HUMAN EMBRYONIC STEM CELLS: SCIENCE, LEGALITY AND ETHICS

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ABSTRACT

Many scientific breakthroughs in human embryonic stem cell research have occurred in the past decade. Such research is beneficial because it has the ability to assist with treatment and prevention of degenerative diseases. Despite the benefits, the breakthroughs in stem cell research have also sparked debate in the community about the ethics of destruction of human embryos used in this research. Prompted by this debate, this paper undertakes an analysis of the regulatory framework of human stem cell research in Australia, and compares it with practices in two other common law jurisdictions, the United States and United Kingdom. A discussion of embryo ethics is undertaken, focusing on issues such as the right to life, paying women to donate eggs for research and the benefits of human reproductive cloning. The author adopts the position that regulation of stem cell research in Australia is mostly appropriate. However, it warrants reform in some respects, specifically paying women to donate eggs, with a view to facilitating ongoing human embryonic stem cell research.

I INTRODUCTION

Human embryonic stem cell research has gained increasing attention in the scientific community in the preceding decade because of the promise it may lead to medical breakthroughs and cure diseases. Embryonic cells have been hailed as the 'holy grail' of stem cells because they are pluripotent — they have an ability to differentiate into any other kind of cell in the human body.[1] While the scientific research is justified on the basis that it holds ground-breaking medical potential, it is also confronted by ethical objections because it involves the destruction of embryos. In 2013, American scientists used a cloning technique to transfer genetic material from an adult cell into an egg cell to derive embryonic cells.[2] Subsequently, American scientists used human embryonic stem cells to treat multiple sclerosis in mice.[3] Most recently, Chinese scientists used human embryonic stem cells to reverse Alzheimer's in mice.[4] While these scientific breakthroughs are often greeted with enthusiasm, the destruction of human embryos in the research process attracts criticism and ethical objections. Prompted by the recent developments and public scrutiny, this paper addresses contemporary scientific, ethical and regulatory issues in embryonic stem cell research. Part II examines three types of stem cells (adult, human embryonic and induced pluripotent) involved in research and the scientific justification for using human stem cells for research. Part III considers the regulatory framework for human stem cell research by examining the legal position in Australia compared with the

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1 Loane Skene, 'Recent Developments in Stem Cell Research: Social, Ethical and Legal Issues for the Future' (2010) 17(2) *Indiana Journal of Global Studies* 211, 214.

2 Masahito Tachibana et al, 'Human Embryonic Stem Cells Derived by Somatic Cell Nuclear Transfer' (2013) 153(6) *Cell* 1228.

3 Lu Chen et al, 'Human Neural Precursor Cells Promote Neurologic Recovery in a Viral Model of Multiple Sclerosis' (2014) 2(6) *Stem Cell Reports* 825.

4 Wei Yue et al, 'ESC-Derived Basal Forebrain Cholinergic Neurons Ameliorate the Cognitive Symptoms Associated with Alzheimer's Disease in Mouse Models' (2015) 5 *Stem Cell Reports* 1.

United States and United Kingdom. Part IV examines the ethical issues which arise with respect to human embryonic research, including paying women for egg donation. In conclusion, Part V points to the need for continuous reform in this rapidly changing field.

II THE SCIENCE OF STEM CELLS

A *What is Human Stem Cell Research and Why Do We Need It?*

Described as a 'blank canvas' of cells, stem cells have the ability to turn into more specialised cells in the body — skin, blood or muscle cells for example.[5] Stem cells are created at all stages of human development and have the ability to multiply. There are different types of stem cells including adult stem cells, embryonic stem cells and induced pluripotent stem cells.[6] Cells undergo several changes throughout their lifespan from being totipotent (most versatile and capable of developing into any cell type including placenta cells) to pluripotent (capable of developing into many different types of cells) to multipotent (limited in development) before becoming a specialised cell.[7]

Adult stem cells are found in organs and tissues in the human body, including bone marrow, blood, heart and liver. Their purpose is to replace the dead cells in the organ or tissue in which they are found.[8] An adult stem cell is *multipotent*, meaning it is very limited in the cell types it can turn into. Thus a stem cell sourced from one body part such as bone marrow can only be used to create bone marrow cells, not heart or liver cells, for example.[9] Adult stem cell therapy is frequently used to transplant bone marrow to treat leukaemia.[10] Research on adult stem cells does not attract the same ethical criticism as embryo research because it does not involve destruction of embryos. However, the potential of adult stem cells for innovative medical discoveries is more limited. In addition, some types of adult cells are not available in large quantities for scientists to conduct stem cell research.[11]

Human embryonic stem cells (hES cells) derive from embryos in early stages of development.[12] These cells are *pluripotent*, which means they can replicate to become any of a wide range of other types of cells: hES cells can differentiate themselves into three layers allowing them to develop into any of more than 220 cell types in the human body.[13] Thus hES cells are very useful in research with the aim of curing diseases. Theoretically, instead of conducting an organ transplant, one could take a sick patient with a diseased organ and instead inject the patient with healthy cells to regenerate the diseased organ.[14] There are additional benefits in replicating cells that do not replicate frequently. For instance, cells in the spinal cord do not regenerate easily.[15] Accordingly, if a patient sustained spinal cord injury, hES cells could be differentiated into spinal nerve cells to heal the injury.[16] Across a range of applications hES cells can be viewed as 'special', and thus contrasted with other cells, because they have

5 National Health and Medical Research Council, *Stem cells, cloning and related issues* (2013) <http://www.nhmrc.gov.au/health-ethics/human-embryos-and-cloning/stem-cells-cloning-and-related-issues>.
6 Ibid.
7 Christine Hauskeller and Susanne Weber, 'Framing pluripotency: iPS cells and the shaping of stem cell science' (2011) 30(4) *New Genetics and Society* 415, 420.
8 National Health and Medical Research Council, above n 3.
9 Skene, above n 1, 214.
10 Kyu Won Jung, 'Perspectives on Human Stem Cell Research' (2009) 220 *Journal of Cellular Physiology* 535, 536.
11 Ibid.
12 National Health and Medical Research Council, above n 3.
13 Miyako Takagi, 'Ethical Issues in Embryonic Stem Cell Research and Possible Solutions using Induced Pluripotent Stem Cells: Ethical Comparison of Embryonic Stem (ES) Cells and Induced Pluripotent Stem (iPS) Cells' (2010) 8(6) *The International Journal of Humanities* 65, 65.
14 Skene, above n 1, 213.
15 Lucas Misna, 'Stem Cell Based Treatments and Novel Considerations for Conscience Clause Legislation' (2010) 8(2) *Indiana Health Law Review* 471, 484.
16 Ibid.

potential to treat a variety of conditions including heart and liver disease, diabetes, Parkinson's and Alzheimer's diseases.[17]

While hES cells hold much hope for regenerative medicine, research that uses them is clouded in ethical controversy, because it involves the destruction of a human embryo which has the possibility of developing into a human. One of the methods used to develop embryonic cells is somatic cell nuclear transfer (SCNT), used interchangeably with the term 'therapeutic cloning'. The process involves taking an adult cell from the human body (such as a skin cell), removing the nucleus from that cell and inserting it into an egg from which the nucleus has been removed. The egg is stimulated to form an embryonic cell.[18] Therapeutic cloning can be contrasted with reproductive cloning, which involves implanting the embryo created through SCNT into a human uterus and allowing it to develop into a human or animal. In 1997 this process was used to clone the first animal, a sheep named Dolly.[19]

The third type of stem cell relevant to the discussion consists of induced pluripotent stem cells (iPS cells). These are adult cells reprogrammed to give them the pluripotency of embryonic cells. In 2006 Japanese scientists were able to produce pluripotent cells from an adult mouse skin cell. The process was refined in 2007, when Japanese and US scientists inserted viruses into a human adult cell to reverse its development.[20] In 2015, scientists were able to reprogram adult skin cells to produce mini-kidneys.[21] A recent study has highlighted the ability of pluripotent stem cells to be turned into embryos.[22] The use of iPS cells is viewed as an ethical alternative to using hES cells because iPS cell research does not involve the destruction of human embryos. However, the drawback of iPS cells is their link to cancer. The manner in which this occurs is that iPS cells may retain a 'memory' of the original cell used for the reprogramming.[23] Ultimately the incomplete cellular repogramming may cause the cells to become cancerous.[24]

Given that stem cells are contained in vital organs and tissues in the human body, research on them has been become increasingly important for various reasons. One of the main reasons for undertaking stem cell research is the potential to study and cure diseases and regenerate damaged organs by using healthy stem cells to replace damaged cells in the body.[25] It also allows scientists to test drugs and medical treatments on cells developed from stem cells in order to ensure a drug's safety prior to its being made available to the public.[26] Arguably, if a product can be tested on a specific cell to which the product relates this ensures accurate and reliable results.[27] A drug used to treat colon cancer would require a vast number of human colon cells for testing, and the cells for testing can be derived from stem cells.[28] A further benefit of stem cell research is that it allows scientists to study cell differentiation and repair for potential genetic deficiencies during the human development stage.[29] The benefits and use of stem cells will be addressed in further detail in Part IV of this article in the context of ethical issues.

17 Skene, above n 1, 213.

18 National Health and Medical Research Council, above n 3.

19 Ian Wilmut et al, 'Viable offspring derived from fetal and adult mammalian cells' (1997) 385 *Nature* 810, 810.

20 Kazutoshi Takahashi et al, 'Induction of induced pluripotent stem cells from adult human fibroblasts by defined factors' (2007) 131 *Cell* 861.

21 Minoru Takasato et al, 'Kidney Organoids From Human iPS Cells Contain Multiple Lineages and Model Human Nephrogenesis' (2015) 526 *Nature* 564.

22 Martin Pera et al, 'What If Stem Cells Could Turn Into Embryos in a Dish?' (2015) 12(1) *Nature Methods* 917.

23 Rachael Panizzo, 'Setback in Non-Embryonic Stem Cell Use', (2010) *BioNews* 2 August, 569 <http://www.bionews.org.uk/page_67367.asp>; Erica Check Hayden, 'The Growing Pains of Pluripotency' (2011) 473 *Nature* 272, 273; Steve Connor, 'Plan for non-embryo stem cell technique suffers setback', *The Independent* (online), 20 July 2010 <http://www.independent.co.uk/news/science/plan-for-nonembryo-stem-cell-technique-suffers-setback-2030346.html>.

24 Tina Saey, 'ImPerfect Mimics' (2010) 178(8) *Science News* 28.

25 Hauskeller and Weber, above n 7, 418.

26 Jung, above n 10, 535.

27 Ibid.

28 Ibid.

29 Ibid.

II THE LEGAL FRAMEWORK

A *The Australian Regulatory Framework*

In 1997 the cloning of Dolly the sheep demonstrated to the public that cloning was no longer a matter of science fiction but rather a genuine scientific progression which would continue to advance. It became apparent that the cloning of a sheep could lead to the ability to clone a human, and that notion did not rest easily with some members of the public. The subsequent decade and a half witnessed rapid progress in the field of stem cell research and, as the scientific possibilities expanded, so did the need for legal intervention. In Australia prior to 2002 there was no uniform legislation governing reproductive cloning or stem cell research.[30] Only in Victoria, South Australia and Western Australia was there legislation governing assisted reproductive technology.[31] The *Infertility Treatment Act 1995* (Vic) governed the research that could be undertaken on embryos and people who could receive IVF treatment. It further provided for a licensing system for persons authorised to conduct IVF procedures.[32] The legislation strictly prohibited the destruction of human embryos.[33] The lack of legislative consistency posed practical problems because Victoria, South Australia and Western Australia had different legislative provisions, while states without legislation relied on guidelines published by the National Health and Medical Research Council (NHMRC). In addition, each of the three legislating states adopted a slightly different definition of cloning.[34] In 2001, prompted by factors including the birth of Dolly the cloned sheep and the isolation of human embryonic cells, a House of Representatives Standing Committee on Legal and Constitutional Affairs conducted an inquiry and released a report which addressed the issues associated with research involving cloning techniques.[35] The recommendations culminated in two pieces of federal legislation, the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) (PHCR Act) and the *Research Involving Human Embryos Act 2002* (Cth) (RIHE Act), with the states and territories adopting mirror acts.

The purpose of the PHCR Act was to prohibit human cloning and other equally undesirable practices. The RIHE Act permitted certain practices provided they were carried out under licence.[36] The PHCR Act prohibited reproductive and therapeutic cloning, the creation of human–animal hybrid embryos and commercial trading of gametes or embryos.[37] The RIHE Act prohibited research on excess embryos developed from Assisted Reproductive Technology (ART) unless a licence was obtained from the Embryo Research Licencing Committee of NHMRC.[38] A requirement was imposed that the legislation be reviewed by 19 December 2005. A review was carried out by an independent Legislation Review Committee appointed by the Australian Government. The committee was chaired by former Federal Court justice, the Honourable John Lockhart, and became known as the Lockhart Committee. After extensive community consultations the Lockhart Committee published a report in December 2005. The report made 54 recommendations maintaining that the majority of prohibitions already

30 Sonia Allan, 'Regulatory design strategies and enforcement approaches for research involving human embryos and cloning in Australia and the United Kingdom – time for a change' (2010) 32 *Sydney Law Review* 617, 620.

31 Ibid.

32 Helen Szoke, Lexi Neame and Louise Johnson, 'Old technologies and new challenges: Assisted reproduction and its regulation' in Ian R. Freckelton and Kerry Anne Petersen (eds), *Disputes and Dilemmas in Health Law* (The Federation Press, 2006) 202.

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

34 Sonia Magri, 'Research on human embryos and cloning: Difficulties of legislating in a changing environment and model approaches to regulation' (2005) 12(4) *Journal of Law and Medicine* 483.

35 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (August 2001) at 1.1 and 1.5.

36 Allan, above n 30, 621; Louise Johnson and Tracey Setter, 'Regulation of ART' in Steven Fleming and Simon Cooke (eds), *Textbook of Assisted Reproduction for Scientists in Reproductive Technology* (Vivid Publishing, 2008) 361–2.

37 Shih-Ning Then, 'Regulation of Human Stem Cell Research in Australia' (2009) 5(1) *Stem Cell Reviews and Reports* 1, 2.

38 Ibid.

in existence should remain in place.[39] One noteworthy recommendation proposed to allow the creation of embryos for research using SCNT for research, provided it was conducted under licence. A further recommendation proposed to allow the transfer of human somatic cell nuclei into animal eggs provided the transfer was carried out under licence. The Lockhart Committee's recommendations were not accepted by the Federal Government. However, a private bill sponsored by Senator Kay Patterson resulted in a majority of Senate votes in favour of the amendments.[40] It should be noted, however, that the recommendation of using SCNT in animal eggs was not accepted.[41] The amendments were incorporated via the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth), which required a review three years after commencement.

In December 2010 an independent Legislative Review Committee chaired by the Honourable Peter Heerey, which became known as the Heerey Committee, conducted a review of the legislation.[42] The Heerey Committee made 33 recommendations, which essentially provided that the PHCR Act and RIHE Act (as amended in 2006) should remain unaltered.[43] The Australian regulatory framework implemented in 2002 and reviewed by the Heerey Committee in 2006 remains in force.In brief, the current legislative regime provides for criminal sanctions for prohibited conduct and promotes a licensing regime for certain research. Ultimately, the legislation is far more consistent than initial attempts to legislate in this field.

In Australia, the current regulatory framework provides that research on *excess* ART embryos (effectively research on spare embryos from women undertaking fertility treatment) is an offence unless authorised by licence.[44] It is also an offence to use an embryo created by the fertilisation of a human egg by human sperm (which is not an excess ART) for any purpose other than ART treatment in a woman.[45] However, creation of human embryos for research is permitted under licence provided this is achieved via means other than the fertilisation of a human egg by human sperm.[46] In other words, a human embryo may be created via therapeutic cloning. The PHCR Act prohibits many practices that the public strongly opposes. These include placing a human embryo clone into the body of a human,[47] developing a human embryo outside the body of a woman for more than 14 days,[48] creating an animal–human hybrid embryo,[49] placing a human embryo in the body of an animal or vice versa,[50] and commercial trading in human embryos.[51] The Australian legislative framework on cloning and stem cell research is far more effective now than the initial attempts to legislate by the states. The legislation is consistent in its application across Australia. It is comprehensive in that it regulates all important aspects of stem cell research and prohibits conduct which remains controversial with the public. In one sense the legislative regime may be described as conservative and prohibitive in nature, and this is apparent when compared with the United States and United Kingdom regulatory approaches.

39 Australian Government (2005), Legislation Review: *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*, Reports, Canberra, December 2005.

40 Andrew Sinclair and Peter Schofield, 'Human Embryonic Stem Cell Research: An Australian Perspective' (2007) 128 *Cell* 221, 222.

41 Ibid; Then, above n 37, 2.

42 Legislation Review Committee, Legislation Review: *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002*, Reports, Canberra. June 2011.

43 Ibid 15–19.

44 *Research Involving Human Embryos Act 2002* (Cth) s 10.

45 Ibid s 11.

46 Ibid s 20(1).

47 *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 9.

48 Ibid s 14.

49 Ibid s 17.

50 Ibid s 19.

51 Ibid s 21.

B *International Perspectives*

Given that stem cell research and human cloning are international scientific issues it is useful to conduct a comparison of the Australian regulatory framework with international counterparts. To achieve this, an analysis of the United States and United Kingdom regulation with respect to stem cell research and human cloning is undertaken. The United States regulatory approach has been described as a 'conservative' and 'decentralized system, with little regulatory control and high uncertainty',[52] while the United Kingdom is seen as more progressive despite being highly regulated.[53]

1 *United States*

The United States does not have an extensive legislative framework for embryo research and remains largely unregulated in this field. Instead, the focus seems to be on obtaining federal funding to conduct research.[54] As a starting point, research on human embryos (whether spare embryos from ART or embryos created specifically for research) is not illegal in the United States, as there is no law prohibiting such conduct. The only situation in which human embryo research is prohibited is where a state has specifically legislated to impose such a prohibition. For example, Indiana and Michigan prohibit research on cloned embryos, Illinois prohibits research on live embryos and Louisiana prohibits research on in vitro fertilised embryos.[55] In 1996, Congress introduced a ban, incorporated via an amendment known as the Dickey Amendment, prohibiting federal funding for the creation or destruction of a human embryo. In 2001, former United States President George W. Bush prevented the National Institute of Health from funding research on human embryonic cells by limiting funds to research on certain cell lines. Essentially, research could be conducted on non-embryonic stem cells and embryonic stem cell lines which were already in existence. In 2006 a bill attempting to loosen the federal funding restrictions was passed by the House of Representatives and Senate but vetoed by President Bush. On March 2009, by Executive Order, President Barrack Obama revoked the limitations on funding imposed by President Bush.[56] Subsequently, the National Institute of Health guidelines were amended to allow federal funding for research on spare ART embryos.[57] Accordingly, no federal funding is permitted for research which involves the creation of a human embryo. It should be noted that this does not affect research conducted by private organisations that are not bound by the restrictions. States are also not bound by the restrictions and are free to legislate in a permissive manner to expressly allow human embryo research. For example, California and New Jersey have statutes allowing therapeutic cloning.[58] It is striking that there is no federal legislation prohibiting reproductive cloning. Theoretically, no law prevents the creation of a cloned human being provided one has the means to do so.

It is evident that the United States has avoided a prescriptive regulatory structure and instead favoured self-regulation by the private sector. From one perspective that may be viewed favourably because it allows science to develop without legislative confinement. If a private organisation is prepared to fund the research, it may lead to great scientific breakthroughs. The disadvantage, however, is that researchers who are dependant on federal funding will be deprived of the ability to undertake research which may lead to breakthroughs. Some authors

52 Jody Schechter, 'Promoting Human Embryonic Stem Cell Research: A Comparison of Policies in the United States and United Kingdom and Factors Encouraging Advancement' (2010) 45 *Texas International Law Journal* 603.

53 Ibid.

54 Ibid 608.

55 Ibid.

56 Press Release, Office of the Press Secretary, White House, Remarks of President Barack Obama – As Prepared for Delivery: Signing of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum (9 March 2009) < http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing- of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/>.

57 National Institute of Health, *Guidelines on Human Stem Cell Research* (7 July 2009) <http://stemcells.nih.gov/policy/pages/2009guidelines.aspx>.

58 Schechter, above n 52, 614.

59 Ibid 609.

have also identified absurd consequences which may arise. For instance, a federally funded institute can lose funds because a privately funded scientist used the wrong refrigerator to store embryos for research which does not comply with the guidelines.[59] These inconsistencies may prevent the United States leading international stem cell developments. On the other hand, there is a risk that lack of stringent regulation may lead down the slippery slope of human cloning, which is unlikely to be acceptable to the general public.

2 *United Kingdom*

The United Kingdom adopts a similar regulatory approach to that in Australia, in the sense that it clearly outlines acceptable and prohibited conduct in the field of stem cell research and cloning. However, there are some differences which lead to the United Kingdom having a more permissive stance on some matters. Unlike the United States, the United Kingdom legislature has consistently been in favour of permitting embryonic stem cell research.[60] Following the birth of the first IVF baby in 1978, a government committee known as the Warnock Committee was commissioned in 1982 to conduct an enquiry into human fertilisation and embryology. Its report was released in 1984.[61] The Warnock Committee was in favour of allowing research on human embryos provided a regulatory body was created to monitor such research. As a result the *Human Fertilisation and Embryology Act 1990* (UK) was passed, and the Human Fertilisation and Embryology Authority was established as a licensing authority to oversee the research. In 2007 a major review of the 1990 legislation was conducted, resulting in the *Human Fertilisation and Embryology Act 2008* (UK), which amended the 1990 Act. The current law allows research under licence on excess ART embryos and embryos created specifically for research (whether by SCNT or by the fertilisation of a human egg by human sperm) provided they are outside the human body. Research on embryos older than 14 days is not permitted.[62] Although therapeutic cloning is permitted, reproductive cloning is prohibited under the *Human Reproductive Cloning Act 2001* (UK). Interestingly, the 2008 amendments permit the insertion of restricted amounts of animal cells into human cells for the purpose of research. However, the creation of a 'true hybrid' involving the fertilisation of a human egg with animal sperm or vice versa is prohibited.

3 *International Society for Stem Cell Research*

In a discussion comparing the Australian position to international regulatory perspectives on stem cell research, reference must be made to guidelines developed by the International Society for Stem Cell Research (ISSCR). The ISSCR is a team of experts in science, medicine, ethics and law from 14 countries, formed to address cultural, political, legal and religious issues arising from stem cell research.[63] In 2006, the ISSCR published Guidelines for the Conduct of Human Embryonic Stem Cell Research. In relation to human cloning, the ISSCR position is that human cloning should be prohibited.[64] The guidelines recommend that all experiments involving hESC research or incorporation of human cells into animal chimeras should be strictly monitored by an oversight body.[65] The guidelines divide research into three separate categories. Category 1 covers permissible research on existing stem cell lines. Category 2 covers research which is only permissible if it is subject to review by a specialised body, and includes scientific research which requires greater justification. Category 3 outlines research which should not be conducted. The prohibited research in category 3 is divided into three subcategories: (1) Any post-fertilisation human embryos that might manifest human organismal potential for longer than 14 days or until formation of the primitive streak begins; (2) Research in which any products of research involving human totipotent or pluripotent cells are implanted into a human

60 Ibid 614.

61 Allan, above n 30, 619.

62 *Human Fertilisation and Embryology Act 1990* (UK), s 3.

63 International Society for Stem Cell Research, *Guidelines for the Conduct of Human Embryonic Stem Cell Research* (21 December 2006) < http://www.isscr.org/docs/default-source/hesc-guidelines/isscrhescguidelines2006.pdf>.

64 Ibid guideline 6.1

65 Ibid guideline 8.1

or non-human primate uterus; and (3) Research in which animal chimeras incorporating human cells with the potential to form gametes are bred to each other.[66] The guidelines recognise the need for scientific research to progress, and as this occurs new ethical challenges and regulatory issues will arise. The guidelines may be described as liberal because although they take ethical concerns into account and project a firm stance on prohibited conduct, they place strong emphasis on the need for an evolving regulatory approach to keep up to date with scientific development.

III Embryo Ethics

The regulation of hESC research would not be contentious if there were no underlying ethical issues. This section of the article will address the most common ethical objections which arise in the context of hESC, including the right to life and destruction of embryos, payment for eggs provided for research, and human cloning, along with the argument that hESC is redundant in light of iPS cells. Each issue will be discussed in detail and reasons will be provided as to why the ethical issues do not create a strong enough reason to prevent hESC research from being undertaken. The ethical issues are particularly relevant in light of recent media coverage relating to stem cells being derived from a cloned embryo. In May 2013 it was announced that US scientists had created, from an adult skin cell, a cloned human embryo out of which embryonic stem cells were extracted.[67] Scientists used SCNT and took the nuclei from a human skin cell and transferred it into a human egg cell whose nucleus had been removed. The process created a cloned human embryo from which embryonic stem cells almost genetically identical to the person who provided the skin cells could be derived.[68] The media headlines varied in their reporting approaches: some focused purely on factual reporting,[69] some on the medical breakthrough perspective,[70] while others appealed to the public's fear that the breakthrough may lead to human reproductive cloning.[71] This recent scientific development (together with others referred to in this article) and the media coverage surrounding these developments have once again made discussion of the ethics of stem cell research relevant.[72]

A *The Right to Life and Destruction of Embryos*

One of the most ethically controversial issues which arises with respect to stem cell research is that SCNT involves the creation and destruction of a human embryo for research purposes. For some the destruction of a human embryo is the equivalent of destruction of human life.[73] That argument is based on the potential of an embryo to develop into a human being, which makes an embryo different from other cells in the body.[74] Strong opposition comes from members of the religious communities, particularly the Catholic Church, which believes that human life

66 Ibid guideline 10.3.

67 Nicky Phillips, 'Breakthrough: stem cells from a cloned embryo', *The Age* (online), 16 May 2013 <http://www.theage.com.au/technology/sci-tech/breakthrough-stem-cells-from-a-cloned-embryo-20130515-2jmwp.html>.

68 Ibid.

69 Ian Sample, 'Human embryonic stem cells created from adult tissue for first time', *The Guardian* (online), 16 May 2013 <http://www.guardian.co.uk/science/2013/may/15/human-embryonic-stem-cells-adult-tissue>.

70 Daniela Ongaro and Fiona Macrae, 'Stem cell research breakthrough in the US celebrated in Australia', *Herald Sun* (online), 17 May 2013 <http://www.heraldsun.com.au/news/national/stem-cell-research-breakthrough-in-the-us-celebrated-in-australia/story-fndo317g-1226644816352>; James Gallagher, 'Embryonic stem cells: Advance in medical human cloning', *BBC News* (Online), 15 May 2013 <http://www.bbc.co.uk/news/health-22540374>; Nicky Phillips, 'One giant step for humankind', The Sydney Morning Herald (online), 18 May 2013 <http://www.smh.com.au/technology/technology-news/one-giant-step-for-humankind-20130517-2jrvn.html>.

71 Fiona Macrae, 'New spectre of cloned babies: Scientists create embryos in lab that "could grow to full term"', *Daily Mail* (online), 15 May 2013 < http://www.dailymail.co.uk/sciencetech/article-2324970/New-spectre-cloned-babies-Scientists-create-embryos-lab-grow-term.html>.

72 See for instance Anna Salleh, 'Stem cell experts urge ethical debate over embryo creation', *ABC News* (online), 13 October 2015 < http://www.abc.net.au/news/2015-10-13/stem-cell-experts-urge-ethical-debate-over-embryo-creation/6837798>.

73 Takagi, above n 13, 65.

74 Ibid.

begins with fertilisation.[75] While all religious beliefs should be respected, one may argue that religion does not have a place in scientific research. Embryos are formed in vitro (outside of a living organism) and unless they are implanted in a human uterus do not have potential to develop into a human being. It is accepted that as part of in vitro fertilisation (IVF) procedures couples may have excess embryos which are frozen and subsequently discarded or donated to research. In other words, embryos are regularly discarded as part of the IVF process, and this seems to be acceptable because it is seen as helping couples who would not normally be able to have children be able to do so. Similarly, the creation and destruction of human embryos may be defended on the basis that hESC research has potential to treat conditions or cure diseases for thousands of living people, which leads to questions of whether destruction of embryos is justified on the premise it will do good to a great number of people. This is a clearly utilitarian theory.[76] However, some may object to that theory on the basis that respect for life and human dignity should be valued above all. Ultimately it is difficult to support an argument based on religion when science offers potential for medical cures which could lead to life-saving procedures.

B *Payments for Eggs*

If scientists are permitted to continue undertaking hESC research, then a constant supply of eggs will be needed.[77] The concern is that eggs obtained from IVF treatment or through altruistic donation will not be sufficient and will lead to egg shortages, which may in turn cause organisations to exploit poor or vulnerable women by offering payment for eggs.[78] This is a contentious issue that has attracted much debate and discussion.[79] It is also particularly relevant, given a position statement issued by the ISSCR released in March 2013 which recommended that paying women to donate eggs is ethically justifiable if the payment is a form of compensation to the woman for undertaking the process of egg donation rather than a payment for the eggs.[80] In Australia, it is currently an offence to offer valuable consideration for the supply of an egg, sperm or embryo.[81] The United Kingdom in 2009 amended their legislation to allow payment to egg donors for reasonable expenses associated with the donation[82] and in 2011 increased the payment to £750 for each cycle of donation to accommodate a demand for eggs.[83] The United States does not regulate payment for eggs at federal level, but in 2009 New York became the first American state to allow the use of public funds for payment of eggs donated for research.[84]

Continuing hESC research in Australia will undoubtedly require an ongoing supply of eggs and a financial incentive should be given to women to donate eggs. Egg donation can be contrasted to other altruistic donations for therapeutic or research purposes (such as blood, organ or tissue donation) because it is an invasive surgical procedure.[85] Similarly, egg donation can be contrasted with sperm donation, which is a far quicker process and does not involve any

75 Ibid.

76 T Hope, J Savulescu and J Hendrick, *Medical Ethics and Law: The Core Curriculum* (Churchill Livingstone, 2008) 3-4.

77 Phillips, above n 70.

78 Loane Skene, 'Should women be paid for donating their eggs for human embryo research?'(2009) 28(4) *Monash Bioethics Review* 28.1, 28.5.

79 Donna Dickenson, 'Good Science and Good Ethics: Why We Should Discourage Payment for Eggs for Stem Cell Research' (2009) 10 *Nature Reviews Genetics* 743; Susan L. Crockin, 'A Legal Defense for Compensating Research Egg Donors' (2010) 6 *Cell Stem Cell* 99; Insoo Hyun, 'Fair payment or undue inducement?' (2006) 442 *Nature* 629.

80 Erica Haimes and Loane Skene et al (ISSCR Ethics and Public Policy Committee) (2013), Position statement on the provision and procurement of human eggs for stem cell research, *Cell Stem Cell* 12, 285, 289.

81 *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 21.

82 *Human Fertilisation and Embryology Act 1990* (UK) s 12(1)(e).

83 Human Fertility and Embryology Authority, 'HFEA agrees new policies to improve sperm and egg donation services' (Press Release, 19 October 2011) < http://www.hfea.gov.uk/6700.html>.

84 New York State Stem Cell Science, *Statement of Empire State Stem Cell Board on the Compensation of Oocyte Donors* (2009) <http://stemcell.ny.gov/docs/ESSCB_Statement_on_Compensation_of_Oocyte_Donors.pdf>.

85 Donna Dickenson, *Body Shopping*: *The Economy Fuelled by Flesh and Blood* (Oxford: Oneworld, 2008) 84.

invasive procedures. Altruistic egg donation is far rarer than blood or sperm donation because the egg donation process is onerous, painful, and may contain risks which are not as yet known. The donor must take drugs to suppress the menstrual cycle and receive daily injections for weeks to stimulate the production of eggs. This stimulation of eggs also risks exposing the donor to ovarian hyperstimulation syndrome,[86] and drugs taken by women can produce very unpleasant side effects including bleeding, cramping and mood swings.[87] Other suggested risks associated with this process have not been fully established, including long-term side effects of the drugs, a potential risk of early menopause and a risk that that drugs contribute to uterine cancer.[88]

Those opposed to paying women for egg donation argue that it would exploit vulnerable women, that it would set a precedent for a black market for organs and that it would lead to commodification of eggs. These are valid arguments, but if payment for egg donation is regulated then it will prevent, or at least deter, black market trade or exploitation of women. That is the position that Australia should be adopting and it is hoped that the ISSCR position and statement and New York decision may have some influence on the Australian legislature. Further, some may argue that payment for egg donation is akin to payment for surrogacy or the donation of organs. Arguably, these can be differentiated because surrogacy involves a long-term commitment and emotional involvement, and the donation of organs involves an altruistic donation of an organ that can never grow back. Finally, advocating prohibition of hESC research solely because there is a fear it would lead to exploitation of women in obtaining eggs for research is not persuasive, since appropriate oversight by ethics committees to monitor recruitment procedures and consent forms can address the issue.[89]

C *Human Reproductive Cloning*

A controversial feature of hESC research is that it opens up the doors to human reproductive cloning. The subject raises significant ethical backlash from the public because cloning is perceived to be undesirable and unacceptable. One reason the public is so firmly against human reproductive cloning may be a fear of the unknown. Unless a person has a thorough understanding of the scientific principles behind hESC research, it is probable that their source of information pertaining to cloning may be mainstream sources of media or movies. It is therefore unsurprising that even the mere possibility that scientists could create a human clone invokes fear. For instance, the *Herald Sun* reports that there is 'little to stop a rogue scientist copying their work to try and clone humans'.[90] The *Sydney Morning Herald* quotes CSIRO's Andrew Laslett describing SCNT as being 'at a very similar stage where you could implant it back into a surrogate and theoretically get a human'.[91] Dr David King, from campaign group Human Genetics Alert, calls for an international legal ban on all human reproductive cloning and states that even the publishing of the recent research is 'irresponsible in the extreme'.[92]

There are also many other objections to human reproductive cloning, namely that it defies human individuality, that it attracts great potential for abuse and that the cloned human may have significant health risks.[93] One significant benefit of human reproductive cloning is that it can support research with therapeutic purposes. Thus Professor Julian Savulescu argues that it is morally justifiable to employ cloning techniques to provide cells, tissues or organs

86 Donna Dickenson, 'Good Science and Good Ethics: Why We Should Discourage Payment for Eggs for Stem Cell Research' (2009) 10 *Nature Reviews Genetics* 743.

87 Insoo Hyun, 'Fair payment or undue inducement?' (2006) 442 *Nature* 629.

88 Dickenson, above n 86, 85.

89 Loane Skene, 'Recent moves to compensate women who provide their eggs for research and implications for Australia' (2013) 20(4) *Journal of Law and Medicine* 845, 850.

90 Ongaro and Macrae, above n 70.

91 Phillips, above n 70.

92 Gallagher, above n 70.

93 Julian Savulescu, 'Should we clone human beings? Cloning as a source of tissue for transplantation' (1999) 25 *Journal of Medical Ethics* 87, 87.

for therapy.[94] If cloning could be used either to treat genetic diseases or even to prevent life-threatening diseases occurring, then the benefits far outweigh the risks.

Another important benefit employs a different type of human reproductive cloning with the aim of assisting couples to have children. Professor Loane Skene argues that if it could be established that it is safe for a cloned child to be born, this may eventually enable infertile couples to have a genetically related child,[95] and this is a further justification for ongoing support for scientific research in this field.

D *ESC v iPS Cells*

Since the discovery of iPS cells, opponents of hESC research have argued that there is no longer a need for research on embryos when iPS cells present as a more ethically acceptable alternative.[96] Dr David van Gend is one such opponent who has argued that cloning is unnecessary in light of the 2007 breakthrough by Japanese scientist Shinya Yamanaka with respect to cellular reprogramming.[97] Dr van Gend describes the use of iPS cells as 'marvellous science' which does not attract the same social and ethical stigma associated with the creation and destruction of embryos.[98] Dr van Gend continues his criticism of hESC research by posing two questions: why use embryos when iPS cells can be used instead, and why use iPS cells when adult stem cells can be used instead?[99]

However, iPS cells are a relatively new finding and are not without risks. Recent studies have shown that iPS cells retain a 'memory' of the original adult cell used for the cellular reprogramming.[100] The concern is the retention of memory and lack of complete cell reprogramming may cause the cells to become cancerous.[101] Further, iPS cells have been described as being 'inferior to cloned embryonic stem cells in a similar way a plastic watch cannot compare with a Swiss-made timepiece'.[102] Some authors have argued that adult stem cell research is not a substitute for hESC research nor vice versa, and that the two fields of research should be treated separately.[103] Both hESC and iPS cell research have scientific and medical potential and it is too soon to dismiss either method. Instead, focus should be on facilitating both types of research to allow studies of the benefits and risks of both methods to be discovered.

E *Legislative Reform and the Future of Stem Cell Research*

The discussion of embryo ethics has demonstrated that research on human embryos is a contemporary and controversial issue. The Australian legislature has recognised this and attempted to address community concern with the enactment of the PHCR Act and RIHE Act. The legislation should be viewed favourably because it provides a comprehensive, uniform regime of federal legislation adopted by the states. It clearly delineates prohibited and acceptable conduct, which eliminates the kind of confusion and uncertainty experienced in the United States. Regulatory coherence is desirable, according to theories of law that supports the proposition that political and social considerations influence the design and implementation of regulation.[104] Accordingly, research on human embryos warrants regulatory intervention to protect research integrity and to avoid misuse. This will strike a balance between permitting

94 Ibid.
95 Skene, above n 1, 236.
96 Hauskeller and Weber, above n 5, 425.
97 David van Gend, 'An obituary for human cloning' (2010) 4 *Viewpoint Magazine* 28, 30.
98 Ibid 28.
99 David van Gend, 'Cloning: The Blighted Science' (2011) 55(11) *Quadrant* 104, 109.
100 Panizzo, above n 23; Hayden, above n 23, 273.
101 Saey, above n 24, 28.
102 Phillips, above n 70.
103 Gregory Dolin, 'A Defense of Embryonic Stem Cell Research' (2009) 84(4) *Indiana Law Journal* 1203, 1211–12.
104 See for example Benedict Sheehy and Donald Feaver, 'Designing Effective Regulation: A Normative Theory' (2015) 38(1) *University of New South Wales Law Journal* 392.

freedom of research and avoiding harm. A coherent regulatory framework will avoid the negative effects experienced in countries such as South Korea that lack regulation. A prime example is the controversy involving Woo-Suk Hwang, a South Korean scientist, who fraudulently claimed to have cloned human embryos. The human eggs sourced for his research involved serious comprises of research ethics and integrity, as it was discovered that the women who donated eggs did not give proper consent and were paid cash incentives to provide eggs.[105]

However, a matter which requires specific legislative reform is paying women to donate eggs to allow stem cell research to continue.[106] Professor Skene has highlighted not only the current need for human eggs for scientific research, but that compensating women for egg donation may increase the number of eggs available for research.[107] Some jurisdictions such as the United Kingdom and the state of New York have recognised this and legislated in favour of payment. This is the position which, I argue, should be adopted in Australia.

IV CONCLUSION

The last fifteen years have seen tremendous scientific progress in the field of biomedicine. The scientific breakthroughs and developments have opened many doors for treatment and prevention of degenerative diseases. Simultaneously, these developments have sparked ethical and moral questions about the legitimacy of treatment made possible through the destruction of human embryos. There are no simple answers to these questions, and undoubtedly the debate will continue to be influenced by scientific, political and religious views. This paper has examined the Australian law on hESC research compared with international perspectives. The conclusion arrived at is that the Australian law for the most part is appropriate but that it requires ongoing reform, particularly with respect to paying women to donate eggs for research.

105 Rachel Saunders and Julian Savulescu, 'Research Ethics and Lessons From Hwanggate: What Can We Learn From the Korean Cloning Fraud?' (2008) 34(3) *Journal of Medical Ethics* 214; Françoise Baylis, 'For Love or Money? The Saga of Korean Women Who Provided Eggs for Embryonic Stem Cell Research' (2009) 30(5) *Theoretical Medicine and Bioethics* 385.

106 Skene, above n 89,, 847-848.

107 Ibid.