reproductive Cloning: An Analysis of the Andrews Report" (2002) 21 (1) *Monash Bioethics Review* 79.

[24] Andrews Report, n 22 at [7.109].

[25] Andrews Report, n 22 at [7.112]-[7.115]. Stem cell therapies can be custom-made for a particular patient. The stem cells are extracted from SCNT embryos created using the patient's own cells as the somatic cells. This provides an opportunity to obtain a precise match for the patient of whom the human embryo clone is a copy. It is thought that treatment of such a patient with their matched stem cells would prevent immune rejection problems: Issues Paper, n 4, p 11.

[26] Andrews Report, n 22 at [7.107]-[7.119]. The Standing Committee cited evidence presented by Professor Trounson and Robert Klupacs, the general manager and chief executive officer respectively of ES Cell International Pty Ltd.

[27] Andrews Report, n 22 at [7.122]-[7.125], [12.42].

[28] A national scheme was needed since the Commonwealth did not have the constitutional power to legislate with respect to all organisations or persons who might be involved in embryo research. Although most embryo research is conducted by fertility clinics which are trading corporations, State legislation is needed to regulate the activities of individuals, higher education institutions and State government agencies. The Commonwealth relies on the head of power in s 51(xx) of the *Commonwealth of Australia Constitution Act 1900* (Cth), giving it jurisdiction to legislate with respect to foreign corporations and trading or financial corporations formed within the limits of the Commonwealth.

[29] Part 2A and s 166 (and relevant provisions of Pt 1) of the amended *Infertility Treatment Act 1995* (Vic); Pt 4B and relevant provisions in Div 1 of Pt 3 of the amended *Human Reproductive Technology Act 1991* (WA); *Human Cloning and Embryo Research Act 2004* (ACT); *Research Involving Human Embryos (New South Wales) Act 2003* (NSW); *Human Cloning and Other Prohibited Practices Act 2003* (NSW); *Research Involving Human Embryos and Prohibition of Human Cloning Act 2003* (Qld); *Research Involving Human Embryos Act 2003* (SA); *Prohibition of Human Cloning Act 2003* (SA); *Human Cloning and Other Prohibited Practices Act 2003* (Tas); *Human Embryonic Research Regulation Act 2003* (Tas).

Prior to this national approach, Victoria, Western Australia and South Australia had their own legislation regulating research on embryos. However, each jurisdiction varied in how "embryo" was defined and consequently in the practices that were permitted in relation to embryo research.[30] In all three States, destructive research on embryos was illegal. This State position conflicted with the national ethical guidelines which permitted researchers to apply to the National Health and Medical Research Council (NHMRC) for a licence to conduct destructive research on excess ART embryos.[31] Other States, which had enacted no specific legislation, however, were also subject to the national ethical guidelines.[32]

THE CURRENT LAWS

The current regulatory scheme to which ART clinics and scientists are subject consists of this Commonwealth, State and Territory legislation, in addition to ethical guidelines. ART treatment centres are required to be accredited by the Reproductive Technology Accreditation Committee (RTAC) and, to be eligible for such accreditation, they need to comply with the NHMRC Ethical Guidelines[33] and the Code of Practice of the Fertility Society of Australia.[34]

The combined effect is that, in Australia, embryos cannot be created purely for research purposes either by SCNT or by fertilisation. The creation of embryos using nuclear transfer techniques, termed "human embryo clones",[35] is currently illegal, as is using such an embryo for human reproduction, a practice referred to as "reproductive cloning".[36] ART clinics are permitted to create human embryos in vitro via such procedures as in vitro fertilisation (IVF), only for the purpose of achieving pregnancy in a woman.[37] A further restriction is that clinics are not permitted to develop a human embryo outside the body of a woman for more than 14 days.[38]

The *Prohibition of Human Cloning Act 2002* (Cth) also prohibits other practices such as creating embryos containing the genetic material of more than two people,[39] and altering the genome of a cell so that the alteration is heritable by descendants of the human whose cell was altered.[40] Legislation currently prohibits the importing or exporting of SCNT embryos, and prohibits the importing into Australia of stem cells derived from SCNT embryos and other prohibited embryos, produced overseas. However, stem cells derived from excess ART embryos can be imported. The exportation of limited quantities of Australian produced stem cells is also permitted.[41]

Often in the course of fertility treatment, the number of embryos created exceeds the reproductive needs of the couple in question. These extra embryos can be frozen or cryopreserved for use in

[30] *Infertility Treatment Act 1995* (Vic); *Human Reproductive Technology Act 1991* (WA); *Reproductive Technology (Code of Ethical Research Practice) Regulations 1995* (SA), reg 1, repealed. For a detailed discussion see Magri S, "Research on Human Embryos and Cloning: Difficulties of Legislating in a Changing Environment and Model Approaches to Regulation" (2005) 12 JLM 483 at 486.

[31] *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (Cth), Revised Explanatory Memorandum, p 27.

[32] In all States and Territories, publicly funded institutions and private clinics registered with the Fertility Society of Australia were required to comply with the NHMRC Ethical Guidelines, n 20.

[33] *Research Involving Human Embryos Act 2003* (Cth).

[34] The Fertility Society of Australia Reproductive Technology Accreditation Committee, *Code of Practice for Centres Using Assisted Reproductive Technology* (revised April 2002): see http://www.fsa.au.com/rtac viewed 7 February 2006.

[35] *Prohibition of Human Cloning Act 2002* (Cth), ss 9 and 13.

[36] *Prohibition of Human Cloning Act 2002* (Cth), s 10. It is also unlawful to develop an embryo that has been created by a cloning procedure: *Prohibition of Human Cloning Act 2002* (Cth), s 13.

[37] *Prohibition of Human Cloning Act 2002* (Cth), s 14(1); NHMRC Ethical Guidelines, n 20.

[38] *Prohibition of Human Cloning Act 2002* (Cth), s 16.

[39] *Prohibition of Human Cloning Act 2002* (Cth), s 15.

[40] *Prohibition of Human Cloning Act 2002* (Cth), s 18.

[41] Legislation Review Committee Report, n 3, p 127; *Customs (Prohibited Imports) Regulations 1956* (Cth), reg 3; *Customs (Prohibited Exports) Regulations 1958* (Cth), Sch 6. Export of stem cells is permitted provided that the volume of the container is less than 50 ml.

subsequent ART treatments.[42] When the couple has completed their family, they will usually have embryos left over that are excess to their needs.[43] These embryos can be stored up to a maximum of 10 years,[44] after which time the legislation requires that they must be removed from storage.[45] At that time, the couple must decide whether to donate them to another infertile couple, donate them to research or have them destroyed.[46]

The *Research Involving Human Embryos Act 2002* (Cth) regulates the use of such "excess ART embryos" and permits destructive research to be performed, subject to strict regulation. The Embryo Research Licensing Committee of the NHMRC[47] oversees the granting of licences to approved ART clinics to conduct research on excess human embryos.[48] To obtain a licence, the clinic must show that it has put the necessary protocols in place and has obtained research approval from the institutional Human Research Ethics Committee (HREC). When deciding whether to grant a licence, the Licensing Committee must be satisfied that the proposed research is likely to contribute to a "significant advance in knowledge or improvement in technologies for treatment ... which could not reasonably be achieved by other means".[49] It also must be convinced that the research proposal restricts the number of excess ART embryos to the minimum number required to achieve the desired research goals.[50]

In general, it is illegal to export ART embryos. However, an application can be made to the Minister of Justice and Customs if, eg, a couple who have been undergoing ART treatment are moving overseas and wish to take their embryos with them for further treatment.[51] These provisions are in force until 31 July 2006 and formed part of the terms of reference of the Lockhart Review.[52] The import of ART embryos is permitted for reproductive use.

Subsequent to the creation of embryos via an ART process, some couples will also take advantage of a procedure known as "pre-implantation genetic diagnosis" (PGD). This process is available to couples who are seeking to avoid the implantation of an embryo which has a genetic disorder.[53] At the conclusion of this process, embryos rejected due to genetic defects are destroyed.[54] They do not fall within the current legislative definition of "excess ART embryos" as they are not left over at the conclusion of ART treatment when a couple has completed their family.[55] However, many scientists believe that these embryos are potentially valuable research tools, to assist scientists to learn more about the relevant disease and how to treat it.

The creation of embryos via SCNT has been the most ethically controversial in terms of human embryo research. Apart from the existing Commonwealth legislation preventing SCNT, Australia

[42] Bryant, Sullivan and Dean, n 6 at 1.

[43] There are a significant number of cyropreserved embryos held in storage at any one time and eligible for donation. For example, as of 31 December 2002 there were 92,541 such embryos in storage in Australia and New Zealand: Bryant, Sullivan and Dean, n 6, p 12.

[44] NHMRC Ethical Guidelines, n 20 at [8.8.1].

[45] NHMRC Ethical Guidelines, n 20 at [8.8.2].

[46] For a discussion of couples choosing to donate their embryos to research, see Kovacs G, Breheny S and Dear M, "Embryo Donation at an Australian University In-vitro Fertilisation Clinic: Issues and Outcomes" (2003) 178 (3) MJA 178.

[47] *Research Involving Human Embryos Act 2002* (Cth), s 13.

[48] *Research Involving Human Embryos Act 2002* (Cth), s 20.

[49] *Research Involving Human Embryos Act 2002* (Cth), s 21(4)(b).

[50] *Research Involving Human Embryos Act 2002* (Cth), s 21.

[51] *Customs (Prohibited Exports) Regulations 1958* (Cth), reg 7.

[52] *Customs (Prohibited Exports) Regulations 1958* (Cth), reg 7; Issues Paper, n 4, p 21.

[53] NHMRC Ethical Guidelines, n 20 at [12.1]. PGD is available to "detect serious genetic conditions, to improve ART outcomes and, in rare circumstances, to select an embryo with compatible tissue for a sibling".

[54] Lockhart Review Committee, Submission 509, Pera, Trounson et al, Monash University, p 5: see http://www.lockhartreview.com.au/public/content/ViewCategory.aspx?id=14 viewed 7 February 2006 (hereafter LRC 509, Monash University).

[55] *Research Involving Human Embryos Act 2002* (Cth), s 9.

voted, on 8 March 2005, as part of the United Nations General Assembly, in favour of the *United Nations Declaration on Human Cloning*. The terms of the Declaration do not define "human cloning". However, the Declaration sets out that "Member states are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life".[56] It is not clear whether this provision covers reproductive cloning or therapeutic cloning or both types of cloning. As a result, several countries at the forefront of stem cell research voted against the Declaration, as it could be interpreted to prohibit SCNT. Among these countries were the United Kingdom, South Korea and Singapore.[57]

A REVIEW OF THE EVIDENCE PRESENTED TO THE LOCKHART REVIEW

A critical analysis of some of the conflicting arguments raised in the submissions presented to the Lockhart Review, and of the underlying theoretical justifications for these policy positions, can assist with an understanding of the Review recommendations.

Numerous submissions to the Lockhart Review supported lifting the current ban on SCNT and continuing to allow all excess ART embryos to be eligible for donation to research.[58] Researchers reported that the recent lifting of the requirement that only embryos created prior to 5 April 2002 could be donated to research has meant that scientists now have access to a greater number of embryos which will enable the creation of more stem cell lines. Concern was expressed that, if access to excess ART embryos was again restricted, the number of available embryos would deplete rapidly due to the legal storage time limits.[59] Some researchers also called for embryos with genetic conditions that are discarded after pre-implantation genetic diagnosis to be made available for research.[60] These submissions argued that embryos found to have a genetic disease, such as cystic fibrosis and Huntington's disease, are currently never frozen and are simply destroyed. They pointed out that stem cell lines could be created from such embryos which would enable research into the cause and development of certain genetic diseases and how they can be prevented or treated.[61]

The overriding theme of the many submissions in support of destructive embryo research was the potential for stem cell research to benefit the large number of Australians currently suffering from serious diseases.[62] Many submissions from relatives of people suffering from such conditions supported this view.[63] A clear example was previously provided to a Senate committee in 2002, that 100,000 adults and children with Type 1 diabetes in Australia, requiring insulin injections to stay alive, could potentially benefit from stem cell research.[64]

Embryonic stem cells possess a quality known as "pluripotency", not possessed by adult stem cells, which potentially enables them to become any type of cell.[65] This means that they may have the potential to treat any condition in which a patient's cells are damaged or diseased. There are

[56] The vote was 84 for, 34 against and 37 abstentions: see "Ad Hoc Committee on an International Convention against the Reproductive Cloning of Human Beings" at http://www.un.org/law/cloning/#2004 viewed 21 November 2005.

[57] The United States voted in favour of the Declaration: *Official Records of the United Nations General Assembly*, 59th Session, 82nd Plenary Meeting: see http://daccessdds.un.org/doc/UNDOC/GEN/N05/260/35/PDF/N0526035.pdf?OpenElement viewed 21 November 2005.

[58] For example, LRC 509, Monash University; LRC 308, SpinalCure Australia; LRC 396, Stem Cell Ethics Australia: see http://www.lockhartreview.com.au/public/content/ViewCategory.aspx?id=22 viewed 10 October 2005.

[59] LRC 509, Monash University, p 4.

[60] LRC 509, Monash University; Legislation Review Committee Report, n 3, pp 168-169.

[61] LRC 509, Monash University, p 5.

[62] For example, LRC 819, Sydney IVF.

[63] Confidential submissions LRC 412 and LRC 216, quoted in Legislation Review Committee Report, n 3, p 61.

[64] The Senate, Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (October 2002) pp 48-51.

[65] "Pluripotent" is defined as the "ability of a single stem cell to develop into many different cell types of the body, including cell types from all three germ layers (endoderm, mesoderm and ectoderm)": Legislation Review Committee Report, n 3, Glossary, p 251.

indications that stem cell therapies may be developed to assist with, or cure, serious conditions such as Type 1 diabetes, Parkinson's disease and spinal injury.[66] It is anticipated that therapies developed from stem cells harvested from SCNT embryos will be custom-made for a particular patient using the patient's own cells, ensuring that the cell therapy is unlikely to be rejected by the patient's immune system.

The evidence presented to the Review Committee, along with a literature review, showed that, as was the case in 2001, successful medical therapies have not yet been fully developed from embryonic stem cells. However, the research is now indicating strong potential towards the development of successful therapies in the future.[67] One researcher reported:

> My experience, relating to research that is being done at the Diabetes Transplant Unit and from reviewing the literature, has left me with no doubts that human embryonic stem cells are extraordinarily valuable and have the potential in time to bring great benefits to our society. Although the therapeutic potential will most likely be seen over the long term, the advances that are currently being made in basic research are significant.[68]

It is, however, clear that the public benefit that embryonic stem cell research holds, particularly therapies derived from SCNT, is hard to ascertain as, at present, scientists are looking into a crystal ball of possibilities. Some submissions from the scientific community called for more public funding to be directed at adult stem cell research and less at embryonic research, as they considered that adult stem cells have demonstrated greater promise.[69] Others questioned whether stem cells created via SCNT will ever achieve the potential of therapeutic applications, as the fact that stem cells therapies would be "custom-made" for the patient may subsequently mean that the cost of such therapies is prohibitive.[70]

Other submissions argued that, although it could take up to 10 years before existing research is realised in medical treatments, this should not be a reason for prohibiting such research.[71] It was also pointed out that stem cells derived from SCNT can initially be used to prepare models for research on the development and function of different cell types and the features of certain cellular disease states. This enables scientists to study the way that diseases progress and potentially how to prevent or treat them.[72] Some submissions also argued that disease-specific stem cell lines can also be of benefit to the pharmaceutical industry when screening new drugs.[73]

A key factor put forward in support of a more liberal legislative environment for stem cell research was economic considerations and the perceived need to stay competitive with overseas countries such as the United Kingdom, the United States, Singapore and South Korea which are now taking the lead in this area.[74] It was argued that, although Australia was once considered a world leader, its scientists have now been relegated to a "second tier" below researchers in other countries.[75] Another concern was that a restrictive environment means that Australia cannot benefit from the

[66] Issues Paper, n 4, p 11; Robertson JA, "Human Embryonic Stem Cell Research: Ethical and Legal Issues" (2001) 2 (1) *Nature Reviews: Genetics* 74.

[67] Legislation Review Committee Report, n 3, pp 40-53.

[68] Oral evidence, Justin Lees, Diabetes Transplant Unit, Prince of Wales Hospital, Sydney, LRC 441; Legislation Review Committee Report, n 3, p 50.

[69] Legislation Review Committee Report, n 3, p 47.

[70] LRC 985, Centre for Worldwide Studies, p 5. See also Wertheim M, "Clones, Stem Cells and the Future of Medicine" (2002) 23 (8) *Australian Science* 23 at 27.

[71] Legislation Review Committee Report, n 3, p 63.

[72] LRC 450, AusBiotech Ltd, p 9; LRC 614, Australian Association of Neurologists. See Legislation Review Committee Report, n 3, p 62; Issues Paper, n 4, p 11.

[73] LRC 318, Stem Cell Sciences Ltd; Legislation Review Committee Report, n 3, p 62.

[74] LRC 930, Queensland Government, p 7; LRC 396, Stem Cell Ethics Australia, p 6; LRC 450, AusBiotech Ltd.

[75] LRC 450, AusBiotech Ltd, pp 15, 21; LRC 819, Sydney IVF.

economic potential of such research, such as in attracting international private investment.[76] Some submissions expressed a fear that eminent Australian scientists, along with research investment, will be tempted overseas into less restrictive jurisdictions and pointed out that Australia had already lost some of its scientists to countries such as Singapore.[77] This was described in one submission as "the loss of intellectual and creative capital".[78] Concern was also expressed that the current restrictions on the SCNT process and the importation of SCNT embryos and stem cell lines into Australia has meant that Australian scientists have been unable to participate in, or further develop, certain types of research.[79]

In contrast, the key assertion presented in submissions against any form of embryonic stem cell research was the concern that such research is unethical as it involves the destruction of the embryo itself and that this raises "right to life" issues.[80] It was stated that "it is inconsistent with the dignity belonging to human beings to freeze them, call them 'excess' as if they were an assembly line product, and use them for destructive purposes".[81] Regarding the potential for stem cells derived from SCNT embryos to create medical therapies, one submission stated that "human beings are not to be treated as custom made repair kits for other diseased bodies".[82]

These contentions were based on two fundamental principles:

- that an embryo is "human life", as fertilisation begins the process of life and that such a being should be protected by society from the time that it comes into existence;[83] and
- that to allow embryos to be used in research treats them as a product or unit of commerce, a position that has been described as "the commoditisation of children".[84] There was a concern that by allowing excess ART embryos to be used as what was termed "laboratory material, we are establishing human embryos as a resource, the demand for which may continue and increase".[85]

There was also concern that to permit SCNT would lead Australia down the path of human reproductive cloning.[86] However, an alternative argument that has previously been raised is that a more reasonable stance would be to acknowledge that the divide between SCNT, also referred to as "therapeutic cloning", and the practice of "reproductive cloning" is clear and that it is not necessary to prevent SCNT and relinquish all of the medical benefits that it may offer, merely to address concerns about reproductive cloning.[87]

Another key contention was that embryonic stem cell research is unnecessary as research on adult stem cells can achieve the same results.[88] This argument is premised on the basis that, to date, no successful stem cell therapies have been developed from embryonic stem cells. However, adult stem cells have already been used to treat human diseases, eg by the use of bone marrow transplants. Such submissions argued that adult stem cells can also be derived from the patient, avoiding any problems

[76] LRC 930, Queensland Government, p 7; LRC 396, Stem Cell Ethics Australia, p 6.

[77] LRC 509, Monash University; LRC 308 SpinalCure Australia, p 3, LRC 396, Stem Cell Ethics Australia, p 6.

[78] LRC 450, AusBiotech Ltd, p 8.

[79] Legislation Review Committee Report, n 3, p 133.

[80] Luntz S and Nolsch G, "Stem Cells: Embryo Research: The Next Battle" (2002) 23 (4) *Australasian Science* 20 at 21; LRC 451, Southern Cross Bioethics; Legislation Review Committee Report, n 3, p 61.

[81] LRC 376, Queensland Right to Life.

[82] LRC 486, Bioethics Committee of Uniting Church in Australia, Synod of Victoria.

[83] LRC 376, Queensland Right to Life.

[84] LRC 376, Queensland Right to Life.

[85] LRC 376, Queensland Right to Life; LRC 672, Anglican Diocese of Sydney, p 3. This argument has been put forward by Finnis J, "Some Fundamental Evils in Generating Human Embryos by Cloning" in Mazzoni CM (ed), *Ethics and Law in Biological Science* (Kluwer Academic Publishers, 2002) pp 104-106.

[86] LRC 364, Queensland Institute of Medical Research, p 2; LRC 672, Anglican Diocese of Sydney, p 3; LRC 451, Southern Cross Bioethics; Legislation Review Committee Report, n 3, p 61.

[87] Robertson, n 66 at 77.

[88] LRC 895, Centre for Worldview Studies. Sources of adult stem cells include umbilical cord blood and bone marrow.

of rejection when reintroduced into the patient's body.[89] The Review Committee noted that one United States research group has reported having success in making tailor-made embryonic stem cells; however, this research had not been published in peer-reviewed literature at the time the Lockhart Report was released.[90]

The fact that the SCNT process is very resource- and labour-intensive was also raised. For example, Professor Alan Mackay-Sim stated that the process is "a long and laborious procedure" and that his team had created over 40 adult stem cell lines.[91] However, he conceded that such advances in adult stem cell research should not mean that researchers are prevented from exploring the potential of embryonic stem cell research.[92] Other submissions argued that it is too early to determine whether adult stem cell research will be capable of developing therapies to treat some afflictions, such as spinal cord injuries, and that scientists should have access to both types of research in order to fully develop the range of possible medical therapies.[93]

Concerns were also expressed that the development of stem cell lines would require a supply of human eggs and that this could lead to the "manipulation and exploitation of women in order to obtain eggs".[94] Some submissions also raised fears that couples engaged in fertility treatment may be encouraged by ART clinics to donate their embryos, when they otherwise would have maintained them in storage for later reproductive use. Others respondents pointed out that there are currently strict ethical guidelines regulating the donation of excess ART embryos to research which could be mirrored in the ethical requirements for egg donation to the SCNT process.[95] A submission from Sydney IVF suggested that egg donation for stem cell therapies could be managed as organ donation is currently. If the patient was female, her own ooctyes could be used to develop a stem cell therapy. If the patient was a male or female not of egg-producing age, a relative, friend or stranger could choose to donate their eggs for the creation of such a therapy.[96]

In support of a less restrictive environment was the contention that Australia purports to uphold the principles of a liberal democracy, and that liberal values support the contention that couples engaging in ART procedures should have the freedom to choose the fate of their own genetic material.[97] It follows that the creating couple should decide whether to donate their excess ART embryos to stem cell research, regardless of the disapproval of some sections of the community. This view was expressed in the submission from SpinalCure Australia[98] which quoted recent surveys carried out by the ACCESS Infertility Network that revealed that almost 60% of IVF couples were prepared to donate their excess embryos to research.[99] The submission also quoted surveys carried out by Biotechnology Australia showing that the percentage of Australians who support the use of excess ART embryos in medical research has increased from 53% in 2002 to 65% in 2005.[100]

[89] LRC 217, Professor Alan Mackay-Sim, Deputy Director, Eskitis Institute for Cell and Molecular Therapies, Griffith University; LRC 376, Queensland Right to Life; LRC 361, Australian Family Association.

[90] Legislation Review Committee Report, n 3, p 58.

[91] This submission revealed that the professor and his team had created over 40 adult stem cell lines derived from people with schizophrenia, Parkinson's disease and motor neurone disease: LRC 217, Professor Alan Mackay-Sim, Deputy Director, Eskitis Institute for Cell and Molecular Therapies, Griffith University.

[92] LRC 217, Professor Alan Mackay-Sim, Deputy Director, Eskitis Institute for Cell and Molecular Therapies, Griffith University.

[93] LRC 509, Monash University; LRC 308, SpinalCure Australia.

[94] LRC 419, Queensland Bioethics Centre and Archbishop Bathersby and the Archdiocese of Brisbane.

[95] NHMRC Ethical Guidelines, n 20; LRC 246, National Civic Council; Legislation Review Committee Report, n 3, p 65.

[96] LRC 819, Sydney IVF, p 9.

[97] For a discussion of liberalism, including the emphasis on individual rights, see Bottomley S and Parker S, *Law in Context* (2nd ed, Federation Press, Sydney, 1997) pp 22-38.

[98] LRC 308, SpinalCure Australia, p 4.

[99] LRC 308 SpinalCure Australia.

[100] LRC 308, SpinalCure Australia.

This argument that liberal ideals should be upheld was also used to contend that ART couples should be able to transport their embryos overseas, without having to obtain the approval of the Minister for Customs, as is currently required.[101] For example, the submission from Sydney IVF called for the lifting of the current tight restrictions on exporting human embryos, which were referred to as an "interference with a couple's dominion over their reproductive intentions".[102]

There was much support among the scientific community for a national stem cell bank. Submissions spoke of the benefits of ensuring that scientists would have maximum exposure to a large variety of stem cell lines and that such lines would be of international quality. It was thought that a stem cell bank would ensure the most efficient use of available embryos and prevent scientists from creating the types of stem cell lines that are already in existence.[103] Such submissions also requested a lift on the ban of importing, and of the restrictions placed on the exporting, of stem cells in order that research can progress. It was argued that such stem cell lines could come from approved international stem cell banks.[104] One submission stated: "The exchange of information and materials between laboratories is the lifeblood of science, and is essential in order for experiments to be replicated."[105]

Although submissions made to the Lockhart Review contained many conflicting policy positions, the Review Committee basically resolved this conflict by adopting a utilitarian approach. The Committee reasoned that whether sections of the community were of the view that the creation and destruction of a human embryo for research purposes was morally right or wrong, it was demonstrated that the research is overwhelmingly for the public benefit, and it therefore should be allowed to progress.[106] The Committee therefore rationalised that the good that stem cell research may have the potential to provide should prevail over the many ethical and practical concerns of various sectors of the Australian community. It concluded:

> The social and moral value that some communities attach to the human embryo needs to be balanced against the social and moral value that other communities attach to the treatment of disease and to helping people to have a family.[107]

As a result of this approach, the Lockhart recommendations reveal that the Review Committee has taken a very progressive and pragmatic approach towards Australian human embryo research.

THE RELEVANT RECOMMENDATIONS OF THE LOCKHART REVIEW REPORT

The key recommendations of the report are that the creation of embryos by nuclear transfer should be legalised and that all excess ART embryos, not just those created prior to a particular date, should continue to be available for donation to research. The Review Committee also recommended that public education and consultation be conducted in the areas of embryo research so that the general community can understand the proposed legislative amendments.[108]

The Review Committee acknowledged that many submissions raised ethical concerns with the creation and destruction of human embryos for research purposes. However, the Committee was of the view that the strongest objections from the community were that the legalising of the creation of SCNT embryos would lead to the practice of reproductive cloning.[109] It agreed that the reproductive

[101] LRC 218, Adrianne Pope, Fertility Society of Australia and Monash IVF. It was also submitted that the current requirements make the process of obtaining approval to transport embryos overseas "very slow and cumbersome".

[102] LRC 819, Sydney IVF, p 25.

[103] LRC 450, AusBiotech Ltd, p 19; LRC 790, National Health and Medical Research Council, p 16.

[104] LRC 450, AusBiotech Ltd, p 18.

[105] LRC 449, Third Year Bachelor of Biomedical Science Students, University of Melbourne.

[106] Beauchamp TL and Childress JF, *Principles of Biomedical Ethics* (5th ed, Oxford University Press, New York, 2001) pp 340-343.

[107] Legislation Review Committee Report, n 3, p xiii.

[108] Legislation Review Committee Report, n 3, p xxi.

[109] Legislation Review Committee Report, n 3, p xiv.

cloning of humans was ethically unacceptable and that there were safety issues associated with such technology.[110] However, the Committee was satisfied that Australian scientists had no intention of engaging in reproductive cloning and that if the practice continued to be illegal this would ensure that it would not occur.

The Lockhart Review recommended that the creation of embryos by the nuclear transfer process be permitted, under licence, "to create and use human embryo clones for research, training and clinical application, including the production of human embryonic stem cells".[111] This recommendation was on the proviso that it would be illegal to implant the resulting embryos into the body of a woman or to develop them in vitro for more than 14 days.[112]

The Committee was of the view that all excess ART embryos should continue to be available for donation to research, provided that the couple provide informed consent. The Committee recommended that the use of such embryos "continue to be permitted, under licence, for research, training and other uses to improve the practice of ART".[113] As there was evidence that there had been more excess ART embryos donated than there were research projects to utilise them, the Committee suggested that a register of excess ART embryos be established to ensure the most efficient use of such a valuable resource.[114] The Review Committee was also of the view that embryos rejected through the pre-implantation genetic diagnosis process should be permitted to be used in research, and for training and clinical practice, rather than being discarded. It was considered that ethical guidelines needed to be established in this regard.[115]

Another important recommendation was that the definition of "embryo" be amended in both the *Prohibition of Human Cloning Act 2002* (Cth) and the *Research Involving Human Embryos Act 2002* (Cth) to ensure that the starting phase of an embryo would be defined at a later stage than is currently provided for in the legislation, and to include embryos created other than by fertilisation, eg, by the nuclear transfer process. The Committee was concerned that many important research practices were currently illegal due to the earlier starting phase of the definition of "embryo", eg, research on the culture and maturation of immature eggs, termed "in vitro maturation of oocytes".[116] The Committee reasoned that adopting a definition of "embryo" at a slightly later stage of the development process would enable much valuable research to occur which was not currently legal.

The current legislative definition provides that the starting point of an embryo is the appearance of two pro-nuclei.[117] Submissions made to the Review Committee highlighted that this has prevented any research requiring experimental fertilisation of an egg with sperm because, once the two pronuclei are visible, according to the definition, an embryo has been created and the creation of an embryo for research purposes is not permitted.[118] This definition has also prevented a range of research to improve ART processes such as the testing of sperm quality and fertilisation research.[119] Further, the

[110] Legislation Review Committee Report, n 3, p 55.

[111] Legislation Review Committee Report, n 3, Recommendation 23, p 172.

[112] Legislation Review Committee Report, n 3, Recommendation 23, p 172.

[113] Legislation Review Committee Report, n 3, p xv.

[114] Legislation Review Committee Report, n 3, p xvi.

[115] Legislation Review Committee Report, n 3, p xvi.

[116] Legislation Review Committee Report, n 3, p xv, sets out other research practices that are currently not permitted under the present definition of "embryo".

[117] The current definition of "embryo" is "a live embryo that has a human genome or altered 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": *Prohibition of Human Cloning Act 2002* (Cth), s 8.

[118] *Prohibition of Human Cloning Act 2002* (Cth), s 14.

[119] Legislation Review Committee Report, n 3, p 30.

definition of "human embryo clone" currently includes parthenogenetically activated oocytes, which renders the creation of such an entity illegal, preventing research on activated oocytes.[120]

The Review Committee considered that a better starting point for a human embryo was when the maternal and paternal chromosomes align and a new genetic entity is formed,[121] termed "syngamy".[122] The Review Committee concluded that, as this is difficult to pinpoint, the definition should refer to the first cell division. The following amended definition of "human embryo" was proposed:

> A human embryo is a discrete living entity that has a human genome or an altered human genome and that has arisen from either:
>
> (i) the first mitotic cell division when fertilisation of a human oocyte by a human sperm is complete; or
>
> (ii) 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, 14 days
>
> and has not yet reached eight weeks of development.[123]

The Review Report also suggested that human embryos should be permitted to be created by other scientific methods. It recommended that all nuclear and pronuclear transfer methods (including transfer of stem cell nuclei) should be permitted, under licence. It also suggested that parthenogenetic activation of oocytes be permitted to allow oocyte maturation research.[124] The report also canvassed recommendations that the creation of embryos using the genetic material from more that two people should be legalised, along with the creation using precursor cells from a human embryo or fetus.[125] It was also of the view that cytoplasmic transfer (including transfer of mitochondrial DNA) be permitted for research on mitochondrial diseases and to improve ART treatment.[126]

It was considered that the current process of HREC then NHMRC, Embryo Research Licensing Committee approval, to obtain a licence to conduct embryo research, should continue. It was suggested that the Licensing Committee powers be widened to include the consideration of licences for nuclear transfer and the other processes which would be legalised, if the recommendations are implemented. It was also considered that the Licensing Committee should have increased powers to exercise discretion when considering research proposals which do not fit squarely within the legislative guidelines, so that constant legislative amendments are not required.[127] It suggested that the Licensing Committee be given the power to make binding rulings on the interpretation of legislation and the ability to grant licences on the basis of those rulings, providing regular reports to the NHMRC and Commonwealth Parliament.[128]

The Review Committee was of the view that ART consumers should be able to more easily transport their embryos out of the country if they were moving and wishing to continue their ART treatment. It also recommended that the import and export of ethically derived human embryo clones and human embryonic stem cell lines should be permitted, provided that approval had been obtained from the relevant authority.[129] This was on the basis that there continue to be a prohibition on any

[120] Legislation Review Committee Report, n 3, p 30.

[121] Legislation Review Committee Report, n 3, p 173.

[122] "Syngamy" means "The stage of fertilization when the chromosomes from the male and female pronuclei combine into a single diploid set": Legislation Review Committee Report, n 3, Glossary, p 252.

[123] Legislation Review Committee Report, n 3, Recommendation 28, p 174.

[124] This process is permitted in the United Kingdom. See n 12.

[125] Legislation Review Committee Report, n 3, Recommendations 25-27, p 172.

[126] Legislation Review Committee Report, n 3, Recommendation 19, p 168.

[127] Legislation Review Committee Report, n 3, Recommendations 50-53, p 183.

[128] Legislation Review Committee Report, n 3. Recommendations 50-53.

[129] Legislation Review Committee Report n 3, p xx.

trade in human gametes or embryos.[130] The Committee was also of the belief that a national stem cell bank would be an effective way to progress medical research, as it would provide scientists with a wide variety of stem cell lines, the ability to be aware of the types of stem cell lines already in existence, and would also improve quality control.[131]

For many sectors of Australian society these recommendations are controversial. It is therefore interesting to compare the approach of the Lockhart Review to that of overseas jurisdictions. It is also of benefit to examine where the recommendations, if adopted, would position Australia in terms of worldwide human embryo research.

WHERE WOULD THE LOCKHART RECOMMENDATIONS POSITION AUSTRALIA?

Around the world, it could be argued that the most permissive approach in relation to embryo research is to allow the creation of embryos by both fertilisation and nuclear transfer, for research purposes. This is the current position in the United Kingdom, Belgium and China.[132] The next most liberal position could be said to be where the country permits the creation of SCNT embryos for research, but restricts the creation of embryos by fertilisation to ART procedures to assist couples to have children. In these countries excess ART embryos can be donated to research, provided that the creating couple gives informed consent. This is the approach contemplated by the Lockhart recommendations. It is also the approach in countries such as Singapore and South Korea.[133]

The next most liberal position could be described as the situation where the country only permits research on excess ART embryos and does not permit the creation of "human embryo clones" by nuclear transfer. There is no restriction on when the ART embryos were created or when the stem cells were derived. This is the current situation in Australia. A more restrictive position is where research can only occur on embryonic stem cell lines derived from excess ART embryos already in existence. For example, in the United States, federal funding can only be obtained where the stem cells were derived prior to 9 August 2001.[134] This was previously the position in Australia when research was only permitted on excess ART embryos created prior to 5 April 2002. An even narrower position is in countries such as Italy and Iceland where research is only permitted on excess ART embryos for the purpose of improving ART processes. Overall, the most extreme position is that no research on any embryos or on existing embryonic stem cell lines is permitted; this is the position in countries such as Austria.

Although the United States has a restrictive approach in relation to federally funded research,[135] it should be noted that States such as California[136] and New Jersey[137] have enacted legislation that permits SCNT. One of the most liberal jurisdictions, the United Kingdom, has permitted the creation of embryos via SCNT since 2001.[138] Scientists in the United Kingdom use eggs which would ordinarily be disposed of by ART clinics, as they have failed to fertilise when mixed with sperm, and

[130] Legislation Review Committee Report n 3, p xx.

[131] Legislation Review Committee Report, n 3, Recommendations 47-48, p 181.

[132] Biotext Pty Ltd, *Human Embryos, Stem Cells and Cloning – Developments in Research and Regulations Since 2001, Literature Review* (prepared for the Department of Health and Aging, August 2005) pp 93-107: see http://www.lockhartreview.com.au/public/content/ViewCategory.aspx?id=34 viewed 6 February 2006.

[133] Biotext Pty Ltd, n 132, pp 93-107.

[134] Biotext Pty Ltd, n 132, p 104.

[135] *Human Cloning Ban and Stem Cell Research Protection Act 2003* (US). This legislation bans human reproductive cloning and provides ethical requirements for SCNT. It does not provide that SCNT is illegal. *Guidelines on Human Embryonic Stem Cells* have recently been released by the United States National Research Council.

[136] Senate Bill 253.

[137] Assembly No 2840.

[138] *Human Fertilisation and Embryology (Research Purposes) Regulations 2001* (UK).

donated oocytes, in the SCNT process. A United Kingdom research team has recently achieved the creation of embryonic stem cell lines from nuclear transfer.[139]

South Korea had been thought to be the world leaders in stem cell research, having reported in 2004 that they had become the first research team in the world to create an embryonic stem cell line through SCNT.[140] In 2005 it was reported that this research team had successfully produced tailor-made stem cell lines.[141] However, these research results have recently been discredited.[142]

Although the Lockhart recommendations would not take Australia as far as the position in the United Kingdom where embryos can be created by both fertilisation and SCNT for research purposes, they would place Australia alongside or ahead of this jurisdiction in some respects, such as with the suggested change to the definition of "embryo", referring to the first cell division. This would permit research to take place while the egg is being fertilised. The current definition of "embryo" in the *Human Fertilisation and Embryology Act 1990* (UK) includes human eggs "in the process of fertilisation". The effect is to restrict scientists conducting research during fertilisation. Therefore some of the research that would be legalised by the Lockhart recommendations is not currently able to take place in the United Kingdom.[143]

The United Kingdom is currently undertaking a review of this Act. Several issues being examined have arisen because the Act was passed in 1990 when some of the technology used today was not even envisaged. For example, the Act does not currently include in its definition of "embryo" entities created by SCNT, as this technology was not available in 1990. The United Kingdom courts have ruled that the legislative definition of "embryo" applies to all human embryos, whether created by fertilisation or by SCNT.[144] However, the United Kingdom review is currently looking at whether the legislative definition should be amended to provide clarity.[145] The Lockhart recommendations would ensure that a SCNT embryo is included in the Australian legislative definition of "embryo".[146]

The United Kingdom review is also looking at whether there should be legislative amendment to permit the creation of embryos via SCNT specifically for therapeutic purposes, such as the creation of medical stem cell therapies, which is currently not explicitly provided for in the legislation.[147] The Lockhart Report has covered this by providing that the creation of embryos by nuclear transfer can occur for "clinical application" in addition to the purposes of research and training.[148]

The creation of embryos for research by SCNT is currently permitted in the United Kingdom; however, the legislation does not permit the use of SCNT techniques on embryos after they have been created. This has implications for research into mitochondrial disorders which cause many inherited diseases.[149] The Lockhart recommendations state that SCNT should be permitted under licence "to create and use human embryo clones for research" which appears to address this issue.[150]

The Lockhart Committee also suggested that, in order to reduce the need for human oocytes, nuclear transfer of human somatic cell nuclei into animal oocytes be permitted, under licence, for the

[139] Legislation Review Committee Report, n 3, p 58.

[140] Legislation Review Committee Report, n 3, p 58.

[141] Legislation Review Committee Report, n 3, p 58.

[142] Sang-Hun C, "Discredited Stem Cell Scientist Apologises in South Korea", *New York Times (online)* (12 January 2006): see http://www.nytimes.com/2006/01/12/international/asia/12cnd-clone.html?ex=1294722000&en=bdab8d932ccda6d5&ei=5088&partner=rssnyt&emc=rss viewed 7 February 2006.

[143] *Human Fertilisation and Embryology Act 1990* (UK), s 1. The definition is currently under review as part of an overall review of the *Human Fertilisation and Embryology Act 1990* (UK): Department of Health, n 13 at [2.26].

[144] *R (on the application of Quintavalle) v Secretary of State for Health* [2003] UKHL 13.

[145] United Kingdom Department of Health, n 13 at [9.46].

[146] Legislation Review Committee Report, n 3, Recommendation 28, p 174.

[147] United Kingdom Department of Health, n 13 at [9.46].

[148] Legislation Review Committee Report, n 3, Recommendation 23, p 172.

[149] United Kingdom Department of Health, n 13 at [9.21].

[150] Legislation Review Committee Report, n 3, Recommendation 23, p 23.

creation of embryos for research, training and clinical application, including the production of human embryonic stem cells.[151] This issue is currently being discussed in the United Kingdom review as, at present, the only permitted practice is the mixing of human sperm and animal eggs for testing the fertility or the normality of human sperm.[152]

In the United Kingdom, the *Human Fertilisation and Embryology Act 1990* (UK) established the Human Fertilisation and Embryology Authority (HFEA).[153] For a research team to conduct research involving the creation of embryos by nuclear transfer and the extraction of stem cells, they must obtain a licence from the HFEA.[154] Approval from an external research ethics committee is also required before the application can be considered. The permitted purposes for obtaining a licence to conduct research involving SCNT or excess ART embryos are more explicitly defined than in the current Australian legislation. To obtain a licence in the United Kingdom, the proposed research must fall within one of the following permitted research activities:

- promoting advances in the treatment of infertility;
- increasing knowledge about the causes of congenital disease;
- increasing knowledge about the causes of miscarriages;
- developing more effective techniques of contraception;
- developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation;[155]
- increasing knowledge about the development of embryos;
- increasing knowledge about serious disease; or
- enabling any such knowledge to be applied in developing treatments for serious disease.[156]

Further, to obtain a licence an applicant must also:

- justify the use of human embryonic stem cells rather than adult stem cells;
- provide detailed information about the fate of the stem cells throughout the research process; and
- provide a sample of all cell lines to the United Kingdom Stem Cell Bank.

The United Kingdom Stem Cell Bank was established in 2002, hosted by the National Institute of Biological Standards and Control (NIBSC). The bank provides a repository for human stem cell lines and also ensures the quality of stem cell lines for use in research and therapy. It has established a central point for the dissemination of research results and research best practice.[157] Two Australian-derived stem cell lines have been accepted by this United Kingdom bank.[158]

The Stem Cell Bank is ultimately controlled by the Medical Research Council which has a draft Code of Practice for the use of human stem cells, including embryonic stem cells. The code provides that "human embryonic stem cell lines are only used by bona fide research groups for justified and valuable purposes that reflect the requirements of the HFEA regulations". These are:

- research that increases the knowledge about the development of embryos or has the long-term goal of helping to increase knowledge about serious diseases and their treatment;
- basic cell research that underpins these aims; and

[151] Legislation Review Committee Report, n 3, Recommendation 24, p 172.

[152] The result of the mixed gametes must be destroyed when the test is complete and no later than the two-cell stage: *Human Fertilisation and Embryology Act 1990* (UK), Sch 2, s 1(1)(f).

[153] *Human Fertilisation and Embryology Act 1990* (UK), s 5.

[154] *Human Fertilisation and Embryology Act 1990* (UK), s 9.

[155] *Human Fertilisation and Embryology Act 1990* (UK), Sch 2, s 3(2).

[156] The last three purposes were added in 2001 by the *Human Fertilisation and Embryology (Research Purposes) Regulations 2001* (UK).

[157] It is overseen by a Steering Committee and is administered by a Management Committee comprising members from research, academia, health care bodies, regulatory bodies and a lay member: see United Kingdom Stem Cell Bank at http://www.ukstemcellbank.org.uk/Overview.html viewed 7 February 2006.

[158] LRC 790, National Health and Medical Research Council, p 16.

- development of cell-based therapies for clinical trials in respect of serious human diseases.[159]

The Code of Practice does not require research ethics approval for research conducted on established embryonic stem cell lines; however, it does expect (but not explicitly require) scientific peer review of such research.

The regulatory position in the United Kingdom provides Australia with an existing example of how human embryo research, particularly the issuing of licences to create SCNT embryos, can be effectively regulated. Australia can also look to its own experience with the issuing of licences for research on excess ART embryos and the requirements of other jurisdictions. For example, in Australia, to obtain a licence to use excess ART embryos for research, the application must demonstrate that the research "could not be reasonably achieved by other means" than the use of such embryos and that the numbers of embryos used is limited to those required for the research outcome.[160] In Belgium, embryos can be created both by both fertilisation and by SCNT for research purposes. However, to obtain permission to create embryos by fertilisation, the research team must demonstrate that their project cannot be carried out on excess ART embryos.[161] In The Netherlands, surplus ART embryos can be created for research; however, the research must be important to medicine and approved by a Central Committee on Research Involving Human Subjects. Further, it must be shown that the research aims can only be met by the use of such embryos.[162]

It is clear that Australian legislators can benefit from examining the overseas experience. It is particularly helpful in assessing what the way forward for Australia should be in terms of amendments to the existing Commonwealth legislation regulating stem cell research.

SUGGESTED FUTURE APPROACH

The Lockhart submissions highlight the concerns of Australian researchers that, without access to sufficient stem cell lines and to the SCNT process, this country is falling behind many of its overseas competitors in its progress in stem cell research. Submissions from some State governments also expressed concern as to the economic implications of such a restrictive research environment.[163] Other submissions, particularly from the scientific community, representative organisations and relatives of patients, focused on the future promise that embryonic stem cell research holds for the development of successful medical therapies. In contrast, there were countless submissions objecting to such research on the grounds that it is clearly unethical and involves harm to human life.

It is argued that Australia is a liberal democracy and, as such, should uphold liberal values in relation to these issues. Couples participating in ART procedures should have the freedom to choose the fate of their excess embryos, including whether to donate them to stem cell research. They should also have the reproductive freedom to transport their embryos overseas, without having unnecessary bureaucratic restrictions imposed upon them.

Australia should follow the pragmatic lead of the United Kingdom and an overall approach premised on the liberal philosophical theory of utilitarianism should prevail. That is, the potential benefit to countless Australians of stem cell therapies should be accorded more weight than the objections of some sectors of the Australian community, which are often premised on individual religious values. Australia is a secular society consisting of people professing adherence to many different religious and moral values. Although successful embryonic stem cell therapies have yet to be developed, it is clear that there is the potential for such treatments to be developed in the foreseeable future.[164]

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[159] Medical Research Council, *Code of Practice for the Use of Human Stem Cell Lines* at [8.1.1]: see http://www.mrc.ac.uk/pdf-public-stem_cell_code_of_practice_june2005.pdf viewed 7 February 2006.

[160] *Research Involving Human Embryos Act 2002* (Cth), s 21(4).

[161] *Law on Embryo Research Act 2003* (Belg), s 4(1).

[162] *Embryos Act 2002* (Neth), s 11.

[163] LRC 930, Queensland Government; LRC 1016, New South Wales Minister for Science and Medical Research.

[164] LRC 396, Stem Cell Ethics Australia.

Many submissions to the Lockhart Review strongly favoured Australia taking a more progressive approach in relation to embryo research, as is currently the case in jurisdictions such as the United Kingdom.[165] Such submissions contended that the legal position in this country achieves a fair balance between assuring the community that reproductive cloning will not occur, while also permitting a more liberal research environment so that real progress towards embryonic stem cell therapies can be made.[166] This has meant that scientists in the United Kingdom have been conducting valuable research, such as research on mitochondrial diseases, that would not currently be legal in Australia.[167]

The Lockhart Report has suggested that legislation could prescribe the specific requirements that would have to be satisfied before a licence to create SCNT embryos for research could be issued. At present, an Australian research application to use excess ART embryos must display "a significant advance in knowledge or improvement in technologies for treatment". It is now open to the Australian Parliament to more clearly define the legislative requirements for SCNT research, as has been the case in the United Kingdom. The *Research Involving Human Embryos Act 2002* (Cth) could be amended to set out the specific research aims that would need to be addressed by eligible projects. Such aims could accord with the areas of research considered to have the highest priority in terms of the anticipated benefit to the community. The legislation could also provide that a licence could only be issued when the proposed research could not be effectively conducted on adult stem cells or excess ART embryos. It could also restrict the number of embryos permitted to be created to those strictly necessary to fulfil the goals of the research project. A further requirement could be that a sample of all resultant stem cell lines be provided to an established national stem cell bank.

Australian scientists have made it clear that they are not interested in pursuing human reproductive cloning and are only interested in the nuclear transfer process for the potential medical benefits it can bring to many Australians. This process is currently permitted in such countries as the United Kingdom, some States of the United States, Singapore, South Korea and Belgium. There is real concern in the scientific community that Australia "has lost some of its biotechnology lead in stem cell science to countries that do not ban nuclear transfer".[168] We now must place such an important issue in the hands of the Parliament to draft legislation that allows stem cell research to progress to its fullest potential, while ensuring that the research is conducted in a manner that can provide the most effective benefit to our community.

[165] LRC 450, AusBiotech Ltd; LRC 396, Stem Cell Ethics Australia.

[166] LRC 450, AusBiotech Ltd, p 5.

[167] United Kingdom Department of Health, n 13 at [9.21].

[168] LRC 18, Australian Academy of Science, p 4.