REGULATING BIOMEDICAL ADVANCES: EMBRYONIC STEM CELL RESEARCH

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INTRODUCTION

Each breakthrough in biomedical technology emphasises the accelerating rate of 'science time'. The pace of scientific development has been directly promoted by substantial increases in OECD (Organisation for Economic Cooperation and Development) government funding for genetic and biotechnological research. Meanwhile, cohorts of government committees and individuals struggle with the scientific, ethical, legal and social implications of these advances in a slower ethics timeframe. Legislators, and in an increasing trend, judges, are having to develop or apply rules to avoid the perils and secure the promises of this new scientific age. This 'law time'[1] operates within national boundaries, whereas science is quintessentially international.

Assisted reproductive technology (ART) and embryo research have posed many challenges to the different timeframes of science, ethics and law. Stem cell technology is the latest development in this controversial branch of science. The unique properties of human stem cells have aroused considerable optimism about their potential as new pathways for alleviating human suffering caused by disease and injury. Submissions to an inquiry by the Australian House of Representatives on stem cell research and cloning proclaimed it to be 'the greatest and most exciting medical breakthrough' and 'one of the biggest breakthroughs in human medicine', promising 'very great potential benefits'.[2] Similar sentiments were expressed at a recent conference in Europe organised by the European Commission.[3]

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1 M Somerville, *The Ethical Canary: Science, Society and the Human Spirit* (2000).

2 See generally: 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) [3.23-3.34].

3 European Life Sciences Group Statement (20 December 2001), <http://europa.eu.int/comm/

However, some of the expressions of optimism may prove to be overstated. Embryonic stem cell technology is still at a preliminary research stage and announcements about its potential may be premature. In other research areas, commercial pressures have resulted in a changed culture with regard to scientific announcements. Scientists no longer wait until the publication of their results in refereed journals before making press statements. In fact, press statements frequently precede official publications. This has led the National Health and Medical Research Council (NHMRC) to publish guidelines on the requirement for appropriate qualifications to scientific announcements to avoid unrealistic expectations in the community for the early introduction of medical products.[4]

Stem cells may be derived from adult tissues but the most potent are extracted from developing human embryos. The ethical and legal controversies that were aroused in the ART debates during the 1980s have been re-ignited with the development of stem cell technology. Experts from around the world are assessing the difficult issue of the extent to which embryonic stem cell research should be allowed to proceed, and to date there is little international consensus on this matter. How, then, should embryonic stem cell research be regulated in Australia?

This issue was considered by the House of Representatives Standing Committee on Legal and Constitutional Affairs in its report entitled *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (hereafter the *Andrews Report*, after the Chair of the Committee, Mr Kevin Andrews, MP) released in September 2001. The report arose out of a recommendation for the Committee to review the report of the Australian Health Ethics Committee (AHEC) of the NHMRC entitled *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings* (hereafter the *AHEC Report*).[5]

In this article we examine embryonic stem cell research and explore the current regulatory framework associated with this research in Australia, with particular reference to the *Andrews Report*. We consider these issues in the contexts of: The increasing public scrutiny and accountability of biomedical research;[6] the use of human embryos in research; the lack of uniform national regulation for embryo research in this country; and the general public debate about reproductive cloning. In these contexts, the current ART regulatory system is also considered.

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research/quality-of-life/stemcells/pdf/press_release_en.pdf> at 21 December 2001.

4 The most obvious example of a pre-publication announcement was the reporting of the Dolly experiment in the US press.

5 Report to the Australian Commonwealth Minister for Health and Aged Care dated 16 December 1998.

6 This was one of the primary reasons for the revisions and public consultation leading to the promulgation of the National Health and Medical Research Council's *National Statement for Ethical Conduct in Research Involving Humans* (1999). See particularly the text of the preamble and Principles 1.1-1.21.

STEM CELL RESEARCH

The Nature of Stem Cells

Stem cell technology in humans derives from earlier and complementary work in animal studies.[7] The defining properties that have aroused excitement in stem cells is their capacity for '… prolonged proliferation with retention of their undifferentiated form … together with a stable developmental potential to give rise to derivative cells …'.[8] Stem cells are claimed to have valuable attributes. For example, in a Report by the UK Chief Medical Officer's Expert Group[9] (hereafter *Stem Cell Research: Medical Progress with Responsibility*), reviewing the potential of developments in stem cell research, stem cells were described thus:

> [a] stem cell is an unspecialised cell at an early stage of development. Under certain conditions, stem cells can divide and differentiate into a large number of cell types that make up the tissues and organs of the body. In addition, they can undergo self-renewal, a process by which an unspecialised stem cell divides to produce two further unspecialised stem cells. The ability of stem cells to self-renew in this way means that a relatively small number of stem cells can be grown in the laboratory into the very large number of stem cells that would be needed for clinical applications.[10]

The US National Academies Committee on the Biological and Biomedical Application of Stem Cell Research also released a Report in September 2001 entitled *Stem Cells and the Future of Regenerative Medicine* (hereafter *Stem Cells and Regenerative Medicine*) addressing the potential of stem cells. That report stated that:

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7 The isolation of embryonic stem cells from mouse embryos was reported as early as 1981. See G Martin, 'Isolation of a Pluripotent Cell Line from Early Mouse Embryos Cultured in Medium Condition by Teratocarcinoma Stem Cells' (1981) 78 *Proceedings of the National Academy of Science* 7634; M Evans and M Kaufman, 'Establishment and Culture of Pluripotential Cells from Mouse Embryos' (1981) 292 *Nature* 154.

8 See Australian Health Ethics Committee, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings A Report to the Commonwealth Minister* (1998) (hereafter the *AHEC Report*) [2.17]. See generally Chapter 2 on the Background Science to the Cloning of Human Beings in General and Stem Cell Technology in Particular. Professor D Chalmers was Chair of AHEC and Chair of the working party of AHEC on Human Cloning during the time of this report. He was invited to make submissions to the Andrews Committee on this report.

9 Department of Health, UK, *Stem Cell Research: Medical Progress with Responsibility* (2000). See also the *Government Response to the Recommendations Made in the Chief Medical Officer's Expert Group Report 'Stem Cell Research: Medical Progress with Responsibility'* Cm4833 (2000).

10 Ibid 17.

> [s]tem cell research offers unprecedented opportunities for developing new medical therapies for debilitating diseases and a new way to explore fundamental questions of biology.[11]

Human stem cell research enables researchers to maintain and grow in culture undifferentiated cells derived from a range of sources including early-stage human embryos,[12] foetal tissue,[13] certain adult organs[14] and the umbilical cord and placenta. Some stem cells, particularly those derived from early embryos are referred to as being *totipotent*, having the potential to differentiate into *all* different cell types, including placentas. At a later stage these cells are sometimes referred to as being *pluripotent*[15] or *multipotent*, having the potential to differentiate into a wide range of different cell types. Others, particularly those derived from adult organs, appear to be more limited in their potency to differentiate into multiple cell types.

Stem Cells: Potentiality and Actuality

Stem cell research offers the prospect of programming cells to differentiate into a whole range of cell types that can then be used for transplantation purposes.[16] Examples of desirable cell types for transplantation therapy include nerve, muscle, various blood cell types, liver, pancreas and heart.[17] The technology is being promoted as having potential for the treatment of diseases of the ageing such as Parkinson's disease and Alzheimer's disease. The proportional increases in the aged population within most OECD countries means that there is growing interest in the diseases of the aged and mental health. Other diseases and injuries that are potential targets for stem cell therapy include diabetes, heart disease and spinal code injury.[18]

Despite this promise, the actualisation of the potential of human stem cell technology in transplantation therapy or any other derivative therapy is still a long way off. In fact, stem cell technology is still at a very embryonic stage of

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11 National Academies Committee on the Biological and Biomedical Application of Stem Cell Research, *Stem Cells and the Future of Regenerative Medicine* (2001) National Academies Press, Washington DC, USA (hereafter *Stem Cells and Regenerative Medicine*) 1. Page references refer to PDF version available at <http://books.nap.edu/books/0309076307/html/R1.html#pagetop> at 8 May 2002.

12 First reported by J A Thomson, et al, 'Embryonic Stem Cell Lines Derived from Human Blastocysts' (1998) 282 *Science* 1145.

13 Including neural stem cells, neural crest cells, haemopoetic (blood) stem cells and progenitors of pancreatic islet cells. See *Stem Cells and Regenerative Medicine,* above n 11, 9; *Stem Cell Research: Medical Progress with Responsibility* above n 9, 17-29.

14 Including bone marrow, brain, blood, skeletal muscle, pancreas, liver, skin, the eye and the lining of the gastrointestinal tract. See *Stem Cells and Regenerative Medicine* above n 11, 12.

15 Although there was a flurry of interest in the distinction between *totipotency* and *pluripotency* there now seems to be a preference for the term *pluripotency* in the lexicon.

16 See *Stem Cell Research: Medical Progress with Responsibility,* above n 9, 17.

17 A great deal of scientific literature exists in this area. See generally *Stem Cells and Regenerative Medicine*, above n 11. A useful collection of articles can be found in a recent edition of *Nature:* (2001) 414 *Nature* 87-138.

18 *Stem Cells and Regenerative Medicine*, above n 11, 5, 8.

development and a great deal more research needs to be done before it is achieved.[19] This has been recognised by the European Life Sciences Group of the European Commission.[20] Similarly the *Stem Cells and Regenerative Medicine* Report noted that:

> [b]ecause human ESCs have only recently become available for research, most of what is known about ESCs come from studies in the mouse, which … cannot be presumed to provide definitive evidence of the capabilities of human cells.[21]

Further caution was expressed about the possibility of tumour development and '[m]ajor questions remain about the genetic or environmental factors in the body that control the fate of ESCs and about the importance of different factors during various stages of cell differentiation'.[22]

Embryonic and Adult Stem Cell Research

Research using adult stem cells is ethically less problematic than research using embryonic stem cells and raises no significantly different ethical issues than those associated with other research involving humans. Indeed, stem cells offer such promise as research tools that some commentators have said that there is an ethical imperative to allow such research to continue.[23] The isolation of stem cells from adults involves minimal invasiveness and little or no physical harm. On balance, research involving adult stem cells is therefore likely to be ethically sound.

Arguments have been put that embryonic stem cell research is not necessary because the ethically less problematic adult stem cell research offers equal promise. However, embryonic stem cells have the advantage of being relatively easy to isolate from early embryos and to maintain in an undifferentiated state in culture. Some of the difficulties with adult stem cell technology were discussed in the *Stem Cells and Regenerative Medicine* Report. In summary, a number of factors are relevant:

- in some situations the use of adult stem cells would be inappropriate, for example where a person carries a genetic condition, making self-transplantation undesirable. Transplantation from a donor would also be unfavourable because the recipient would be subject to immune reaction;
- the technology is new and preliminary conclusions as to therapeutic potential are tentative;

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19 Ibid 23-4.

20 *European Life Sciences Group Statement*, above n 3.

21 *Stem Cells and Regenerative Medicine*, above n 11, 22. The term ESCs is used as an abbreviation for embryonic stem cells in this context.

22 Ibid 23.

23 See 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) (hereafter the *Andrews Report*) [7.30-7.44].

- adult stem cells are rare and difficult to isolate;
- the appropriate culture conditions have not yet been fully elucidated;
- the level of plasticity of stem cells isolated from particular adult tissues is not clear;
- the functionality of the cells that differentiate from cultured adult stem cells is uncertain;
- adult stem cells tend to differentiate quickly in culture; and
- there is scant evidence that human adult stem cells can in fact differentiate into multiple tissue types.[24]

These important scientific differences between adult and embryonic stem cell research were recognised in the *Andrews Report*. A number of submissions to the Committee supported the need for continuing research using embryonic as well as adult stem cells.

Sources of Embryonic Stem Cell Lines

There are four possible sources of embryonic stem cells for research:

- cells extracted from embryos surplus to ART programs;
- cells extracted from embryos created specifically for that purpose;
- cells extracted from embryo-like entities created using cloning techniques akin to those used to create Dolly the sheep;[25] and
- cell lines already in existence.

In the first category, embryos that are surplus to ART programs are routinely stored for a period and then discarded. For example, the Victorian *Infertility Treatment Act 1995* mandates destruction after 5 years of storage.[26] It has been estimated that there are some 65,000 embryos in storage in Australia at the present time.[27] The volume of embryos is well in excess of demand for ART. However, there are severe restrictions on any use of these surplus embryos (see discussion of existing regulation, below).

Generally, in the second category, embryos may only be created for the purpose of infertility treatment or for approved research purposes.[28] In the third category, there are some doubts (certainly in Australia) as to whether existing regulation would allow for the creation of cloned embryo-like entities for this purpose (see discussion

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24 See *Stem Cells and Regenerative Medicine*, above n 11, 16-20. On the issue of the questionable pluripotency of adult stem cells see particularly Q-L Ying, et al, 'Changing Potency By Spontaneous Fusion' (2002) *Nature* DOI: 10.1038/Nature729; N Terada, et al, 'Bone Marrow Cells Adopt The Phenotype Of Other Cells By Spontaneous Cell Fusion' (2002) *Nature* DOI: 10.1038/Nature730.

25 The *AHEC Report* referred to these entities as 'embryoid bodies'. *AHEC Report*, above n 8, [2.21–2.22].

26 *Infertility Treatment Act 1995* (Vic) s 52.

27 *Andrews Report*, above n 23, [7.54].

28 See for example *Infertility Treatment Act 1995* (Vic) s 49.

below). Some researchers argue that this option should not be foreclosed because of the major advantage it offers in producing histocompatible tissue for transplantation.[29] Use of such tissue avoids the medically serious and potentially life-threatening immunological responses to tissue created from stem cells from foreign donors.[30] However, adult stem cell technology may be equally promising in this regard.

The particular complicated ethical and scientific issues associated with the extraction of stem cell lines from embryos led to a strangely ambivalent approach in the US. In August 2001 President Bush announced that federal funding could be used for research involving embryonic stem cells, but only to the extent that it make use of cell lines in existence at that time[31] (that is, the fourth category of cell lines mentioned above). This decision does not allow the destruction of any stored embryos or the creation of new embryos for the purpose of extracting new embryonic stem cell lines. Interestingly, this limitation only applies to publicly funded research and not to private research. The decision fails to recognise that the *useful* life of stem cell cultures may be finite. Although cell lines maintained in culture could, in theory, survive indefinitely, the *Stem Cells and Regenerative Medicine* Report notes that other types of cell lines tend to accumulate harmful genetic mutations.[32] Moreover, existing stem cell lines have generally been cultured in mouse serum, and consequently they cannot safely be used for therapeutic purposes because of the risk of spread of mouse-borne disease.

Stem Cell Research in Australia

Australian scientists are at the forefront of stem cell research in both the private and public sectors.[33] Australian research efforts were recently boosted by Commonwealth Government funding of a National Centre for Advanced Cell Engineering.[34] The Centre will act as a repository of stem cells for national and international research as well as co-ordinating collaborative research between Monash Institute of Reproduction and Development, Monash University, Adelaide University, BresaGen and ES Cell International. This funding reflects a recognition by the Commonwealth Government of the benefits of stem cell research.[35] Notably, some of the stem cell lines developed by BresaGen and by the Monash Institute were included in President Bush's list.[36]

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29 *Stem Cells and Regenerative Medicine*, above n 11, 31.

30 Ibid.

31 See *Andrews Report*, above n 23, [10.72] for an extraction of President Bush's statement.

32 *Stem Cells and Regenerative Medicine,* above n 11, 27.

33 For example, research teams at BresaGen Ltd, based in Adelaide, Monash University and the Monash Institute of Reproduction and Development in Victoria are recognised leaders in the field. See *Andrews Report*, above n 23, [4.8-4.10].

34 Monash Newsline (September 2001), <http://www-spo.adm.monash.edu.au/news/Story.asp?ID=373> at 10 January 2002.

35 S Douez, 'PM Signals Shift on Stem Cell Research' *The Age,* (Melbourne), 2 June 2001, 6.

36 Note also that stem cell research is at the forefront of public debate in Australia, and there is cautious approval by the Australian public of stem cell technology. A recent study showed that

The scientific claims about the potential benefits of stem cell technology are being tested. The next stage is to discuss the ethics and to determine an appropriate regulatory framework for this biomedical advance. This technology has its genesis in animal studies, is related to human ART and has been conflated, at times, within the human reproductive cloning debate. These intersections have created linguistic imprecision.[37] This is not unexpected in new areas of scientific endeavour. However, some agreement must be reached about the new terms to be included in the lexicon or we may end up like Humpty Dumpty, making words 'mean just what [we] choose [them] to mean – neither more nor less'.[38]

Human Cloning

Human reproductive cloning has been the subject of intense international debate in recent years. The technology of somatic cell nuclear transfer (SCNT)[39] and the arrival of Dolly the sheep[40] have engendered most concern. SCNT technology involves the introduction of a nucleus from a somatic cell in a fully developed organism into an enucleated egg cell, which then develops into another living being.

In fact, the technology for cloning animals is not new, being first developed in the 1950s. Further major advances were made in the 1970s and 1980s.[41] Essentially two techniques were developed: embryo splitting and embryonic nuclear transfer. As the term implies, embryo splitting involves the separation of the cells of a single embryo to produce two or more viable progeny. The progeny of embryo splitting are said to be clones of each other. The progeny of nuclear transfer, on the other

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72% of Australians agreed with the utilisation of stem cells extracted from embryos to treat diseases. See Roy Morgan Research, Finding No. 3421. See 'Four-nation Study Finds Support for Controversial Treatment', *The Bulletin*, 24 July 2001, 34.

37 For example, the UK Human Genetics Advisory Commission first promoted the use of the term *therapeutic cloning.* This has proved to be a misleading and imprecise expression. See the joint report by the Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority *Cloning Issues in Reproduction, Science and Medicine* (1998). Note that this potential for linguistic imprecision was reflected in the 'Roy Morgan Research Finding No. 3421' survey, which showed 52% approval of the creation of cloned embryos for therapeutic purposes without actually making clear whether there was genuine public understanding of the distinction between embryonic stem cells and cloned embryos. See Roy Morgan Research, Finding No. 3421. See 'Four-nation Study Finds Support for Controversial Treatment', *The Bulletin*, 24 July, 2001.

38 From Lewis Carroll *Through the Looking Glass* (1871).

39 In *Stem Cell Research: Medical Progress with Responsibility,* above n 9, the acronym SCNT was replaced by CNR (cell nucleus replacement, at [1.15]), which was the preferred term from the joint report of the Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority *Cloning Issues in Reproduction, Science and Medicine* (1998), above n 37.

40 I Wilmut, et al, 'Viable Offspring Derived from Fetal and Adult Mammalian Cells' (1997) 385 *Nature* 810.

41 F Z Sun and R M Moor, 'Nuclear Transplantation in Mammalian Eggs and Embryos' (1995) 10 *Current Topics in Developmental Biology* 147.

hand, are said to be clones of the donor of the nucleus. The term *clone* is used in this sense to mean that the organisms, be they siblings or parents and offspring, share common genetic origins.

The innovative aspect of SCNT is that the nucleus from an adult cell is used, rather the nucleus of an embryonic cell (which is used for embryonic nuclear transfer). The development of this technology has forced reappraisal of the commonly held belief that differentiated cells are genetically irreversible, and, consequently, that the DNA from adult cells cannot be cloned.

Reproductive Cloning

The term *reproductive cloning* is generally used to describe the production of living progeny by means either of embryo splitting or of nuclear transfer. The term is used to differentiate *reproductive* from *therapeutic* outcomes where the intention, in the latter, is not to create a whole human being but to develop organs for transplant. There has been no serious scientific support for the application of this procedure to produce a human being. However, a team led by Dr Severino Antorini has been promoting the technology, along with a handful of academic commentators.[42]

Therapeutic Cloning

Therapeutic cloning has been used as a synonym for stem cell research. As a consequence, stem cell research has been drawn into the debate associated with reproductive cloning. This confusion has been exacerbated with the recognition that a combination of embryonic stem cell technology and SCNT could be used to provide cells for transplantation that have sufficient genetic similarity to the recipient to avoid complications associated with rejection.[43] As an example, a promising early step in this combined technology[44] was the subject of extensive media commentary at the end of 2001.[45] Some doubt has been expressed about the usefulness of term *therapeutic cloning*.[46] It clearly has some ambiguity, having been used to include:

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42 A leading US academic has argued that there may be constitutional arguments based on the claimed US right to reproduction: J Robertson, 'Liberty, Identity and Human Cloning' (1998) 76 *Texas Law Review* 1371. See also S McLean, 'What is Wrong with Reproductive Cloning?' (2002) 2(4) *Genetics Law Monitor* 6.

43 The rationale for this is that the stem cells would produce only the patient's own proteins and hence there would be no immunological response. See *Stem Cells and Regenerative Medicine*, above n 11, 8. See also R P Lanza, J B Cibelli and M D West, 'Prospects for the Use of Nuclear Transfer in Human Transplantation' (1999) 17 *Nature Biotechnology* 1171.

44 Reported in: J B Cibelli, et al 'Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development' (2001) 2 *Journal of Regenerative Medicine* 25.

45 See, for example, D Carrington *First Cloned Human Embryos Created* (2001) NewScientist.com http://www.newscientist.com/news/news.jsp?id=ns99991605 at 30 November 2001.

46 See the joint report of the Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority *Cloning Issues in Reproduction, Science and Medicine* (1998), above n 37.

- the production of embryo-like entities by SCNT or other techniques for the purpose of research or therapy;
- embryonic stem cell research, involving stem cells derived either from embryos which are created specifically for that purpose, or from so-called spare embryos, created for assisted reproductive technology and surplus to requirements;
- adult stem cell research; and
- the combined use of SCNT and embryonic stem cell technology.

These ambiguous uses were recognised in the *Andrews Report* and the Committee opted to avoid use of the term altogether. Rather, it separated out each of these techniques and considered their ethical validity and regulatory framework. The same approach is adopted here.

Broader Research Issues

In the broader research framework, it is vital that the ethical and legal debates are conducted with a clear understanding of the procedures and the terms used. Australia would do well to avoid the adversarial confrontations between scientists and the proponents of the social study of science in the US.[47] A leading proponent of science and technology studies, Professor Jasanoff has remarked that:

> the two sides of the science wars are separated today by almost unbridgeable differences in their habits of reading and interpretation. The dogged defenders of science read with a stem literalism that construes all verbal expressions as fixed in form and immovable in meaning – more so, ironically, than experimental results, which remain in principle, subject to revision on the basis of later observations. The critics' constant fear is that science studies misrepresent the words and works of scientists, citing them out of context or distorting them through unnatural juxtapositions. Not for a moment do they share the humanists' sense of the fluidity and ambiguity of language - even scientific language - … in complex webs of meaning.[48]

Professor Jasanoff concluded that:

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47 This unbridgeable division reached a searing pitch in the US with the Sokal incident. Alan Sokal, 'Transgressing the Boundaries: Towards a Transformative Hermeneutics of Quantum Gravity' (1996) 46/47 *Social Text* 217-252. Rather than a postmodernist philosophical and political analysis of 20th century physical theories, the author confessed a 'farrago of deliberately concocted solecisms, howlers and non sequiturs stitched together so as to look good and to flatter the ideological preconceptions of the editors'. See T Boghossian, 'What the Sokol Hoax Ought to Teach Us', *Times Literary Supplement,* (London), December 13 1996, 14. See also S Fish, 'Professor Sokal's Bad Joke', *New York Times,* (New York), May 21 1996; and the materials at the website <ww.physics.nyu.edu/faculty/sokal>.

48 S Jasanoff, 'A House Built on Sand: Exposing Postmodernist Myths about Science' (1999) 24 *Science, Technology and Human Values* 495, 496. See also T Hughes and T Pinch (eds) *The Social Construction of Technological Systems* (1987); B Latour, 'Aramis or the Seasons' (1997) 276 *Science* 750.

> science studies as a field has not been especially effective thus far in challenging the monopoly of reading claimed by its critics … like all rebuttals, however, these have been forced to operate in the most part with the conceptual limitations set by the attackers, responding bit by bit to the atomizing vision.[49]

ETHICAL ISSUES

It is well recognised that biomedical research involving human participants must be conducted ethically. However, despite strict regulation on research involving human embryos, there are continuing public debates on what is and is not ethically appropriate. Regulators have struggled for many years to find a balance between the special status of the human embryo and the demands of research.[50] Deep philosophic questions remain about the moral status of the embryo.[51] The UK Report *Stem Cell Research: Medical Progress with Responsibility* drew a stark distinction between

> [a] significant minority of people [who believe] that the use of any embryo for research purposes is unethical and unacceptable on the grounds that an embryo is a human being entitled to full human status from the moment of its conception [with] the right to life

and, on the other end of the spectrum

> those who consider that an early embryo is simply a collection of cells, entitled to no greater rights than any other collection of human cells.[52]

Australia has generally followed a conservative approach recognising the special status of the human embryo.[53] Concerns about a lack of respect for the embryo, and possible extensions of experimentation on embryos, led to the introduction of the Commonwealth Human Embryo Experimentation Bill in 1985.[54] One of the difficulties in this area is that the various religions of the world have divergent views on when human life commences. The Catholic view is that human life begins

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49 Jasanoff, above n 48, 500.

50 See R Lee and D Morgan (2001), Ch 3; NBCC *Human Embryo Experimentation*: *A Background Paper and Select Bibliography* (1990) Commonwealth of Australia; D Giesen, 'Developing Ethical Public Policy on Reproduction and Prenatal Research: Whose Interests Deserve What Protection?' (1989) 8 *Medicine and Law* 553.

51 See I Kennedy, 'The Moral Status of the Embryo' (1985) *King's Counsel* 21; M Lockwood, 'The Warnock Report: A Philosophical Appraisal' in M Lockwood, *Moral Dilemmas in Modern Medicine* (1985); L Andrews, 'The Legal Status of the Embryo' (1987) 32 *Loyola LR* 357; A Eser, 'The Legal Status of the Embryo in Comparative Perspective' (1992) 11 *Medicine and Law* 579.

52 *Stem Cell Research: Medical Progress with Responsibility,* above n 9*,* para 4.2.

53 Ibid. The UK report talks at p 36 about the 'middle' ground, where 'the special status of an embryo as a potential human being is accepted, but the significance of the respect owed to developing human life is regarded as increasing *in proportion to the degree of the development of the embryo*' (emphasis added).

54 However, the Bill was never passed by Parliament.

at conception and that the moral obligation to preserve human life outweighs the obligation to reduce other forms of human suffering.[55] Other religious groups place the onset of human life at a later stage of pregnancy, some time after implantation.[56] For those groups, research involving human embryos that is aimed at reducing human suffering may be ethically acceptable provided that it is conducted appropriately. There are also similar diverging views as to the moral status of the embryo based on non-religious reasoning.

As noted above, the isolation of embryonic stem cells involves destruction of the embryo. Indeed, it is unlikely that the isolation of new embryonic cell lines could ever be achieved without damaging or destroying a human embryo. As a result, the question of the ethical appropriateness of embryonic stem cell technology may be intractable and impossible to answer in a way that satisfies the Australian community as a whole.[57] Members of the Andrews Committee, for instance, were unable to agree on a single position on this issue.[58] Four members forming the minority (including the Chair) concluded that Australia should follow the US lead and only sanction embryonic stem cell research using existing cell lines, on the basis that it is unethical to destroy embryos for research purposes. For the minority, this is the case even when the embryos in question are surplus to ART requirements.[59]

However, from the research perspective, embryos surplus to ART programs present a source of research material and access should only be denied if there is clear consensus that it is ethically inappropriate to use them. Importantly, the six-member majority of the Andrews Committee recognised that, provided that clear and stringent guidelines are in place, embryos surplus to ART programs could be used for the purpose of extracting stem cells.[60] This view is consistent with that of the European Life Sciences Group which has accepted the use of 'spare' human embryos for the preparation of embryonic stem cell lines (even though it has expressed respect for the special moral status of the embryo, even prior to implantation), provided that research is 'carefully regulated, peer reviewed, scientifically sound, directed towards substantial goals and ethically controlled'.[61]

A distinction is generally drawn between embryos already in existence and the deliberate creation of embryos for research purposes. The *Andrews Report* concluded that, aside from the ethical sensitivities associated with the use of embryos, the deliberate creation of new embryos is unnecessary because of the

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55 See particularly *Veritatis Splendor* (1993).

56 See *Stem Cells and Regenerative Medicine*, above n 11, 29.

57 See *Stem Cell Research: Medical Progress with Responsibility,* that reported that in the UK it is not '… possible to reconcile to opposing views on the moral status of the embryo and on the use of embryos in research' above n 9, para 4.12.

58 See the *Andrews Report* above n 23, paras 7.107-7.115.

59 Ibid paras 7.112-7.114.

60 Ibid paras 7.109-7.110.

61 See Statement from the European Life Sciences Group at <http://europa.eu.int/comm/research/quality-of-life/stemcells/pdf/press_release_en.pdf> at 21 December 2001.

large number of surplus embryos already in existence.[62] Furthermore, the use of SCNT to create embryo-like entities for research purposes is expensive and inefficient.[63] For these reasons, the majority refused to sanction the creation of embryos or of embryo-like beings using SCNT, even when the sole purpose is for extracting embryonic stem cells, with no intention of producing living human beings.

EXISTING REGULATION

Assisted Reproductive Technology

ART was subjected to extensive scrutiny both in Australia and elsewhere in the 1970s and 1980s.[64] It is now widely accepted as a means of alleviating suffering caused by infertility. It has been noted elsewhere that an Australian woman now has the freedom to make a large range of reproductive choices.[65] Some of these procedures continue to offend the moral sensibilities of some members of the community; equally some are now well accepted, and can be carried out regardless of marital status, sexual orientation, socio-economic background and general health of the woman.[66]

The desirability of consistent regulation across all the jurisdictions of Australia was recognised from an early stage of the debate associated with ART. For example, the Family Law Council Report on Reproductive Technology, *Creating Children,*[67] recommended a national multi-disciplinary body be established to deal with matters relating to reproductive technology. This view was supported in the final report of the Senate Select Committee chaired by Senator Michael Tate on *Human Embryo Experimentation in Australia*, which recommended regulation at the Commonwealth level, with the co-operation of the States and the Northern Territory.[68] The Tate Report envisaged a national body issuing research protocols and conditional research licences for experimentation of any kind undertaken on

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62 Ibid paras 7.116-7.119.

63 Ibid.

64 See generally: R Lee and D Morgan, *Human Fertilisation and Embryology: Regulating the Reproductive Revolution* (2001); S McLean (ed), *Legal Issues in Human Reproduction* (1989); J K Mason, *Medical Legal Aspects of Reproduction and Parenthood* (1990) Chapters 9-11; D Cusine, *New Reproductive Techniques: A Legal Perspective* (1988).

65 L Skene, 'Why Legislate on Assisted Reproduction?' in I Freckelton and K Petersen (eds), *Controversies in Health Care* (1999) 266. See also Lee and Morgan, above n 64, ch 1. These procedures include: taking contraceptive measures; adopting a child; undergoing surgical sterilisation; terminating a pregnancy; as well as use the various ART techniques of artificial insemination by donor, in vitro fertilisation, embryo donation, gamete intra-fallopian transfer and zygote intra-fallopian transfer.

66 Skene, above n 65, 266.

67 Family Law Council, *Creating Children: A Uniform Approach to the Law and Practice of Reproductive Technology in Australia* (1985).

68 Senate Select Committee on the Human Embryo Experimentation Bill 1985, Parliament of Australia *Human Embryo Experimentation in Australia* (1986) (hereafter the Tate Report).

human embryos.[69] Regrettably, no such nationally consistent regulatory regime emerged in Australia.[70] What has resulted is a pot pourri of different legal and non-legal regimes regulating ART across Australia.

Three States have introduced legislation in Australia. The Victorian Parliament was the first legislature in the world to introduce legislation aimed at regulating the application of ART *per se*. The Victorian *Infertility (Medical Procedures) Act 1984* included a strict system of regulation based on criminal penalties. In 1995 this Act was replaced by a new *Infertility Treatment Act,* which introduced a system of licensing of ART service providers by the Victorian Infertility Treatment Authority. The Victorian lead was later followed by South Australia[71] and Western Australia.[72] The legislation adopted in those States introduced a system of licensing reproductive technology programmes, supplemented by codes of practice. The legislation in all three States strictly regulates various aspects of the application of ART addressing issues such as access to the procedures, and the maintenance of records.

The remaining States and Territories have not introduced similar legislation despite having established committees of inquiry into ART or, in the case of New South Wales, a series of detailed reports by their Law Reform Commission.[73] This is not to say that the conduct of ART in those jurisdictions is unregulated. In all jurisdictions, the *National Statement on Research Involving Humans 1999* (hereafter the *National Statement*), and the NHMRC *Ethical Guidelines on Assisted Reproductive Technology 1996* (hereafter the *ART Guidelines*) apply. Although infringement of the provisions of either set of guidelines is not a legal offence, sanctions for infringement usually involve the loss of access to research funds or publication of the names of infringers in Parliament. The *National Statement* and associated guidelines are regarded as national standards of acceptable practice and are responsive to what is a rapidly changing technology. That said, the *National Statement* and *ART Guidelines* are only enforceable against institutions receiving NHMRC funding or other public funding.

There is also a degree of regulation through the constraints of the Fertility Society of Australia.[74] The Society has a separately constituted Reproductive Technology Accreditation Committee, which accredits ART clinics provided that they comply

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69 Ibid, chapter 4, para. 4.25.

70 The Tate Committee was established in response to the Human Embryo Experimentation Bill, introduced as a Private Member's Bill by Senator Brian Harradine. The Tate Committee recommended that the Bill should not be further considered and it lapsed together with the wider recommendations of the Committee, including influential dissenting reports from Senators Crowley and Zakaroff.

71 *Reproductive Technology Act 1988* (SA) ss 10, 13-4.

72 *Human Reproductive Technology Act 1991* (WA) ss 15-21, 27-41, 44-6.

73 For an analysis of the contents of these reports see D Chalmers 'Professional Self-Regulation and Guidelines in Assisted Reproduction' (2002) 9 *Journal of Law and Medicine* in press.

74 See H Szoke, 'Regulation of Assisted Reproductive Technology' in I Freckelton and K Petersen (eds), *Controversies in Health Care* (1999) 243-244.

with its Code of Practice, which in turn requires compliance with NHMRC guidelines.[75] Those States and Territories without formal legislation continue to rely on the Reproductive Technology Accreditation Committee accreditation system. Indeed, self-regulation is now a major platform of public policy making, as it is argued that strict government regulation can now neither be afforded nor supported as an effective deterrent.

Nevertheless, it should be noted that there has always been an underlying suspicion that self-regulation is no regulation. In fact, during the public consultation leading to the development of the *ART Guidelines,* concern was expressed that the Reproductive Technology Accreditation Committee system was not sufficiently independent. The AHEC has**,** on two public occasions, expressed the view that the remaining States and Territories should introduce legislation complementary to that in Victoria, South Australia and Western Australia.[76] Similarly, the *Andrews Report* stated that the nature of ART was too complex to be dealt with adequately by a non-statutory regime.[77]

Human Cloning

International Regulation

The development of SCNT has led to widespread opposition to reproductive. The UNESCO *Declaration on the Human Genome and Human Rights* provides in Article 11 that '[p]ractices which are contrary to human dignity,[78] such as reproductive cloning of human beings shall not be permitted'.[79] Similarly, the Council of Europe added an *Additional Protocol* to its *Convention on Human Rights and Dignity with regard to the application of Biology in Medicine*. The *Protocol on Prohibition on Cloning of Human Beings* states that '[a]ny intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited'.[80]

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75 *Code of Practice for Units using Assisted Reproductive Technology,*in 'Ethical Guidelines on Assisted Reproductive Technology' National Health and Medical Research Council, <http:// www.health.gov.au/nhrmc/publications/pdf/e28/pdf>.

76 See letters to Federal Minister accompanying the *ART Guidelines* and the *AHEC Report*.

77 *Andrews Report* above n 23, paras 9.37-9.50.

78 On the vagueness of this term see J Harris, 'Goodbye Dolly? The Ethics of Human Cloning' (1997) 23 *Journal of Medical Ethics* 353.

79 The Declaration was proclaimed at the 29th Session of the General Conference of UNESCO on 11 November 1997.

80 The *Convention for the Protection of Human Rights and Dignity* with regard to the application of biology and medicine was approved by the Council of Europe in November 1996 and has been signed by some 20 of the 40 member states. The *Draft Additional Protocol on the Prohibition of Cloning Beings* was adopted by the Parliamentary Assembly of the Council of Europe on 22 September 1997 and has been signed by 19 member states.

A large number of European countries have specific legislation which prohibits cloning intended to produce genetically identical individuals.[81] On the other hand, some major jurisdictions have been less hasty in introducing legislation banning the procedure. In the US, the National Bioethics Advisory Commission (NBAC) recommended legislation combined with a moratorium.[82] NBAC cautioned that 'any regulatory or legislative actions undertaken to effect the foregoing prohibition on creating a child by somatic cell nuclear transfer should be carefully written so as not to interfere with other important areas of scientific research'.[83] A similar sentiment underlies the British[84] and Australian[85] reports.

Australian Regulation

The regulatory regime associated with this technology in Australia is messy and ambiguous. The ART-specific statutes in Victoria, South Australia and Western Australia each include provisions relating to human cloning. However, the definition of cloning in each statute is different. The Victorian *Infertility Treatment Act 1995* defines cloning as the formation, outside the human body, of a human embryo that is genetically identical to another human embryo or person. The Act specifies that a person must not carry out or attempt to carry out cloning.

In Western Australia, the *Human Reproductive Technology Act 1991* and *Code of Practice* define cloning as reproductive technology for the purpose of producing, from one original, a duplicate (or duplicates) or descendants that are genetically identical, live born and viable. The Act contains a list of offences including any procedure directed at human cloning.

The South Australian *Reproductive Technology Act 1988* and *Code of Ethical Research Practice* prohibit cloning, defining it as any procedure directed at producing two or more genetically identical embryos from the division of one embryo. This definition probably limits the prohibition on cloning to embryo splitting. The Code does contain further prohibitions, including:

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81 Denmark: Act No. 503 on the *Scientific Ethical Committee System and the Handling of Biomedical Research Projects*, 1992; Act No. 4060 *Medically Assisted Procreation*, 1997; Germany: *Federal Embryo Protection Act*, *1990*; Norway: Law No. 56 *Medical Use of Biotechnology*, 1994; Slovakia: *Health Care Law*, 1994; Spain: Law No. 35 *Assisted Reproduction Procedures*, 1988; Sweden: Law No. 115, 1991; Switzerland is currently considering legislation.

82 See National Bioethics Advisory Commission Report *Cloning Human Beings* (1997) Recommendation II, <http:// bioethics.Georgetown.edu/nbac/pubs.html>.

83 Ibid, Recommendation III.

84 See *Stem Cell Research: Medical Progress with Responsibility*, together with the *Government Response to the Recommendations Made in the Chief Medical Officer's Expert Group Report* Cm 4833 (2000). See also the joint report of the Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority *Cloning Issues in Reproduction, Science and Medicine* (1998).

85 The *AHEC Report* recommended that the Commonwealth Government should reaffirm the UNESCO *Declaration on the Human Genome and Human Rights*, particularly Article 11.

- altering the genetic structure of a cell while that cell forms part of an embryo or an ovum in the process of fertilisation;
- replacing the nucleus of a cell of an embryo or of an ovum in the process of fertilisation with any other nucleus; and
- placing reproductive material in the body of an animal.

However, there must still be some doubt as to whether SCNT would be covered by any of these prohibitions. Whilst SCNT does involve alteration of the genetic structure of an ovum and replacement of the nucleus of an ovum, this does not occur during the process of fertilisation. In fact, the process of fertilisation is avoided entirely.

An additional difficulty comes from the use of the term *genetically identical.* Nuclear transfer does not in fact produce a completely faithful genetic facsimile of the original. This is because genetic material (DNA) is contained in small organelles known as mitochondria in the cytoplasm of the cell as well as in the nucleus. When SCNT is used, the resulting offspring retains the mitochondrial DNA from the host egg cell as well as nuclear DNA from the donor and therefore cannot strictly be said to be *genetically identical* to the donor.

In 1999 the South Australian Council on Reproductive Technology established a working party on cloning to discuss the apparent loopholes in its legislation.[86] In seeking a definition to cover reproductive cloning, the South Australian working party noted that the fluid nature of the technology could potentially circumvent strict legal definitions, and that scientific advances in cloning techniques could defeat the purpose of the legislation.[87] The working party suggested a new definition be given to cloning so as to prohibit 'forming an embryo or an entity capable of embryogenesis which is genetically identical to, or substantially identical to, another human being, living or deceased'.

This proposed definition was described in the *Andrews Report* as 'minimis[ing] the difficulty caused by the focus in existing provisions on genetic identicality'.[88] Nevertheless, the Andrews Committee found that this definition lacked a suitable demarcation between the intention to create a live born and viable offspring and other outcomes.[89] The Committee further warned of the potential for a clone to be specifically engineered not to be genetically identical, by inserting sufficient genetic material from another human being into the clone, thereby bypassing any definition that deals with identicality or substantial identicality.[90]

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86 South Australian Council on Reproductive Technology, Parliament of South Australia, *Enquiry into Scientific, Ethical and Regulatory Aspects of Human Cloning* (1999).

87 Ibid para 2.1.

88 *Andrews Report* above n 23, para 8.39.

89 Ibid para 8.40.

90 Ibid.

The UK Experience

The difficulty with using ART-specific legislation as a means of prohibiting reproductive cloning was highlighted in a UK decision in late 2001.[91] The issue for consideration was whether an organism created by SCNT (which the Court referred to as cell nuclear replacement or CNR) fell within the definition of an embryo in the *Human Fertilisation and Embryology Act 1990*. Section 1(1) provides that:

> In this Act, except where otherwise stated –
> (a) embryo means a live human embryo where fertilisation is complete,
> and
> (b) references to any embryo include an egg in the process of fertilisation, and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote.

The case followed the release of the report by the UK Chief Medical Officer's Expert Group (referred to herein as *Stem Cell Research: Medical Progress with Responsibility*). Whilst the Report did not specifically address the issue of whether this definition covered organisms created by SCNT, Crane J noted that it was clear that this was assumed by the Group,[92] and that the Government's response to the Report had also proceeded on the basis that SCNT-organisms were covered by the definition.[93] The claimant conceded that an organism created by SCNT was an embryo. Nevertheless, Crane J concluded that the specific wording of s1(1) could not be stretched to cover such organisms. The references to *fertilisation* and *the process of fertilisation* were fatal, because there is no fertilisation in the production of an SCNT-organism.

As a result of this decision, organisms produced by SCNT appeared to be left outside the comprehensive statutory licensing framework existing at the time in the UK for the purpose of regulating ART and embryo research. Interestingly, Justice Crane's decision was unanimously overturned by the Court of Appeal on 18 January 2002.[94] The Court in that instance found that, although embryos created by nuclear transfer were not envisaged by the original drafters of the legislation, to include them did not 'strain the language [of the statute] to breaking point'.[95] This extended use of the purposive approach to statutory interpretation was warranted in the UK by virtue of the *Human Rights Act 1998* which extends purposive interpretation where necessary.[96] Whether a similar approach would be taken by the Australian Courts in this respect is unknown.[97]

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91 *The Queen on the application of Bruno Quintavalle on behalf of Pro-Life Alliance v Secretary of State for Health* [2001] EWHC Admin 918.

92 Ibid para 3.

93 Ibid para 4.

94 *R (on the application of Quintavalle on behalf of Pro-Life Alliance) v Secretary of State for Health* [2002] EWCA Civ 29. As a result of the appeal, SCNT performed for non-reproductive purposes will come within the ambit of the *Human Fertilisation and Embryology Act 1990*.

95 Ibid 27.

96 Ibid.

97 However, the Court also relied on other considerations, especially on public policy concerns, which are likely to be a relevant to the Australian context.

Before the appeal was heard the UK parliament rushed through *sui generis* legislation on 4 December 2001. The *Human Reproductive Cloning Act 2001* has only two sections. Section 1(1) provides:

> A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence.

This wording appears to circumvent some of the semantic difficulties discussed above. It avoids altogether use of the terms *genetically identical, cloning* and *reproductive cloning.* Instead, it focuses on outcomes. Effectively, what it achieves is a prohibition on the implantation, and as a consequence, on the live birth, of a cloned embryo. There may come a time when it will not be necessary for a foetus to develop to term in a woman's uterus. However, that time is a long way off, and, as is demonstrated by the actions of the UK Parliament in this case, legislatures do have the capacity to respond rapidly to such new technological developments if they see fit to do so.[98]

Towards National Regulation in Australia

In July 2000 Australian Health Ministers agreed to develop a national framework 'to prevent the exploitation of human cloning'[99] and subsequently, in June 2001, the Council of Australian Governments agreed to develop nationally consistent provisions to prohibit human cloning.[100] However, little progress has been made to date. The *Andrews Report* referred to a sense of frustration at the lack of regulatory activity by some State and Territory governments over this technology.[101]

In contrast to the UK position, the one attempt by the Commonwealth Parliament to prohibit cloning is marred by many of the semantic difficulties discussed above. The *Gene Technology Act* (GTA) was passed late in 2000. The purpose of the Act is to regulate the use of genetically modified organisms. In an eleventh hour policy change in the Senate, the Government moved an amendment to the Bill to include reproductive cloning and other human-related technology.[102] Under section 192B of the GTA, the knowing or reckless undertaking of an activity which 'will result in the cloning of a whole human being' is prohibited. The section further defines cloning of a whole human being as the production of duplicates or descendants

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98 It should be noted, however, that the appropriateness of this action by the UK Parliament has been subject to some criticism. See, for example, C Foster, 'The HFEA 1990 Begins to Leak: ex parte Quintavalle and the *Human Reproductive Cloning Act 2001*' (2002) 2(4) *Genetics Law Monitor* 1; S McLean, 'What is Wrong with Reproductive Cloning?' (2002) 2(4) *Genetics Law Monitor* 6.

99 Hon Dr Michael Wooldridge Commonwealth Minister for Health, National Framework Agreed to Prevent the Exploitation of Human Cloning (Press Release, 31 July 2000) <www.health.gov.au/mediarel/yr2000/mw/mwhmc2006.htm>.

100 See the *Andrews Report* above n 23, para 11.38.

101 Ibid para 11.50.

102 Commonwealth, *Parliamentary Debates*, Senate, 1 December 2000, 20464 (Grant Tambling).

genetically identical to the original. Whilst it may be possible to read the term *genetically identical* as meaning *substantially genetically identical*, use of this terminology is unsatisfactory, principally because it is uncertain in its application.

As well as these definitional problems associated with the cloning provisions in the GTA, there is the additional difficulty of lack of uniform coverage across Australia, arising out of the constitutional limitations on federal law-making powers. This is being remedied by the enactment of compatible legislation by the States and Territories. To date, Victoria, Queensland and South Australia all have *Gene Technology Acts* in force. However, it should be noted that the South Australian Act excludes the prohibition on cloning, presumably because its *Reproductive Technology Act* is deemed to adequately covers this issue. The Tasmanian Parliament has also passed a *Gene Technology Act*, but it has not yet entered into force. The other States and the Territories are also close to finalising their Acts.

The *Pro-Life Alliance* case[103] and the response by the UK Parliament demonstrate the considerable differences in political reactions to cloning for reproductive and non-reproductive purposes. In bringing its case before the Court, the Pro-Life Alliance was attempting to create a legal vacuum where the Government would be 'forced to introduce legislation to deal with the practice of creating embryos… which might well result in the prohibition of the process'.[104] Whilst the Government acted in respect of reproductive cloning, no such legislative reaction eventuated with respect to non-reproductive cloning. Instead the Government chose to allow the vacuum and exhaust the appeal process before attempting to overhaul the existing regime.[105]

The consultation for the *AHEC Report* did not identify any support for reproductive cloning. Consistently, the *Andrews Report* concluded that 'no case has been made in favour of cloning for reproductive purposes'.[106] The consensus view in Australia is for prohibition on reproductive cloning. The only debate would be on the precise wording of nationally consistent legislation. The complex issues associated with other aspects of embryo research, particularly embryonic stem cell research, could then be debated at length in a measured way.

In the UK, as a result of the appeal in the *Pro-Life Alliance* case, the production of embryo-like entities by SCNT will be covered by the licensing regime under the *Human Fertilisation and Embryology Act 1990*. The role of the Human Fertilisation and Embryology Authority (HFEA) in the regulation of embryonic stem cell research was confirmed in the House of Lords Select Committee Report on Stem

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103 *The Queen on the application of Bruno Quintavalle on behalf of Pro-Life Alliance v Secretary of State for Health* [2001] *EWHC*; *R (on the application of Quintavalle on behalf of Pro-Life Alliance) v Secretary of State for Health* [2002] *EWCA*.

104 *R (on the application of Quintavalle on behalf of Pro-Life Alliance) v Secretary of State for Health*, above n 94, 9.

105 Ibid.

106 *Andrews Report,* above n 23, paras 6.70-6.74.

Cell Research, released on 13 February 2002. The Committee recommended that the use of SCNT as a research tool:

> is a sufficiently serious and important objective, particularly if the potential of adult stem cells is to be realised, to justify the use of [SCNT], if licensed by HFEA, provided that (as with embryos created by IVF for research) embryos are not created by [SCNT] unless there is a demonstrable and exceptional need that cannot be met by the use of surplus embryos.[107]

It is only if an embryo created by SCNT or an equivalent technology is implanted into a woman that the *Human Reproductive Cloning Act 2001* comes into play. The situation is more uncertain in Australia, even if all of the definitional difficulties outlined above are ignored. The legislation in Victoria, South Australia and Western Australia focuses on the act of manipulation of the embryo, and would therefore seem to include cloning for both reproductive and non-reproductive purposes. The Commonwealth GTA and equivalent State GTAs, on the other hand, focus on the production of a whole human being, which seems to suggest that they are intended only to cover reproductive cloning. Similarly, the ART Guidelines prohibit '[e]xperimentation with the intent to produce two or more genetically identical individuals, including development of human embryonal stem cell lines with the aim of producing a clone of individuals'.[108]

EXISTING REGULATION TOUCHING ON EMRYONIC STEM CELL RESEARCH

Extraction of Stem Cells from Embryos - Legislation

As with cloning, the existing regulatory framework across Australia relating to the extraction of stem cells from embryos lacks consistency and is incomplete, generally falling within the ambit of the many and varied ART regulatory frameworks. Legislation in Victoria, South Australia and Western Australia relating to ART includes provisions regulating research on embryos. Whilst this legislation recognises the special status of the human embryo, it does not totally prohibit all research involving embryos.[109] The original purpose of this ART legislation was primarily directed towards the key issues of familial relationships, consent to the use of gametes and accountability of ART providers. The legislation was only incidentally concerned with regulating embryo research.

The Victorian *Infertility Treatment Act 1995* contains stringent provisions with regard to research using embryos. Any embryo created must be done so for the purposes of reimplantation[110] or 'approved research',[111] which does not diminish the

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107 House of Lords Select Committee Report on Stem Cell Research (2002) Parliament of the United Kingdom, Recommendation 8, <http:// www.parliament.the-stationary-office.co.uk/pa/Id200102/Idselect/Idstem/83/8301.htm>.

108 *ART Guidelines*, above n 75, para 11.3.

109 *Andrews Report,* above n 23, para 8.43.

110 *Infertility Treatment Act 1995* (Vic) s 49.

111 *Infertility Treatment Act 1995* (Vic) s 22.

capacity of that embryo to be reimplanted into a woman.[112] This effectively prevents the extraction of embryonic stem cells from any embryo. At the same time, the Act provides that all embryos must be discarded after five years of storage.[113]

A slightly more permissive system exists in Western Australia and South Australia, both of which have set up Reproductive Technology Councils. Both States allow limited application for permission to carry out research. However, both legislatures place paramount importance on the protection of the embryo and its ability for reimplantation into a woman.[114] In South Australia, research cannot be 'detrimental' to the embryo,[115] a term which raised the ire of some researchers.[116] Similarly in Western Australia research upon an embryo must be 'therapeutic for that … embryo' and there must be 'existing scientific and medical knowledge indicat[ing] that no detrimental effect on the well-being of [it] is likely thereby to occur'.[117] Both States also require that research on an embryo can only be undertaken for a period not exceeding fourteen days from fertilisation.[118] Embryos may only be stored for three years in Western Australia and ten years in South Australia.[119] Various other Commonwealth and State and Territory statutes impinge on aspects of research involving embryos.[120]

Extraction of Stem Cells from Embryos – Research Guidelines and Codes of Practice

In all States and Territories, the *National Statement* and *ART Guidelines* apply to research undertaken at publicly funded institutions. They also apply in respect of research conducted at private reproductive technology institutions by virtue of the Fertility Society of Australia's Reproductive Technology Accreditation Committee Code of Practice. The Code states that all research in accredited private institutions should comply with the NHMRC guidelines.[121]

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112 *Infertility Treatment Act 1995* (Vic) s 24.

113 *Infertility Treatment Act 1995* (Vic) s 52.

114 *Reproductive Technology Act 1988* (SA) s 10(2) states that '[t]he welfare of any child to be born in consequence of an artificial fertilization procedure must be treated as of paramount importance, and accepted as a fundamental principle, in the formulation of the code of ethical practice'. Similarly, the preamble of the *Human Reproductive Technology Act 1991* (WA) states *inter alia* that 'Parliament considers … this legislation should respect the life created by this process by giving an egg in the process of fertilisation or an embryo all reasonable opportunities for implanting … [Parliament] does not approve the creation of a human egg in the process of fertilisation or an embryo for a purpose other than the implantation in the body of a woman'.

115 *Reproductive Technology Act 1988* (SA) s 14(2)(b).

116 P Kasimba, '*The South Australian Reproductive Technology Act 1988*' (1988) 62 *Law Institute Journal* 728.

117 *Human Reproductive Technology Act 1991* (WA) s 14(2).

118 Reproductive Technology (Code Of Ethical Research Practice) Regulations 1995 (SA) reg 4; Reproductive Technology (Code of Ethical Research Practice) Regulaions 1995 (SA) s 4(b).

119 *Human Reproductive Technology Act 1991* (WA) s 24(4); *Reproductive Technology Act 1988* (SA) s 10(c).

120 See the *Andrews Report,* above n 23, paras 8.68-8.98.

121 *Code of Practice for Units using Assisted Reproductive Technology*, above n 75, guideline 2.1.

The *ART Guidelines* refer specifically to the special status of the embryo, pointing to:

> the recognition that any experimentation and research involved in these technologies should be limited in ways which reflect the human nature of the embryo, acknowledging that there is a diversity of views on what constitutes the moral status of a human embryo, particularly in its early stages of development.[122]

The Guidelines limit embryo experimentation to 'therapeutic procedures which leave the embryo, or embryos, with an expectation of implantation and development'[123] except in 'exceptional circumstances'.[124] Approval in such circumstances requires a human research ethics committee to establish:

- evidence of a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed research;
- the use of a restricted number of embryos; and
- consent to the specific form of research on the part of the gamete providers and their spouses or partners.

Research Using Stem Cell Lines Already in Existence or Created Out of Jurisdiction

The propagation of cells from stem cell lines already in existence would be outside any of the legislative controls on research because they do not contain human reproductive material or embryos. Although the Victorian Infertility Treatment Authority has suggested that totipotent stem cells are equivalent to embryos, and hence that research upon them is prohibited,[125] it is questionable whether this policy reflects the law in Victoria or in any other State. Whilst the current regimes effectively prohibit destructive embryo research within jurisdiction, they neither regulate such research outside jurisdiction, nor do they regulate the use of the products of that research activity within jurisdiction. Therefore, it is likely that those companies and institutions undertaking stem cell research will find it simpler to import embryonic stem cell lines from overseas than to brave the uncertainties of the Australian regime. In fact, this has already occurred in Australia, with the stem cell lines used at the Monash Institute of Reproduction and Development having been produced offshore in a collaborating Singapore laboratory.

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122 Ibid guideline 6.

123 Ibid guideline 6.2.

124 Ibid guideline 6.4.

125 The Authority has indicated its interpretation of the Act is such that it 'bans destructive embryo research [and that] [t]otipotent stem cells are considered equivalent to embryos, whether they arise from fertilisation of nuclear transfer or any other means'. Letter from Professor John Catford, Director, Public Health and Development, to N Tonti-Filippini, 14 October 1999, in P Byrne, 'Bioethics: Move to Harvest Human Embryo Stem Cells', *News Week,* 22 April 2000.

This is not to say that research using stem cell lines is entirely unregulated. It falls within the ambit of research involving humans under the *National Statement* and therefore requires consent from participants, review by a Human Research Ethics Committee and compliance with the other Principles of the *National Statement,* particularly Principles 15.1-15.8 dealing with human tissue.[126] In addition, once stem cell technology has been properly evaluated scientifically and ethically, [127] and introduced into practice, it will be governed by clinical practice guidelines and the by State and Territory *Human Tissue Acts.*[128]

Finally, stem cells, as with other human tissue, can represent a perpetual record of an individual's entire genetic code. This fact raises particular concerns associated with privacy and potential for discrimination and stigmatisation.[129] These issues are important, but are beyond the scope of this article.

ENABLING REFORMS TO FACILITATE STEM CELL RESEARCH

There is a confusing lack of consistency in the regulations in different States and Territories. Within the States that have ART legislation, particularly in Victoria, research that destroys or diminishes the potential for reimplantation of an embryo cannot be undertaken. This has particular impact on stem cell research, because the procedure required to extract stem cells from the embryo is likely to destroy or damage that embryo. The *ART Guidelines*, whilst allowing for destructive experimentation in 'exceptional circumstances' also emphasise the obligation to maintain the well being of the embryo. Despite the considerable benefits likely to arise from embryonic stem cell research, it most likely offends the spirit if not the letter of the *ART Guidelines*, especially if there are available sources of stem cell lines already in existence.

The legislation in Victoria, South Australia and Western Australia only permits the storage of embryos for a limited and seemingly arbitrary time period after which they must be destroyed. There is a certain irony in, on the one hand, prohibiting research that has general therapeutic value but may result in harm to a particular embryo, whilst on the other hand, mandating the destruction of embryos with the passage of time. Nowhere in Australia is there a UK type regime that allows research, particularly of a destructive type, in the first 14 days of development of the embryo.

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126 Compliance with the *National Statement* above n 6, is mandatory for publicly funded research or research conducted in public institutions.

127 The *Stem Cells and Regenerative Medicine Report* above n 11, identified two serious risks associated with stem cell transplants, namely tumour formation and immune rejection, 24.

128 Note, however, that the donation of foetal tissue, spermatozoa, and ova .is expressly excluded from the provisions of the *Human Tissue Acts* dealing with donations of tissue from living persons. See, for example, *Human Tissue Act 1985* (Tas) s 5.

129 Chapter 16 of the *National Statement* above n 6, identifies ethical considerations that are of particular concern in genetic research.

The *Andrews Report*, consistent with the UK, US and AHEC Reports and the Statement of the European Life Sciences Group, strongly endorsed the view that the current regulatory framework cannot be allowed to continue, concluding that:

> [t]he questions raised by human cloning and research involving the use of embryos are complex social and ethical questions and should not be left to individual ethics committees to decide. Nor should the answer to such fundamental questions depend on geography or source of funding.[130]

The *Andrews Report* proposed that the deliberate creation of embryos for research purposes should be banned and that there should be a three-year moratorium on the use of SCNT to create embryos specifically for research or therapy.[131] It further recommended that the importation of embryonic stem cells should only be allowed where the derivation of the cell lines is compliant with the Australian regulatory framework.[132] All members of the Committee, including those in dissent on the issue of use of surplus embryos, agreed that, if research of this nature is to be allowed, it must be regulated by a nationally consistent regime that applies equally to the public and private sector. It must display the features of accountability, enforceability, responsiveness, flexibility, practicality and consistency.[133]

The *Andrews Report* proposed a national licensing scheme, separate from the regulation of ART, whereby individual researchers are licensed for each research project that involves use of an embryo. Such licences would allow the use of surplus embryos from ART for research or therapeutic purposes, provided that strict requirements are followed.[134] Consent of all relevant persons is, quite obviously, a paramount consideration.[135] The Committee proposed that adult stem cell technology would not be subject to this regulatory framework, but would be governed by existing regulatory schemes.[136]

CONCLUSIONS

A tension has always existed between the promotion of freedom in research and the imperative of doing no harm.[137] How is a society to harness the promise of potential benefits of technology and research and, at the same time, minimise or avoid the threat of possible risks? Australian and international reports in relation to stem cell research highlight the need to avoid conflating research, biomedical practice, and

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130 *Andrews Report* above n 23, para 9.50.

131 Ibid para 12.41-12.42.

132 Ibid para 7.121.

133 Ibid para 11.63.

134 Ibid paras 12.42-12.44.

135 Ibid paras 12.69-12.78.

136 Ibid para 12.6.

137 In this respect see article 12 of the *Declaration of the Human Genome and Human Rights,* which states that 'freedom of research, which is necessary for the progress of knowledge is part of freedom of thought. The applications of research ... shall seek to offer relief from suffering and improve the health of individuals and humans as a whole.'

product development. At each of these stages, different regulatory considerations arise, as well as different degrees of harm. It is important to separate these different activities.

In stem cell research, the major concerns are with social and moral harm. This technology directs the searchlight onto the continuing dilemma over the status of the embryo and the permissible limits of research on embryos. We are in a highly ambivalent situation in this country, where governmental funding is being directed to stem cell research but researchers are forced to look overseas for their stem cell lines. This position is questionable for two reasons. First, it assumes that it is unacceptable to destroy an embryo within Australia, but it is acceptable for embryos to be destroyed overseas so that we may experiment upon them here. Secondly, it fails to recognise that thousands of embryos are stored and destroyed every year in this country. On this basis alone, there is justification for allowing the extraction of stem cells from embryos surplus to ART requirements.

The advancement of stem cell research in Australia cannot be achieved under the current patchwork of regulation. A nationally consistent regulatory regime for the extraction of stem cells from embryos surplus to ART requirements is an essential precondition to the development of stem cell technology and future related technologies. In essence this is the major recommendation of the *Andrews Report*. The Andrews recommendation flows in the same direction as the conclusions of the Family Law Council Report in relation to ART, the Tate Report in relation to embryo experimentation and the *AHEC Report* on cloning. Apart from calling for a uniform national approach to regulation, these Reports recommended that all bodies conducting research, whether publicly or privately funded, should be governed by the same rules and that the researchers should be accountable. A licensing authority is the most appropriate vehicle to achieve this end.

A number of key requirements are suggested for this national regulatory regime.

- Cloning for reproductive purposes should be prohibited, based on the existing section 192B of the GTA, but in more felicitous terms.
- The creation of embryos solely for research purposes should also be prohibited.
- Any decision about the use of SCNT for stem cell research should not be foreclosed until the usefulness of such technology can be fully evaluated. In the interim there should be a moratorium on the creation of embryo-like entitles using SCNT.
- The use of embryos surplus to ART requirements for extracting stem cells should be allowed but only under strict oversight.
- The body responsible for overseeing the extraction of embryonic stem cells should have statutory power to carry out its functions.
- All organisations proposing to extract embryonic stem cells should be subject to the same regulation, irrespective of their location or status.

- There needs to be clarification of the nature and extent of any consent by the couple creating an embryo to the use of their embryo for research purposes.
- Research using stem cell lines, whether they are adult or embryonic in origin, should follow the same regulation as for human tissue, provided that those lines have been extracted in accordance with Australian law.

As the *Andrews Report* noted, there is a 'considerable frustration' by all key stakeholders, including researchers and public interest bodies, at the lack of appropriate regulation in this area. One of the difficulties is the constitutional hurdle that must be overcome to establishing a suitable legislative mechanism. Whilst the *AHEC Report* recommended complementary State and Territory based legislation,[138] the *Andrews Report* stated that the Commonwealth has both the obligation and the constitutional power to take the lead in regulating this area.[139] The Commonwealth does have significant heads of relevant constitutional power, most notably the corporations power and trade and commerce power. There is, nevertheless, a risk that some research will not be covered if Commonwealth legislation alone is introduced, particularly when it is conducted by privately funded, unincorporated organisations.

The creation of a new regime will require further debate and consultation among key stakeholders, and effective agreement between Commonwealth, State and Territory Governments. This will only be achieved with the requisite political motivation. Although government leaders across Australia have resolved at a number of Council of Australian Governments (COAG) meetings to properly regulate cloning and stem cell research, consensus as to the permissible limits of this research has been more difficult to achieve. However, at the last COAG meeting on 5 April 2002 a general consensus emerged amongst the government leaders that the use of embryos surplus to ART requirements for embryonic stem cell research should be allowed, but only in limited circumstances and subject to strict regulation.[140] There was also agreement, albeit somewhat more tentative, that therapeutic cloning should be prohibited, at least in the short term. The legislative scheme to achieve these heads of agreement remains to be settled.

The scheme for regulating the use of gene technology across Australia through the Commonwealth and State *Gene Technology Acts* may provide a suitable model. These Acts set up a detailed system for the control, licensing and prohibition of the use of genetically modified organisms in this country. The Office of the Gene Technology Regulator, established and authorised under the Commonwealth GTA, has national coverage. A similar national office should be created by legislation to oversee and license the use of surplus embryos for research purposes.

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138 *AHEC Report* Recommendations 2 and 3.

139 *Andrews Report* above n 23, paras 12.12-12.15.

140 'Anderson Denies Split as Leaders Approve Stem Cell Research' (2002) *ABC Online* at <http://abc.net.au/news/justin/weekly/newsnat-5apr2002-51.htm> at 10 April 2002.

A number of issues must be settled before proposed legislation can be introduced. Some of the points of contention are:

- the appropriate limits on the use of embryos for research purposes. The Prime Minister initially stated that only those surplus embryos already in existence could be used, because of the possibility that new embryos could be created solely for research purposes. However, the Premiers of a number of States were opposed to this restriction.[141] A compromise was reached at the COAG meeting: that there should be a temporary moratorium on the use of newly created embryos for research purposes.[142] The agreement provides that a committee of experts will develop guidelines as to the use of embryos created after 5 April 2002.
- what body should be charged with responsibility for overseeing the use of embryos for these purposes. The Prime Minister has nominated the NHMRC. However, there must be some doubt as to whether it has the competence to achieve the outcomes in point 6, above;
- whether the prohibition on therapeutic cloning may cause some scientists to leave Australia.[143]
- whether appropriate legislation will actually be passed by the Commonwealth Parliament, given that members will be free to give a conscience vote;
- whether, if the Commonwealth fails to move quickly and appropriately, the States will create their own regulatory regimes in the same piecemeal manner as for ART.

Finally, it should be acknowledged that these challenges must be considered beyond national boundaries; benefits and risks must be identified at the international as well as the national level. International scientific research on stem cells and human genes is throwing up the same core ethical, legal and social issues such as the status of the embryo, human rights, privacy and accountability. It is highly desirable that these core international issues should be governed by the same, or at least closely harmonised, international regulations and standards. In the complex territory of modern biomedical technology (which includes both stem cell technology and human genetic technology), spanning pure research, commercial development, medical and health application, interwoven with policy, principle, ethics, and new special perspectives, traditional legal regulation will not be the sole vehicle for

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141 See M Metherell, M Grattan and L Doherty 'Howard's Decision Incites Revolt by Premiers' (2002) *Sydney Morning Herald* at <http://www.smh.com.au/articles/2002/04/04/1017206244840.html> at 5 April 2002.

142 The duration of the moratorium has been reported to be for a one year period. See 'Anderson Denies Split as Leaders Approve Stem Cell Research' (2002) *ABC Online* at <http://abc.net.au/news/justin/weekly/newsnat-5apr2002-51.htm> at 10 April 2002.

143 For commentary on this issue see J Kerin, 'States Sign Up To Stem-cell Plan' (2002) *The Australian* at <http://www.theaustralian.news.com.au/common/story_page/0,5744,4082694%255E2702,00.html>.

protecting the common good. Regulation is not limited to formal lawyers' techniques of legislation or judicial pronouncement. The complexity of the science and the commercialisation of stem cell and genetic technology will require an equally complex regulatory response. Major vehicles will be administrative controls, enforceable and voluntary guidelines and review structures (such as research ethics committees and national bioethics bodies), that apply principles[144] consistent with developing international norms.[145] Stem cell technology offers a panoply of possibilities for the treatment of human disease and injury; this technology should not become an enemy of its own promise.

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144 Respect for persons, avoidance of harm and promotion of justice rank highly in this hierarchy.

145 See B Knoppers, 'Professional Norms Towards the Canadian Constitution' (1995) 3 *Health Law Journal* 1.