Lifting the prohibition

Therapeutic cloning law in Australia

By Kaushalya Mataraaratchi

Therapeutic cloning, the controversial technique for extracting stem cells from human embryos, promises to increase the tools available to scientific researchers and carries the possibility of exciting future innovations in medicine. However, the regulation of therapeutic cloning has always been tempered by ethical and practical concerns that the science might produce unwanted outcomes. And, until a recent Commonwealth Act, therapeutic cloning was prohibited entirely.

On 12 December 2006, after considerable parliamentary debate, community and scientific consultation, and years of a strict prohibition on all forms of cloning technology, the Australian legislature enacted the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act* 2006 (Cth) (the Amendment Act). The Amendment Act significantly departed from the previous legislative regime concerning cloning by allowing therapeutic cloning in certain circumstances. This article examines the legislation, the ethical issues and the science that is now possible under the current regime.

THE SCIENCE

Reproductive cloning is the creation using somatic cell nuclear transfer (SCNT) and implantation of a cloned embryo into a female reproductive tract for the purpose of reproduction. Therapeutic cloning, however, is the process of creating a cloned embryo for the purpose of extracting stem-cell lines from it. Unlike other forms of stem-cell lines (such as adult stem cells), the stem cells extracted from these cloned embryos are precursor cells from which all other cells differentiate, and are an exact genetic match to the donor patient. They provide the following benefits:[1]

- the potential to produce cell lines for clinical treatment without the risk of rejection by the recipient;[2] and
- the potential to study and understand the dynamics of various diseases in a model environment.[3]

Research into these patient-matched stem-cell lines promises cell-replacement therapies and possible cures for diseases such as diabetes, Parkinson's, Alzheimer's and spinal cord injuries.[4]

More specifically, in the context of legislation on this issue, therapeutic cloning is the production of a human embryo clone through SCNT for therapeutic research purposes.[5] The process of SCNT begins with an unfertilised human egg (ooctyte); for example, one that had initially been extracted for the purposes of IVF or other assisted reproductive technology (ART) treatments and has subsequently been donated for research.[6] The nucleus of the egg is extracted (enucleated) and the nucleus of another somatic cell (a body cell other than an egg or sperm cell, often a skin cell) is fused into the egg.[7] The resulting cell is electrically stimulated and begins to develop in the same way as a fertilised egg in the uterus. The resulting embryo is an almost identical genetic copy (clone) of the somatic cell donor.[8] Stem cells extracted from these embryos can then be injected into the original somatic cell donor for potential therapeutic benefits.[9]

The science behind SCNT was discovered in 1952, when the nucleus of a frog's egg was removed and replaced with a frog cell to create a cloned tadpole.[10] In 1997, the Roslin Institute in Scotland produced a cloned sheep, 'Dolly', using SCNT, proving that SCNT could be used to clone complex creatures.[11] This breakthrough also provoked a widespread moral panic over the science.[12] In 2004, researchers in South Korea successfully cloned a human embryo using SCNT[13] and, in 2005, researchers in the UK[14] discovered that human embryos[15] could successfully be cloned using donated nuclei and eggs.

The current aim of this technology is to develop stem cells, tissues and organs for the purposes of therapeutic 'stem cell therapy' – that is, for the treatment of disease – rather than for use in reproductive medicine.[16]

LEGISLATIVE BACKGROUND

Internationally, the United Nations and the United Nations Educational Scientific and Cultural Organization (UNESCO) have made declarations covering human cloning. In 1997, UNESCO adopted the *Declaration on the Human Genome and Human Rights*,[17] article 11 of which prohibited practices contrary to human dignity, such as therapeutic and reproductive human cloning. In March 2005, the United Nations General Assembly adopted the *Declaration on Human Cloning*, which prohibited all forms of human cloning incompatible with human dignity.[18]

Australia enacted national legislation on human cloning in 2002 – the *Prohibition of Human Cloning Act* 2002 (PHC) and the *Research Involving Human Embryos Act* 2002 (RIHE) – in response to recommendations made by the Andrews Committee (the previous legislative review committee).[19] These Acts created a national legislative scheme to govern research into excess ART human embryos,[20] and prohibited >>

National legislation in Australia in 2002 prohibited the creation of human embryo clones for both reproductive and therapeutic purposes.

the creation of human embryo clones for both reproductive and therapeutic purposes.[21] The Acts also created a Licensing Committee[22] to assess and oversee applications in the permitted areas of research. Following the introduction of this national scheme, the Queensland,[23] NSW,[24] Victorian,[25] South Australian,[26] Tasmanian,[27] West Australian[28] and ACT[29] governments enacted concurrent pieces of legislation.[30] Under this legislation,[31] the National Health and Medical Research Council (NHMRC) released the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2004*,[32] which established the Licensing Committee and detailed its purview.

THE LOCKHART REPORT

On 17 June 2005, the Hon Julie Bishop MP commissioned a panel of six experts[33] to conduct a legislative review under s25(3) of the PHC[34] and s47(3) of the RIHE.[35] Six months later, on 19 December 2005, the Lockhart Report was tabled in the Australian Federal Parliament.[36] It is important to note that the scope and purpose of the Lockhart Report differed from its predecessor, the Andrews Report.[37] While parliament charged the Andrews Committee with assessing the appropriateness of a national legislative framework to govern human cloning and research into human embryos,[38] the Lockhart Committee was asked to examine the practical impact of the PHC and RIHE legislation.[39]

Opponents to therapeutic cloning voiced three main ethical objections in the submissions made to the Committee:[40]

- Because the technology used for therapeutic cloning and reproductive cloning is the same, the legalisation of one will inevitably lead to the other;
- A human embryo has 'moral status' and should be afforded human dignity; thus, it is wrong to specifically create human embryos to destroy them (no matter what the potential benefits might be); and
- As the most viable eggs for research purposes are obtained from young women, this could lead to those women being coerced to donate their eggs, a procedure that carries some risk for the donor.

The Lockhart Committee rejected the first objection because it thought that appropriate safeguards – a legislative prohibition on reproductive cloning, reinforced with a ban on developing embryos for more than 14 days in therapeutic cloning processes – would be sufficient to limit the use of human embryo clones to therapeutic purposes.[41]

Proponents of the second objection argued that therapeutic cloning devalues the human embryo by treating it as a means to an end, and that such degradation outweighs any benefit potentially offered by therapeutic cloning. Implicit in this argument is that the value attached to the human embryo is linked to its potential for life. Rejecting this view, the Lockhart Committee reasoned that the 'moral significance of cloned embryos that are not implanted 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'.[42] The Committee's reasoning presumes that if a human embryo has the potential *only* for research (because it has been specially created for that research), then its moral status would be distinct from an embryo with the potential for life. Therefore, the destruction of such an embryo has 'moral significance' only for improving human health through scientific advancement, outweighing the harm to the dignity of the individual embryo.

As regards the third objection, 'ovarian stimulation and egg collection … [and the] potential for young women to be coerced to donate [eggs]',[43] the Lockhart Committee reasoned that if scientists used alternative sources of eggs (such as animal eggs) where possible, and there were sufficient ethical guidelines governing human egg donation, such ethical problems could be appropriately limited.

The Lockhart Committee ultimately recommended that therapeutic cloning be legalised in certain circumstances. It recommended, however, that reproductive cloning should continue to be prohibited.

THE AMENDMENT ACT

The Amendment Act was tabled in the Senate, in the form of a private member's bill, by Senator Kay Patterson on 16 October 2006. Proposing amendments to the PHC and the RIHE based on the recommendations made by the Lockhart Committee, the Bill was passed in the Senate by a conscience vote on 7 November 2006 by a bare majority of 34 to 32, and in the House of Representatives by a majority of 82 to 62. It came into operation on 12 June 2007.[44]

The purpose of the Amendment Act is to incorporate the recommendation of the Lockhart Committee to regulate the research conducted on human embryos.

It makes research in relation to human embryos and cloning technology prohibited unless it is authorised by the NHMRC's Licensing Committee by issue of a licence. In doing so, the Amendment Act permits Australian scientists to explore the opportunities presented by cloning technology, while ensuring that the research is subject to regulatory scrutiny and that it is ethical.

For the purposes of accuracy and consistency, the Amendment Act repealed and inserted a new definition of 'human embryo' developed by the NHMRC.[45] The previous definition of human embryo was scientifically redundant and imprecise, creating confusion among researchers. The

amended definition replaced ambiguous scientific terms with observable characteristics of the embryo, including both embryos created by fertilisation and those created by other means:

- where created by fertilisation, a human embryo is legally recognised as such upon the completion of the fertilisation itself (a phase that is observable during the cell division of the embryo); and
- where created by other means, such as SCNT, embryos become legally defined as such at the point where that entity develops to the stage where the 'primitive streak' appears on it (again a phase that is observable and reliable).[46]

Additionally, the definition of 'proper consent' has been replaced with that provided by the NHMRC under the NHMRC Act 1992, to take into consideration any future ethical issues (and current issues) regarding consent in donating excess ART embryos and the use of those embryos.[47]

To maintain the absolute prohibition against reproductive cloning, and to prevent research practices that are now permitted under licence from entering the reproductive cloning arena, legislators have made the following amendments:

- The PHC has been renamed the *Prohibition of Human Cloning for Reproduction Act* 2002 to clearly distinguish between therapeutic (legal) and reproductive (illegal) cloning.[48]
- Implanting a human embryo clone into the reproductive tract of a woman remains absolutely prohibited.[49]
- The development of a human embryo/human embryo clone is limited to 14 days.[50]
- The creation or development of a human embryo by fertilisation for a purpose other than achieving pregnancy in a woman is prohibited.[51]
- The import and/or export and/or implantation of a prohibited embryo is prohibited.[52]
- Placing a human embryo or human embryo clone in an animal or the body of a human is prohibited.[53]

The maximum penalty for such prohibited acts is 15 years' imprisonment.

The most significant change made by the Amendment Act is that researchers are now allowed to create human embryo clones by means other than fertilisation, specifically for training, research and clinical applications (not for reproduction) under licence. This amendment permits researchers to study and apply SCNT technology for therapeutic purposes. Further amendments related to this are:

- It is an offence to create human embryos through fertilisation for any purpose other than achieving pregnancy.[54] However, human embryos may be created by means other than fertilisation (such as SCNT) as prescribed under licence.[55]
- The creation of an embryo using sperm and egg involving the genetic material of more than two persons is prohibited, while the creation of an embryo by other means (using the genetic material of more than two persons) is permitted under licence.[56]
- It is now permitted to use precursor cells from a human embryo or human foetus to create or develop a human embryo under licence (up to 14 days).[57]
- Researchers can develop and create hybrid embryos up to 14 days under licence for the purposes of testing the sperm quality in an accredited ART centre and create hybrid embryos by SCNT.[58] This amendment reduces the demand for human eggs for the purpose of human embryo clones and the production of human embryonic stem cells (especially in the situation where embryos are required to train researchers in SCNT technology).
- While it remains an offence to import and export human embryo clones under the Amendment Act, the Minister for Customs is commended to make appropriate regulations to permit the import and export of human embryonic stem-cell lines obtained from human embryo clones.[59] Since this amendment has been made, embryonic stem-cell material exported and imported will be material derived using practices consistent with Australian legislation (that is, in line with the prevention of importing and exporting prohibited embryonic stem-cell lines).[60]

For a research application to be approved, the NHMRC Licensing Committee must decide that the proposed research is likely to significantly advance knowledge or improve technologies for treatment. Also, the NHMRC Licensing Committee must set the maximum number of embryos that can be used in each approved research application. >>

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To monitor and regulate the above research, the purview of NHMRC Licensing Committee has been expanded to assess, authorise, monitor and investigate licences granted to:

- create and use human embryo clones using SCNT;
- create, develop and use a human embryo (other than by fertilisation) containing the genetic material of more than two persons;
- create and use human embryos from the precursor cells of a human embryo or a human fetus; and
- create and use a hybrid embryo. [61]

The maximum penalty for conducting such research without licence is 10 years' imprisonment. Protection is provided to researchers where they carry out research under a licence granted by the NHMRC Licensing Committee, but where the licence is found to be invalid (due to technical defect, irregularity, etc) and the researcher was unaware and could not reasonably have been expected to have known of the invalidity.[62]

The Amendment Act also makes provision for its further review three years after the date of assent, and for review of the PHRC and RIHE six years from the date of assent.[63]

In accordance with the above amendments, the NHMRC issued an updated National Statement regarding human research.[64] The new National Statement considers the interests of donors who donate eggs from ART treatment to research and those women and men who are not involved in an ART program but choose to donate gametes (sex cells) in limited circumstances. Considerations brought to the attention of researchers under the new National Statement include: beneficence, consent, respect and generally 'the empowerment of potential donors to make informed decisions on whether to participate; and the significance to many members of the community of the formation of an embryo for research purposes using [such donated material]'.[65]

Further, the NHMRC updated its *Ethical Guidelines on the Use of Assisted Reproductive Technology (ART) in Clinical Practice and Research*, implementing new guidelines for egg donation; research on embryos unsuitable for implantation or created by SCNT; and the process of obtaining proper consent for such research.[66] It also advises researchers on the use, storage and training provided regarding donated embryos. Researchers may apply to the Licensing Committee for a licence regarding research into stem cells in two different categories; that is, for either research into new and developing therapies, or for research into the cell itself.

Following the passage of the Amendment Act, NSW, Victoria, Queensland, South Australia, Tasmania and the ACT passed legislation to complement the new Commonwealth regime. Western Australia rejected the passage of complementary legislation and remains the only state to prohibit the creation and development of human embryo clones absolutely.

RECENT DEVELOPMENTS

On 16 September 2008, the NHMRC issued the first licence permitting the '[r]eproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from human cumulus cells into clinically unusable human eggs'.[67] In approving the licence, the NHMRC Licensing Committee determined that the research would significantly contribute to the study of human disease and thereby result in a significant advance in knowledge that could not be achieved by any other means of research.

The licence, issued to Sydney IVF Clinic, allows the clinic to use SCNT technology to create cloned embryos and extract up to six patient-matched stem-cell lines from these embryos. Under s21 of the RIHE, the licence has been granted for three years and is limited to the following activities:

- the creation of human embryos by SCNT and 'clinically unusable'[68] eggs and human cumulus cells (the somatic cells authorised to be used in the SCNT procedure) obtained during egg retrieval procedures; and
- the derivation of stem-cell lines from cloned human embryos.

The licence aims to establish reproducible methods to create SCNT human embryo clones; demonstrate the feasibility of deriving embryonic stem cells from SCNT human embryos; and establish reliable methods to derive stem-cell lines from SCNT-created human embryos (a practice that has not been achieved to date internationally).

Conditions imposed on the licence attempt to take into account the value or worth of each egg used in the research by limiting the number of eggs used (to 2,400 clinically unusable eggs); documenting the outcome of all 2,400 eggs

and their effect on the research (irrespective of whether or not they are ultimately used in the research); and reducing the number of eggs and human embryos that are used and created to achieve each element of licence objectives, as follows:

- up to 1,600 eggs can be used by the applicant for the purpose of creating a SCNT human embryonic stem cell line (if none is created, then no more eggs can be used);
- only 360 human embryos may be created by SCNT up to the blastocyst[69] stage (if none is created, then no more eggs can be used);
- only 160 blastocysts may be created for the purpose of extracting embryonic stem-cell lines (if no stem-cell lines are extracted, then no more eggs can be used); and
- only six cloned human embryonic stem-cell lines may be created from the blastocysts.

The licence represents an achievement for the proponents of the Amendment Act and offers scientists in Australia the first opportunity to develop SCNT technology and study human embryonic stem-cell lines. The issue of this licence (and similar licences in the future) provides Australian biomedical scientists the tantalising opportunity to explore whether therapeutic cloning will answer its potential and deliver the cures for degenerative diseases that it has touted for the past 10 years.

The manner in which the NHMRC Licensing Committee (through the Amendment Act), monitors, assesses and regulates this and future licence applications in biomedical research involving SCNT human embryos will dictate the future of this area of biomedical science in Australia. ■

Notes: **1** Biotext Pty Ltd (2005) 'Human Embryos, Stem Cells and Cloning – Developments in Research and Regulations since 2001', *Literature Review,* 11. **2** *Ibid,* at xii. **3** Klein R (2005), 'The Next Big Thing', *New Scientist* 19 (6 August 2005); Hansen J E (2002), 'Embryonic Stem Cell Production through Therapeutic Cloning has Fewer Ethical Problems than Stem Cell Harvest from Surplus IVF Embryos', 28 *Journal of Medical Ethics* 86, 86-8; Bogatko J (2001), 'Stem Cell Research: A Comparative Legal Analysis', 6 *Journal of Medicine and Law* 123, 130; Harris J (2004), *On Cloning,* Routledge, 16-20. **4** Finkel E (2005), *Stem Cells – Controversy at the Frontiers of Science,* ABC Books.
5 Legislation Review Committee, Parliament of Australia, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002* (2005). Hereafter referred to as 'The Lockhart Report' at 199-202; Biotext, see n1, 6, 9-14; Harris, see n3, 2-9. **6** Gilbert S F, Tyler A L and Zackin E J (2005), *Bioethics and the New Embryology: Springboards for Debate,* W H Freeman and Company, 50-75. **7** Harris, see n3 at 9; Knowles L P (2000), 'Science Policy and the Law: Reproductive and Therapeutic Cloning', 4(13) *Legislation and Public Policy,* 22. **8** Lockhart Report, see n5, 201. **9** Bioxtext, see n1 at 10; Slabbert M (2003), 'Cloning and Stem Cell Research: A Critical Overview of the Present Legislative Regime in Australia and the Way Forward', 10 *Journal of Law and Medicine* 514, 515-6. **10** McLaren A (2000), 'Cloning: Pathways to a Pluripotent Future', 288 *Science,* 1775. **11** Wilmut I et al (1997), 'Viable Offspring Derived from Fetal and Adult Mammalian Cells', 385 *Nature,* 810. **12** See n4 generally. **13** Hwang W S et al (2004), 'Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst', 303 *Science,* 1669. **14** Stojkovic M et al (2005), 'Derivation of A Human Blastocyst After Heterologous Nuclear Transfer to Donated Oocytes', 11 *Reproductive Biomedicine Online* 226, 226-31; Biotext, see n1 at 40. **15** As compared to animal embryos, which had been used in the past. **16** Harris, see n3 at 6-15. **17** *United Nations Educational, Scientific and Cultural Organization Universal Declaration on the Human Genome and Human Rights,* GA Res 53/152, UN GAOR, 29th sess, [11 November 1997], [Article 11] (1998): 'Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted…' **18** *United Nations Declaration on Human Cloning,* GA Res 29/280, UN GAOR, [on the report of the Sixth Committee], 82nd plen mtg, UN Doc A/C.6/59/L.27/Add.1 [2] (2005). **19** House of Representatives Standing Committee on Legal and Constitutional Affairs, Parliament of Australia, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem-Cell Research* (2001) (the Andrews Report). **20** *Research Involving Human Embryos Act* 2002 (Cth), s3. Hereafter referred to as the 'RIHE'. **21** *Prohibition of Human Cloning Act* 2002 (Cth), s9. Hereafter referred to as the 'PHC'. **22** RIHE, s39(1)(c). **23** *Research Involving Human Embryos and Prohibition of Human Cloning Act* 2003 (Queensland). **24** *Research Involving Human Embryos Act* 2003 (NSW). **25** *nfertility Treatment Act* 1995 (Victoria). **26** *Research Involving Human Embryos Act* 2003 (South Australia). **27** *Human Embryonic Research Legislation Act* 2003 (Tasmania). **28** *Human Reproductive Technology Act* 1991 (Western Australia). **29** *Human Cloning and Embryo Research Act* 2004 (ACT). **30** No legislation has been enacted by the Northern Territory government on the issue. **31** RIHE, s13. **32** National Health and Medical Research Council, Parliament of Australia, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2004). **33** Legislation Review Committee, 'Lockhart Review Supports Strong Regulation of Research Involving Human Embryos' (Press Release, 19 December 2005). **34** PHC, s25(3). **35** RIHE, s47(3). **36** Lockhart Report, see n5 at i. **37** Andrews Report, see n19. **38** *Ibid* 263-5. **39** *Ibid* 3-22. **40** Lockhart Report, see n5 at 170-2, 55-89. **41** *Ibid,* 170. **42** *Ibid,* 170; Brownsword R (2003) 'Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the "Dignitarian Alliance"', 17 *Notre Dame Journal of Law, Ethics and Public Policy,* 15. **43** Lockhart Report, see n5 at 171. **44** *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act* 2006 (Cth), s2. **45** Lockhart Report, see n 5 at 173; NHMRC (2005), *Discussion Paper: Human Embryo – A Biological Definition;* Commonwealth, Parliamentary Debates, Senate, 19 October 2006, 24 (Kay Patterson, Senator). **46** *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act* 2006 (Cth), Sch 1 item 3. **47** *Ibid,* Sch 2 item 8. **48** *Ibid,* Sch 1 items 1 and 2. **49** *Ibid,* Sch 1 item 19(2). **50** *Ibid,* Sch 1 items 14 and 20(4)(d). **51** *Ibid,* Sch 1 item 12. **52** *Ibid,* Sch 1 items 10 and 20. **53** *Ibid,* Sch 1 items 9 and 19. **54** *Ibid,* Sch 1 items 22 and 23(a). **55** *Ibid,* Sch 2 item 10A. **56** *Ibid,* Sch 2 item 23. **57** *Ibid,* Sch 2 item 23A. **58** *Ibid,* Sch 2 item 23B. **59** *Ibid,* Sch 1 item 23C. **60** See *Customs (Prohibited Exports) Regulations* 1958 (Cth) and *Customs (Prohibited Imports) Regulations* 1956 (Cth). **61** *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act* 2006 (Cth), Sch 2 item 15. **62** *Ibid,* Sch 2 item 12A. **63** *Ibid,* Sch 1 item 25A and Sch 2 item 47A. **64** National Health and Medical Research Council (2007), *The National Statement on Ethical Conduct in Research Involving Humans.* **65** National Health and Medical Research Council (2007), *Ethical Guidelines on the Use of* Assisted Reproductive Technology (ART) in Clinical Practice and Research, 75. **66** National Health and Medical Research Council, see n64 at 33, 69 and generally. **67** National Health and Medical Research Council (2008) 'Licence Issued to Sydney IVF Clinic', available at http://www.nhmrc.gov.au/research/embryos/monitor/_files/309712.pdf. At the time of publication, two further licence applications are being considered by the Licensing Committee as a result of the Amendment Act. **68** Eggs that are unsuitable for fertilisation, failed to fertilise normally or have no potential for 'normal development'. The eggs are obtained from donors who have given their informed consent for the donation and have received no payment or inducement for their donation. **69** A structure created at the early developmental stage of a human embryo.

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