Submission to Senate Community Affairs Committee

- Legislative responses to recommendations of the reports of the Legislation Review Committee on the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* (the Lockhart review).

By Donna Cooper, Lecturer, Queensland University of Technology, member Health Law Program
d.cooper@qut.edu.au

One submission to the Lockhart Review from leading Australian scientists stated of the SCNT process that 'denial of access to this technology will severely hamper Australian medical research.'[1] This submission further explained, 'while SCNT employs aspects of cloning technology, its goal is not to produce a clone or copy of an existing individual, but rather to achieve reprogramming of an adult cell nucleus in order to develop pluripotent stem cell lines for use in research or therapy.'[2]

The use of the term 'therapeutic cloning' has led to many public misconceptions in relation to the nuclear transfer process. It is submitted that due to this, it would be preferable if the term 'cloning' could be deleted from any future legislation and that instead, terms such as 'somatic cell nuclear transfer' (SCNT) or 'nuclear transfer' could be used.

The following submission summarises out some of the key reasons in support of the SCNT process being legalised in Australia.[3]

[1] Lockhart Review Committee Submission ('LRC') 509 Professor Pera, Professor Trounson et al at 2.
[2] Ibid at 7.
[3] Many of these submissions have been derived from the following articles: Donna Cooper, 'The Lockhart Review: Where now for Australia?' (2006) 14 *Journal of Law and Medicine* 27 available at <http://www.aph.gov.au/senate/committee/clac_ctte/leg_response_lockhart_review/legis_doc/sen_patterson_tabled_docs.htm> and Donna Cooper, 'The Lockhart Report and the ethics of the creation and destruction of preimplantation embryos for medical research purposes' (2006) 25 (2) *Monash Bioethics Review* 9 available at <http://www.arts.monash.edu.au/bioethics/cooper.html> viewed 4 October 2006.

A majority of the Standing Committee involved in the Andrews Report favoured legalisation of SCNT

In 2001, prior to the drafting of the current legislation covering stem cell research, the issues surrounding human embryo research, including the creation of embryos by nuclear transfer, were investigated by the House of Representatives Standing Committee on Legal and Constitutional Affairs. As a result, a report, known as 'the Andrews Report', was presented to Commonwealth Parliament making various recommendations.[4]

The Andrews Report revealed that a majority of the Standing Committee supported SCNT being legalised, primarily on the basis of the potential for such research to develop stem cell therapies to treat various diseases.[5] Only a minority of the committee were opposed to such research due to concerns about the ethics of the destruction of human embryos for research. 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 at that time no reported success with embryonic stem cell therapies.

As the potential of embryonic stem cell research was unclear at that time and there appeared to be a sufficient supply of stem cells being derived from excess ART embryos, the Standing Committee reached 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.

It is submitted that the evidence presented to the Lockhart Review Committee revealed that considerable progress has been made since the time of the Andrews Report in the development of stem cell research.[6] Although stem cell therapies have not yet been successfully developed, scientists are certainly closer to that goal. Both

[4] House of Representatives Standing Committee on Legal and Constitutional Affairs, The Parliament of the Commonwealth of Australia, *Human Cloning: Scientific, ethical and regulatory aspects of human cloning and stem cell research* (August 2001) ("The Andrews Report").
[5] The Andrews Report, ibid [7.109].
[6] Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002: Reports* (December 2005) ("The Report") at <http://www.lockhartreview.com.au/> viewed 3 October 2006.

Senators Patterson and Stott-Depoja have provided evidence, in the form of academic articles, detailing the scientific progress that has been made.[7] Further, scientists provided considerable information to the Lockhart Review as to the properties that SCNT embryos possess that are not possessed by adult stem cells or even stem cells derived from excess ART embryos, which should now convince us of the value of legalisation of the SCNT process.[8] There was also an extensive literature review prepared for the Lockhart Review which set out in great detail scientific developments in the field.[9]

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.[10] This means that they may have the potential to treat any condition in which a patient's cells are damaged or diseased. There are 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.[11] 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.[12] The likely benefits to medical research of the SCNT process have been set out in detail in submissions made to the Lockhart Review.[13]

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[7] Documents tabled in the Senate on 14 September 2006 by Senator Patterson available at <http://www.aph.gov.au/senate/committee/clac_ctte/leg_response_lockhart_review/legis_doc/sen_patterson_tabled_docs.htm> viewed 4 October 2006. Commonwealth of Australia, Senate, Senator Stott-Despoja's Introductory Speech, Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006 available at <http://www.aph.gov.au/senate/committee/clac_ctte/leg_response_lockhart_review/legis_doc/intro_speech.htm> viewed 4 October 2006.

[8] See for example LRC509 Professors Pera and Trounson et al at 10-14.

[9] Biotext Pty Ltd, Prepared for the Department of Health and Aging, *Human Embryos, stem cells and cloning – developments in research and regulations since 2001*, Literature Review (August 2005) at xxxii-xxiv and Chapter 7 at <http://www.lockhartreview.com.au/committeedocs.html> viewed 4 October 2006.

[10] "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)." The Report, Glossary at 251.

[11] 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") at 11. Robertson JA, "Human embryonic stem cell research: ethical and legal issues" (2001) 2(1) *Nature Reviews: Genetics* 74.

[12] LRC308 SpinalCure Australia at 2.

[13] See for example LRC509 Professors Pera and Trounson et al at 10-14.

SCNT showing strong potential towards the development of successful medical therapies

The evidence presented to the Lockhart 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.[14]

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.'[15]

Although some submissions to the Lockhart Review conceded that it could take up to ten years before existing research is realised in medical treatments, it was strongly argued that this should not be a reason for prohibiting such research.[16] Further, 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.[17] Some submissions also argued that disease specific stem cell lines can also be of benefit to the pharmaceutical industry when screening new drugs.[18]

Other submissions to the Lockhart Review detailed the developments made in stem cell research revealing, for example, that research performed on animals has shown some promise that stem cell therapies have the potential to improve the function of

[14] The Report at 40-53.
[15] Oral evidence, Mr Justin Lees, Diabetes Transplant Unit, Prince of Wales Hospital, Sydney, LRC 441, The Report at 50.
[16] The Report at 63.
[17] LRC450 AusBiotech Ltd at 9, LRC 614 Australian Association of Neurologists. See The Report at 62. Issues Paper, n 11 at 11.
[18] LRC 318 Stem Cell Sciences Ltd, The Report at 62.

spinal cord injury patients.[19] In the United Kingdom, a research team is studying motor neurone disease using SCNT.[20]

It is also argued that embryos with genetic conditions that are discarded after pre-implantation genetic diagnosis will be valuable for research.[21] Embryos found to have a genetic disease, such as Cystic Fibrosis and Huntingdon's disease, are currently destroyed. 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.[22] The Lockhart recommendations supported the view that embryos rejected through the pre-implantation genetic diagnosis process should be permitted to be used in research, rather than discarded, and for training and clinical practice. It was considered that ethical guidelines needed to be established in this regard.[23]

Potential for stem cell research to benefit Australians suffering from serious diseases

Many submissions to the Lockhart Review argued that SCNT embryo research has the potential to benefit the large number of Australians currently suffering from serious diseases.[24] For example there were many submissions to the Lockhart Review from relatives of people suffering from such conditions supporting this view.[25] 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.[26] A submission from the Diabetes Transplant Unit to the Lockhart Review indicated that if nuclear transfer was

[19] LRC308, SpinalCure Australia, p. 3. This submission contains extracts from several research articles revealing promising research results regarding the use of stem cells to regenerate the spinal cords of animals. See for example McDonald et al, 'Repair of the Injured Spinal Cord and the Potential of Embryonic Stem Cell transplantation' *Journal of Neurotrauma* vol. 21, 2004 at 383.
[20] Ibid.
[21] Submission to Lockhart Review, LRC509, Monash University, The Report at 168-169.
[22] LRC 509, Monash University at 5.
[23] The Report at xvi.
[24] For example, LRC 819 Sydney IVF.
[25] Confidential submissions LRC412 and 216 quoted at 61 of The Report.
[26] The Senate, Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (October 2002) at 48-51.

legalised in Australia, the Unit would apply for a licence to create stem cell lines that could be used as models for studying Type 1 diabetes.[27]

Australian legislation should reflect changing societal values. In this regard values have changed markedly since the question of SCNT was last considered in 2001

For law to be relevant to society it must reflect changing societal attitudes. A recent telephone survey has revealed that eighty-two per cent (an increase of 12% from 70% in November 2001) of Australians (14 years and over) approve of the extraction of stem cells from human embryos for the treatment of diseases and injuries, such as heart disease and Alzheimers.[28] In this same survey, 80% of Australians indicated that they were in favour of embryonic stem cell research as scientists can now make embryonic stem cells for medical research by merging an unfertilised egg with a skin cell, in which case no fertilisation takes place. Only eleven per cent of those people polled opposed this type of embryonic stem cell research, while 9% stated that they were undecided.

Economic considerations

Another argument in support of the legalisation of SCNT is economic considerations and the need to stay competitive with overseas countries such as the United Kingdom, United States and Singapore which are now taking the lead in this area.[29] Although Australia was once considered a world leader in embryo research, it has been reported that our scientists have now been relegated to a 'second tier' below researchers in other countries.[30]

Another concern is that a restrictive environment means that Australia cannot benefit from the economic potential of such research, such as in attracting international

[27] LRC 180 Diabetes Transplant Unit, at 1.
[28] Roy Morgan Research "Large Majority of Australians Approve Extraction of Stem Cells from Human Embryos for Medical Research." 21 June 2006 available at <http://www.roymorgan.com/news/polls/2006/4036/> accessed 3 October 2006. Note also that 13% disapproved and 5% were undecided.
[29] LRC 930, Queensland Government at 7, LRC 396, Stem Cell Ethics Australia at 6, LRC450 AusBiotech Ltd.
[30] AusBiotech Ltd at 15, 21, LRC 819 Sydney IVF.

private investment.[31] There is 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.[32] This has been described as "the loss of intellectual and creative capital".[33] 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 or further develop certain types of research.[34]

Scientists do not wish to engage in reproductive cloning

An objection to the legalisation of SCNT in the past has been that to legalise this process would lead Australia down the path of human reproductive cloning.[35] However, the Lockhart Review Committee was clearly 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. [36] In both draft Bills currently tabled before the Senate, the practice of human reproductive cloning is clearly illegal.[37] Further the proposed legislation strictly regulates the creation of embryos by the nuclear transfer process as it will only be permitted by the obtaining of a licence.[38]

It is an unreasonable stance to prevent scientists from being to utilise the SCNT process and to relinquish all of the medical benefits that it may offer, merely to address unfounded concerns about the possibility of reproductive cloning.[39]

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[31] LRC 930, Queensland Government at 7, LRC 396, Stem Cell Ethics Australia at 6.
[32] LRC 509, LRC308 SpinalCure Australia at 3, LRC 396, Stem Cell Ethics Australia at 6.
[33] LRC 450 AusBiotech Ltd at 8.
[34] The Report at 133.
[35] LRC 364, Queensland Institute of Medical Research at 2. LRC 672 Anglican Diocese of Sydney at 3, LRC 451 Southern Cross Bioethics, The Report at 61.
[36] The Report at 55.
[37] *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* (Cth), s9. *Somatic Cell Nuclear Transfer (SCNT)and Related Research Amendment Bill 2006* (Cth) s 9.
[38] Ibid, s 22.
[39] Robertson JA, "Human embryonic stem cell research: ethical and legal issues" (2001) 2(1) *Nature Reviews: Genetics* at 77.

Advances in adult stem cell research should not prevent embryonic stem cell research

Another argument against SCNT has been that embryonic stem cell research is unnecessary as research on adult stem cells can achieve the same results.[40] This argument is premised on the basis that, 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 some human diseases, an example being bone marrow transplantation. Such submissions argued that adult stem cells can also be derived from the patient, avoiding any problems of rejection when reintroduced into the patient's body.[41] The Lockhart Review Committee noted that one United States research group had 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.[42]

The fact that the SCNT process is very resource and labour intensive has also been raised. For example, Professor Alan Mackay-Sim stated to the Lockhart Review that the process is "a long and laborious procedure" and that his team had created over forty adult stem cell lines.[43] However, the Professor 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.[44] 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.[45]

[40] LRC 895 Centre for Worldview Studies. Sources of adult stem cells include umbilical cord blood and bone marrow.
[41] 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.
[42] The Report at 58.
[43] This submission revealed that the Professor and his team had created over forty 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.
[44] LRC 217.
[45] LRC 509, Monash University, LRC 308 SpinalCure Australia.

Management of egg supply

Concerns have been 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".[46] Fears have been raised that woman may be encouraged by ART clinics to donate their eggs to be used in the SCNT process. 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.[47] In the United Kingdom, supplies of eggs have been obtained from those rejected in the IVF process as not being viable, they therefore would have been destroyed if not used in stem cell research.

The proposed Bill by Senator Patterson also provides a specific provision alleviating these concerns by stating that the sale of human eggs or embryos is an offence with a maximum penalty of ten years.[48] This provision provides that reasonable expenses can be paid, however, that no inducement, discount or priority can be provided in the provision of services to someone in relation to the supply of a human egg, sperm or embryo. This specifically covers the scenario where an ART clinic may seek to encourage a woman to donate her eggs for SCNT research.

Further, a submission from Sydney IVF to the Lockhart Review 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.[49]

National stem cell bank

The Lockhart submissions revealed much support amongst 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

[46] LRC 419 Queensland Bioethics Centre and Archbishop Bathersby and the Archdiocese of Brisbane.
[47] NHMRC Ethical Guidelines. LRC 246 National Civic Council, The Report at 65
[48] *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* (Cth), s 21.
[49] LRC 819 Sydney IVF at 9.

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.[50] 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 that such stem cell lines could come from approved international stem cell banks.[51] One submission stated that "The exchange of information and materials between laboratories is the lifeblood of science, and is essential in order for experiments to be replicated".[52]

Legalisation of SCNT is consistent with the legal status of human embryos

It is also argued that the legalisation of the SCNT process is consistent with the legal and ethical status of a SCNT embryo.

In general, Australian law does not consider developing humans to have the same rights and protections as children or adults. A foetus has generally been held to have no legal personality[53] until it is born and has a separate existence from its mother.[54] It therefore does not have an entitlement to human rights such as the right to life and bodily integrity. Although abortion is technically illegal in a number of Australian states[55], it has been held that it is not unlawful when the person performing the procedure had a reasonable belief that it was necessary to avert serious danger to the mother's physical or mental health'.[56] The mother's interests therefore prevail over the rights of her unborn child.

[50] LRC 450 AusBiotech Ltd at 19, LRC 790 National Health and Medical Research Council at 16. .
[51] LRC 450 AusBiotech Ltd at 18.
[52] LRC 449, Third Year Bachelor of Biomedical Science Students, University of Melbourne.
[53] A legal person is an entity on which a legal system confers rights and imposes duties.
[54] *Watt v Rama* [1972] VR 353. See also *F and F* (1989) FLC 92-031 where the Family Court refused to grant an injunction to a husband who was seeking to restrain his estranged wife from having an abortion. The husband argued that the unborn child had a right to life. The court rejected this argument on the basis that a foetus has no legal personality and 'cannot have a right of its own until it is born and has a separate existence from its mother.' In criminal law, a child becomes a person capable of being killed when it has completely proceeded in a living state from the body of its mother, whether it has breathed or not, and whether it has an independent circulation or not, and whether the navel-string is severed or not. *Criminal Code, 1989* (Qld), section 292, however, under section 313 it is an offence to kill an unborn child.
[55] For example, *Crimes Act, 1958* (Vic), *s 10*.
[56] For example, *R v Davidson* [1969] VR 667.

'In relation to ART embryos, assisted reproductive technology legislation envisages that an embryo may develop into a child and talks about the 'prospective welfare of any child to be born consequent upon a procedure' being taken into consideration.[57] The NHMRC Ethical Guidelines state that ART embryos are not to be treated as 'mere tissue'.[58] It is, however, clear that frozen ART embryos are considered to be the 'property' of the creating couple, rather than 'human life' as they cannot be dealt with, except according to the couple's wishes.[59] This idea of ART embryos being considered as 'property' is reinforced by the fact it has been accepted for many years that embryos that are excess to a couple's ART treatment needs can either be donated to another couple, destroyed or donated to medical research. In fact they must be dealt with at the end of the maximum storage term of ten years. [60] It is the creating couple that decides the fate of their excess embryos, so as such the embryos do not possess legal 'rights'. If we had to allocate a status to the excess ART embryo we may come to the conclusion that they hold a position somewhere in between a 'legal person' and 'mere tissue', and could perhaps therefore be described as a 'potential person'.

It seems to follow that a SCNT embryo must have a lesser status in Australian law than an excess ART embryo. However, as SCNT embryos are created for the purposes of destructive research and are never intended to be implanted, they clearly cannot hold the status of a 'potential person'. Some scientists argue that the cells created through the SCNT process do not have the potential to develop into a human being, that they 'have no developmental competence at all. They can't develop into any kind of organised embryo whatsoever, but they can produce embryonic stem cell lines that might be useful for research.'[61]

It was argued to the Lockhart Committee that there should be difference classes of embryos based on the method of creation and that 'Cells that are to be studied entirely

[57] For example, Section 4(1)(d)(iv) *Human Reproductive Technology Act 1991* (WA).
[58] NHMRC Ethical Guidelines, 15.2.
[59] For example, under s 21B of the Infertility Treatment Act 1995 (Vic) an embryo cannot be considered an 'excess ART embryo' unless the couple consent and it is excess to their treatment needs.
[60] NHMRC Ethical Guidelines, [8.8.1-8.8.2].
[61] Tom Noble, 'Let us create diseases stem cells – researcher' (Press Release, 5 June 2005) 1 < http://www.theage.com.au/news/National/Let-us-create-diseased-stem-cells--researcher/2005/06/04/1117825104834.html> at 16 August 2005.

in vitro in a research context, and are not formed from a fertilised embryo, should not be regarded as embryos...'[62] Consistent with this approach, it has been previously argued that for an embryo to be regarded as a human life or as an entity with interests it must possess 'a nervous system capable of sentience, if not also of cognition and consciousness.'[63] It is clear that an embryo in the primitive stage of development at the time when stem cells are extracted is far removed from the stage when it will commence to develop a nervous system.

The Lockhart Review Committee concluded that the moral significance of SCNT embryos 'is linked more closely to their potential for research developments, including the development of treatments for serious medical conditions, than to their potential as a human life.'[64] The Committee effectively weighed the SCNT embryo's rights against the potential benefits of using such embryos in research and determined that the good that the embryos can contribute to medical research must prevail over any rights that such embryos are entitled to.

Legalising SCNT would place Australia in a more competitive position in the world in terms of embryo research

The legalisation of SCNT would clearly place Australia in a more competitive position in relation to human embryo research.

Currently 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.[65] 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

[62] LRC18, Australian Academy of Science, The Report, at 72.
[63] Robertson JA, 'Human embryonic stem cell research: ethical and legal issues' *Nature Reviews: Genetics*, vol. 2, no. 1, 2001, at 74, 75.
[64] The Report, p. 170.
[65] Biotext Pty Ltd, Prepared for the Department of Health and Aging, *Human Embryos, stem cells and cloning – developments in research and regulations since 2001*, Literature review (August 2005) 93-107 at http://www.lockhartreview.com.au/public/content/ViewCategory.aspx?id=34 viewed 6 February 2006.

embryos can be donated to research, provided that the creating couple give informed consent. This is the approach contemplated by the Lockhart recommendations. It is also the approach in countries such as Singapore and South Korea.[66]

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.[67] 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[68]it should be noted that states such as California[69] and New Jersey[70]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.[71] Scientists in the UK use eggs which would ordinarily be disposed of by ART clinics, as they have failed to fertilise when mixed with sperm, and donated oocytes, in the

[66] Biotext Pty Ltd, *Human Embryos, stem cells and cloning – developments in research and regulations since 2001* at 93-107.
[67] Biotext Pty Ltd, *Human Embryos, stem cells and cloning – developments in research and regulations since 2001* at 104.
[68] *Human Cloning Ban and Stem Cell Research Protection Act of 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.
[69] Senate Bill 253.
[70] Assembly No 2840.
[71] *Human Fertilisation and Embyology (Research Purposes) Regulations 2001* (UK).

SCNT process. A UK research team has recently achieved the creation of embryonic stem cell lines from nuclear transfer.[72]

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.[73] 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.[74]

In the United Kingdom, the *Human Fertilisation and Embryology Act 1990* (UK) established the Human Fertilisation and Embryology Authority (HFEA).[75] 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.[76] 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

[72] The Report at 58.
[73] *Human Fertilisation and Embryology Act 1990* (UK), s 1. The definition is currently under review as part of an overall review of the UK Act, Department of Health, *Review of the Human Fertilisation and Embryology Act, A Public Consultation*, n13 [2.26] 15.
[74] Recommendation 23, The Report at 23.
[75] *Human Fertilisation and Embryology Act 1990* (UK), s 5.
[76] *Human Fertilisation and Embryology Act 1990* (UK), s 9.

- 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[77]
- 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[78]

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 UK 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[79]

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

[77] *Human Fertilisation and Embryology Act 1990* (UK), schedule 2, s3(2).
[78] The last three purposes were added in 2001 by the *Human Fertilisation and Embyology (Research Purposes) Regulations 2001* (UK).
[79] It is overseen by a Steering Committee and is administered by a Management Committee comprising of members from research, academia, health care bodies, regulatory bodies and a lay member.UK StemCellBank at http://www.ukstemcellbank.org.uk/Overview.html viewed 7 February 2006.

- Basic cell research that underpins these aims
- Development of cell based therapies for clinical trials in respect of serious human diseases[80]

The Code of Practice does not require research ethics approval for research conducted on established embryonic stem cell lines, however, 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. We can also look to our 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.[81] 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.[82] 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.[83]

Suggested 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

[80] Medical Research Council, Code of Practice for the Use of Human Stem Cell Lines [8.1.1] at 12 at http://www.mrc.ac.uk/pdf-public-stem_cell_code_of_practice_june2005.pdf viewed 7 February 2006.
[81] *Research Involving Human Embryos Act 2002* (Cth), 21(4).
[82] *Law on Embryo Research Act 2003*, s 4(1).
[83] *Embryos Act 2002*, s 11.

implications of such a restrictive research environment.[84] Other submissions, particularly from the scientific community, representative organisations and relatives of patients focussed 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.

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, that 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.[85]

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 as the United Kingdom.[86] Such submissions contended that the legal position in this country achieves a fair balance between assuring the community that reproductive cloning will not occur, however, permitting a more liberal research environment so that real progress towards embryonic stem cell therapies can be made.[87] This has meant that scientists in the United Kingdom have been conducting valuable research that would not currently be legal in Australia, such as research on mitochondrial diseases.[88]

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

[84] LRC 930 Queensland Government, LRC 1016 New South Wales Minister for Science and Medical Research.
[85] LRC 396, Stem Cell Ethics Australia.
[86] LRC 450 AusBiotech Ltd, LRC 396 Stem Cell Ethics Australia.
[87] LRC 450 AusBiotech Ltd at 5.
[88] Department of Health, *Review of the Human Fertilisation and Embryology Act: A Public Consultation*, at [9.21] 62-63.

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 our 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 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."[89] We now must legislate to legalise SCNT to allow 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.

[89] LRC 18 Australian Academy of Science at 4.