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Therapeutic cloning in Australia: One small  
stem from man, one giant leap for mankind

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# Therapeutic cloning in Australia: One small stem from man, one giant leap for mankind

Irene Nemes

## Abstract

In 2002 the Australian Parliament enacted legislation which prohibited both therapeutic and reproductive embryonic cloning. Just four years later, in December 2006, this same legislation was amended, reversing the prohibition on therapeutic cloning, while retaining the ban on reproductive cloning. The Prime Minister, sensing the political mood, allowed a conscience vote. This contrasted with his decision several months earlier against introducing any changes to the 2002 Act, despite 54 recommendations having been made by a Statutory Review Committee. Approval of the legislation had as much to do with the careful drafting of the provisions as with any rational, social or scientific factor. The legislation is narrow in scope, retains an absolute prohibition on reproductive cloning and contains strict regulations with heavy criminal penalties. The Act requires a review after three years. A number of questions remain. Does stem cell research demand a global rather than a local approach, by way of an international Covenant? Does the legal status of a cloned embryo need further examination? Will the embryo have a separate legal standing recognised by law? These are some of the questions which will need addressing as the law tries to keep up with science.

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## INTRODUCTION

In 1997 the world's first cloned mammal was created<sup>1</sup> amid great excitement in the scientific community. Around the same time, the first human embryonic stem cells were derived.<sup>2</sup> Only 10 years later, on 5 September 2007, the United Kingdom Human Fertilisation and Embryology Authority (HFEA) has given "in principle" approval for the creation of hybrid human-animal embryos<sup>3</sup> from which scientists can extract stem cells for research purposes. The United Kingdom has one of the world's most permissive schemes for stem cell research.

Teams of scientists around the world are already carrying out research on human embryonic stem cells, as more and more countries are introducing legislation to permit such research to be done. Australia introduced its own modest federal legislation<sup>4</sup> in December 2006,<sup>5</sup> amending earlier legislation which allowed research on excess IVF embryos but banned all forms of somatic cell

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<sup>1</sup> On 24 February 1997 Scottish scientists I Wilmut, AE Schnieke, J McWhir, AJ Kind and KH Campbell announced that they had cloned "Dolly" the sheep by using nuclear transfer.

<sup>2</sup> Thomson JA et al, "Embryonic Stem Cell Lines Derived from Human Blastocysts" (1998) 282(5391) *Science* 1145. Embryonic stem cells are pluripotent, which means that they can turn into any cell type in the adult body.

<sup>3</sup> The animal eggs, which are the subject of the HFEA approval, will have been almost completely stripped of all content except for mitochondrial DNA, or outer shell, which contains energy and is involved in the process of cell division. This animal shell will be injected with human DNA, so the resulting embryo would be 99.9% human and .1% animal. An alternative term for this entity is a "cybrid" or cytoplasmic hybrid embryo. The term "cybrid" was first coined in the 1960s and referred to an interspecies embryo. Two teams, from China and the United States of America, have so far created cytoplasmic hybrid embryos: see Human Fertilisation and Embryology Authority, *Hybrids and Chimera, A Consultation on the Ethical and Social Implications of Creating Human/Animal Embryos in Research* (April 2007).

<sup>4</sup> *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* (Cth).

<sup>5</sup> The Commonwealth legislation came into force on 12 June 2007.

nuclear transfer (SCNT).<sup>6</sup> SCNT will now be permitted to be carried out in Australia, subject to licence by the National Health and Medical Research Council (NHMRC). However, in its current form, the legislation<sup>7</sup> places significant restrictions on the scope of research activities. For example, it is not possible to obtain a licence to create hybrid embryos, such as has been considered for licensing by the United Kingdom HFEA.

In January 2008, the HFEA in the United Kingdom granted licences to two teams of scientists to create hybrid embryos using hollowed-out cow eggs mixed with human DNA. The first such “cytoplasmic” hybrid embryos were created in April 2008, by a team at Newcastle University. As a result, the potential for making scientific advances in the United Kingdom is much greater than in Australia, as human egg shortages present a serious impediment to medical breakthroughs. Such is the speed of scientific advance that a regulatory scheme which does not anticipate future scientific possibilities becomes an anachronism within a short time.

The Australian *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) (PHC Act), as amended, permits the creation of human embryos by SCNT for the purpose of research, subject to a licensing system administered by the NHMRC.<sup>8</sup> There are limits on what is permitted, with strict criminal penalties for breaches. It is possible to obtain a licence to create a human-animal hybrid embryo for the purposes of testing sperm quality in an accredited Assisted Reproductive Technology (ART) facility, but for no other purpose. The NHMRC does not have the power to grant the type of licence which the counterpart United Kingdom authority<sup>9</sup> has considered. The HFEA does have the remit to decide whether it will grant such a licence because the regulatory scheme is worded broadly enough to accommodate this type of procedure. The Australian legislation is more prescriptive. The ambit of authority given to the NHMRC to license various techniques is strictly determined, with little discretion beyond the parameters included in the legislation.<sup>10</sup>

Although the PHC Act allows animal-human hybrid embryos to be created (though not developed),<sup>11</sup> subject to a licence, the *Research Involving Human Embryos Act 2002* (Cth) (RIHE Act) lists the activities for which a licence may be granted. Research on human-animal embryos is not included in the list. There is therefore no possibility of the NHMRC issuing a licence for scientists to create human-animal embryos for research purposes.

The PHC Act and the RIHE Act are likely to undergo further parliamentary debate when they come up for review in 2009-2010. By then, it could be that Australian scientists become frustrated by an insufficient supply of human eggs (oocytes), and move their expertise overseas<sup>12</sup> to places where the regulatory scheme is more permissive, where funding is more plentiful or they may move into other types of research altogether.

Considering the fact that human embryonic stem cell (hESC) research is still in its infancy, and that it may take as many as 50 years of continuous research before the technology can be used for

<sup>6</sup> *Prohibition of Human Cloning Act 2002* (Cth). For a comprehensive history preceding the enactment of this Australian Commonwealth legislation, see Dodds S and Ankey RA, “Regulation of hESC Research in Australia: Promises and Pitfalls for Deliberative Democratic Approaches” (2006) 3 *Bioethical Inquiry* 95.

<sup>7</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) and *Research Involving Human Embryos Act 2002* (Cth).

<sup>8</sup> The NHMRC funds medical research in Australia, as well as providing ethical guidelines for medical research. Having a licensing authority as an extra gateway provides additional protection and oversight.

<sup>9</sup> HFEA will merge with the Human Tissue Authority to become the Regulatory Authority for Tissue and Embryos (RATE) around 2009.

<sup>10</sup> *Research Involving Human Embryos Act 2002* (Cth).

<sup>11</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 23B(3)(b).

<sup>12</sup> Professor Alan Trounson, Australia’s leading stem cell researcher, announced on 15 September 2007 that he was leaving Australia for California. Trounson has been named as the new president of California’s US\$3 billion stem cell institute, the California Institute for Regenerative Medicine, <http://www.californiastemcellreport.blogspot.com/2007/09/californias-3-billion-stem-cell.html> viewed 17 September 2007. Other recent departures from Australia to work in the United States have included Martin Pera and Dianna DeVore of the Melbourne-based Australian Stem Cell Centre and Paul Simmons of the Peter MacCallum Cancer Centre.

human disease application, the public needs to be realistic about the speed with which medical outcomes can be delivered. Discoveries may occur only after thousands of embryo clones are created. In experiments with animals, the majority of resultant animal clones have been found to be subject to abnormalities which make them unusable. It is likely that human clones will react similarly. An inflexible regulatory regime, with narrow parameters and a strictly limited licensing scheme, acts as a barrier to scientific breakthroughs.

If Australia wishes to be a serious player in the race to find cures for debilitating diseases, Parliament should permit the NHMRC to decide whether to grant licences for animal-human embryos for research. The NHMRC is itself bound by guidelines to only approve research which meets strict ethical standards. It should be allowed to carry out its task without one hand tied behind its back.

The manner in which HFEA conducted the public consultation in the United Kingdom serves as a good example of a licensing body exercising its power in a responsible and ethical way. Perhaps in 2010, when the Australian legislation will be reviewed, Parliament may see fit to replace the provision which was removed by a late amendment in the Senate, allowing the NHMRC to license the use of animal eggs, subject to rigorous ethical oversight.

Public perceptions about mixing animal and human material can be easily distorted. Australian scientists should continue to educate the public on all matters concerned with stem cell research. The enactment of the PHC Act is not a *carte blanche* for hESC research. Scientists are best placed to communicate advances as they occur, and also to appeal for incremental legal change as required. While the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth) has unlocked the door to potentially beneficial research, the door may need to be pushed wider in the future. Issues such as artificial wombs, reproductive cloning technology and genetic manipulation will be on the scientific agenda in the not too distant future.

## AUSTRALIA UNLOCKS THE DOOR TO THERAPEUTIC CLONING

Somatic cell nuclear transfer<sup>13</sup> is now permitted in Australia,<sup>14</sup> as a result of a protracted debate in the Australian Parliament in 2006. This debate occurred four years after the Australian Parliament had enacted legislation prohibiting both therapeutic and reproductive cloning.<sup>15</sup> Pursuant to the 2002 legislation, a six-member committee was appointed<sup>16</sup> in June 2005 to review the legislation. The Committee's reports were tabled in both Houses of Parliament and presented to the Council of Australian Governments (COAG) in December 2005. The Lockhart Committee made 54 recommendations, including overturning the ban on therapeutic cloning. While sensitive to the variety of religious, moral and ethical views regarding therapeutic cloning, the Lockhart Committee nonetheless accepted that there were strong reasons for permitting SCNT. The Committee believed that by regulating the activity strictly, eg by banning reproductive cloning and not allowing the human clone to develop beyond 14 days, it was possible to find the right balance between the potential benefits of the research and associated ethical concerns.<sup>17</sup>

Federal Cabinet initially rejected the Committee's recommendation for lifting the ban on therapeutic cloning, but subsequently the Prime Minister took the unusual step of allowing a

<sup>13</sup> Also referred to as therapeutic cloning, or embryonic stem cell research.

<sup>14</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) and *Research Involving Human Embryos Act 2002* (Cth), as amended by the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth).

<sup>15</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth); *Research Involving Human Embryos Act 2002* (Cth). The 2006 Bill did not alter the position in relation to reproductive cloning, which remains prohibited in every jurisdiction where therapeutic cloning has been permitted.

<sup>16</sup> Legislative Review Committee (chaired by the late retired Federal Court Judge, Justice John Lockhart AO QC), *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002* (Lockhart Review).

<sup>17</sup> For a comprehensive overview of the process see Sinclair AH and Schofield PR, "Human Embryonic Stem Cell Research: An Australian Perspective" (2007) 128 *Cell* 221.

conscience vote in Parliament,<sup>18</sup> while maintaining his personal opposition to changes to existing legislation. The conscience vote resulted in Australia joining those jurisdictions around the world where therapeutic cloning is permitted.<sup>19</sup> A generally supportive media, the involvement of a number of lobby groups,<sup>20</sup> as well as appeals by respected scientists were all influential in the process to amend previous legislation. It remains to be seen whether a push by scientists in countries with restrictive laws will have a similar effect.<sup>21</sup>

As more nations adopt permissive policies for human embryonic stem cell research, those scientists working in countries with restrictive policies may find their research possibilities curtailed. Were it not for a group of committed people who overcame what seemed at times an insurmountable hurdle, Australia risked being in this position.

In October 2006, Senator Kay Patterson introduced a private member's Bill (the Patterson Bill),<sup>22</sup> in the Senate. The Patterson Bill received support in the Senate by a narrow majority.<sup>23</sup> One month later the Bill was passed in the House of Representatives.<sup>24</sup>

The Australian Federal Parliament has no specific power to pass legislation on human cloning and embryos.<sup>25</sup> Section 51(xx) of the Commonwealth *Constitution* allows Parliament to pass laws relating to "foreign corporations, and trading or financial corporations formed within the limits of the Commonwealth". Except for some limited organisations involved in therapeutic cloning,<sup>26</sup> the majority of groups working in stem cell research do not fit within the definitions in s 51(xx), ie "trading or financial corporations". For this reason it is necessary for State and Territory governments to pass corresponding legislation to create a consistent framework throughout Australia. State governments are responsible for the provision of health systems. A nationally consistent scheme will be created when each State and Territory enacts corresponding legislation to that passed by the Commonwealth Parliament in December 2006. Leaders of the Council of Australian Governments signed a document in April 2007 indicating that they would use their best endeavours to introduce legislation into their jurisdictions by 12 June 2008, so as to ensure a nationally consistent scheme. To

<sup>18</sup> After strong lobbying by a number of Coalition backbenchers.

<sup>19</sup> Including Andalusia (Spain), Belgium, China, Czech Republic, India, Israel, Japan, Russia, Singapore, South Africa, South Korea, Sweden, the United Kingdom, Israel and the United States (some States). The United States does not permit federal funds to be used for stem cell research, except on human embryonic stem cells lines which were created before 9 August 2001. Although President George W Bush has vetoed all attempts to secure federal funding for stem cell research in the United States, California Governor Arnold Schwarzenegger has endorsed Proposition 71 and has been able to borrow US\$3 billion using California state bonds, to be used on stem cell research. Proposition 71 established the California Institute for Regenerative Medicine. In effect, although there is a prohibition on using federal funds for stem cell research, the area is federally unregulated, so even reproductive cloning is theoretically free from federal regulation. The most recent veto by President Bush occurred in June 2007, when he stated that "destroying human life in the hopes of saving human life is not ethical".

<sup>20</sup> Such as the Coalition for the Advancement of Medical Research in Australia (CAMRA).

<sup>21</sup> Germany currently has some of the most restrictive laws in relation to embryonic stem cell research, due no doubt to Germany's sensitivity about its Nazi history. Yet in July 2007, the National Ethics Council voted by 14 to 10 to recommend a softening of the legal prohibitions so as to allow German scientists to conduct stem cell research. On 23 May 2008, the German Parliament approved a relaxation of the previous strict limits so as to permit scientists to import stem cell lines created before 1 May 2007. In March 2005, the General Assembly of the United Nations issued the *Declaration on Human Cloning* where "Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life". This Declaration is a non-binding political statement which does not have the force of law unless Member States pass domestic legislation. The vote was not unanimous, with 84 nations voting in favour, 34 against, with 37 abstentions. Interestingly, Australia voted in favour of prohibiting all forms of cloning, yet less than two years later the Australian Parliament enacted legislation contrary to its earlier position.

<sup>22</sup> The *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* (Cth).

<sup>23</sup> 34 votes in favour to 32 votes against, on 7 November 2006.

<sup>24</sup> 82 votes in support to 62 votes against.

<sup>25</sup> Section 51 of the *Commonwealth of Australia Constitution Act 1900* (Cth) limits the Australian Federal Parliament's power to pass laws to those areas listed in s 51.

<sup>26</sup> Such as IVF clinics.

date, Victoria,<sup>27</sup> New South Wales,<sup>28</sup> Tasmania<sup>29</sup> and Queensland<sup>30</sup> have enacted such complementary legislation, while similar legislation was defeated by 18 votes to 15 in the Western Australian Parliament in May 2008. South Australia has introduced draft legislation into its State Parliament.

The federal legislation must be reviewed after three years, with the review taking into consideration factors such as local and international research developments, community standards and the effectiveness of legislation.<sup>31</sup> Scientists who argued in favour of the amending legislation stressed that SCNT technology was unlikely to yield practical outcomes for many years. Since scientific endeavours involve a painstaking process of trial and error, there is likely to be a dearth of significant outcomes when the legislation comes up for review. The lack of instant cures for diseases should not lessen the resolve of Parliament in allowing scientists to continue this valuable research. With the change in the Federal Government in November 2007, it is difficult to predict how members of Parliament will vote or what issues will be prominent. The factors which swayed Parliament in 2006 may not necessarily be the same ones that gain prominence in 2009-2010.

## THE PROHIBITION OF HUMAN CLONING FOR REPRODUCTION AND THE REGULATION OF HUMAN EMBRYO RESEARCH AMENDMENT BILL 2006 (CTH)

### Voting patterns in Parliament

The voting patterns in Parliament attest to the fact that gender played a significant role in the passing of the Bill. Women voted overwhelmingly in favour of the Patterson Bill. In the Senate, the female vote was 20 in favour and four against the Bill passing, while in the House of Representatives, the female vote was 27 in favour and nine against. In the Senate twice as many males voted against the Bill as those who voted in favour of it,<sup>32</sup> while in the House of Representatives, the numbers were almost evenly split.<sup>33</sup> Why did so many more women than men vote in favour of the amending legislation? Perhaps women are more sympathetic to research which is concerned with mechanisms of reproduction and cures for diseases, or perhaps they have a more optimistic outlook for the long-term outcomes of therapeutic cloning research. There may be myriad reasons for such a significant difference in voting patterns, and it is beyond the scope of this article to examine them in detail.

Voting patterns by State were almost evenly divided in the Senate, except for South Australia, where there were more than double the number of Senators voting yes than no.<sup>34</sup> In the House of Representatives, Western Australia stood out as the State where the majority of parliamentarians voted yes.<sup>35</sup> The Australian Labor Party showed the most significant differentiation between the yes and no vote, in both the Senate and the House of Representatives.<sup>36</sup>

<sup>27</sup> *Infertility Treatment Amendment Act 2007* (Vic), passed on 3 May 2007.

<sup>28</sup> *Human Cloning and Other Prohibited Practices Amendment Act 2007* (NSW), passed in the Legislative Council on 26 June by 27 votes to 13, and backdated to commence on 12 June 2007. Prior to the vote in the New South Wales Parliament, Sydney Cardinal George Pell urged politicians to vote against the Bill, which he called "immoral legislation". He suggested there may be "consequences" for members in supporting the Bill. A parliamentary inquiry considering whether public comments made by Cardinal Pell constituted a contempt of Parliament decided on 19 September that no contempt had been found. On 6 August 2007 New South Wales Premier Morris Iemma announced a \$500,000 grant towards stem cell research.

<sup>29</sup> *Human Cloning and Other Prohibited Practices Amendment Bill 2007* (Tas).

<sup>30</sup> *Research Involving Human Embryos and Prohibition of Human Cloning Amendment Bill 2007* (Qld).

<sup>31</sup> *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth), s 25A.

<sup>32</sup> 28 No to 14 Yes.

<sup>33</sup> 55 Yes to 53 No.

<sup>34</sup> 9 Yes to 4 No.

<sup>35</sup> 13 Yes to 1 No.

<sup>36</sup> Senate: 17 Yes to 8 No; House of Representatives: 43 Yes to 16 No.

## Relevant considerations discussed in Parliament

The parliamentary debates preceding the conscience vote canvassed a wide range of issues. Those supporting the legislation included the following reasons as being most persuasive:

- the benefit to humanity;
- curing debilitating diseases;
- the adequacy of safeguards against abuse;
- scientific discovery is a long and slow process;
- we cannot expect instant results;
- Australia risks being left behind in this field if we do not proceed;
- the slippery slope argument is exaggerated;
- threat of a scientific brain drain if the amendments are not passed; and
- this legislation is a modest increment to existing legislation.

Those opposed to the legislation were most concerned with the following issues:

- reproductive cloning will be the likely outcome;
- women could be exploited and incur risks to their health;
- cloning commodifies human life;
- adult stem cells provide an alternative source of research;<sup>37</sup>
- there already exists an ample supply of unused frozen eggs; and
- this legislation will result in unintended consequences.

Ethical and religious issues were paramount for those who believed that the destruction of a human life form, no matter how early, cannot be justified by the promise of a far-off and hypothetical cure for disease.<sup>38</sup> Opponents also feared the misuse of cloned embryos by unethical scientists.

## Legislative provisions

The amended *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) is divided into separate parts for practices which are completely prohibited and for those which are prohibited unless authorised by licence.<sup>39</sup> Completely prohibited practices carry a maximum penalty of 15 years imprisonment. They include the following:

- placing a human embryo clone in the body of a human or an animal;<sup>40</sup>
- importing or exporting a human embryo clone<sup>41</sup> or a prohibited embryo;<sup>42</sup>
- creating a human embryo (by fertilisation with sperm) for a purpose other than pregnancy in a woman;<sup>43</sup>
- creating or developing a human embryo by fertilisation that contains genetic material of more than two persons;<sup>44</sup>

<sup>37</sup> In June 2007, two teams of scientists from the United States and Japan announced that they could turn ordinary mouse tissue cells into fully functioning embryonic stem cells without the use of eggs or embryos. Although not yet tested in humans, these findings, if found to operate in human adult skin cells, could avoid the ethical problems associated with the destruction of human embryos. See "Stem Cells: From Adult to Embryo", *New Scientist* (6 June 2007), <http://www.newscientist.com/article/mg19426073.800-stem-cells-from-adult-to-embryo.html> viewed 10 June 2008.

<sup>38</sup> Religious views on the issue of human embryonic stem cell research vary. See eg Winston RML, "Does Government Regulation Inhibit Embryonic Stem Cell Research and Can It Be Effective?" (2007) *Cell Stem Cell* 27.

<sup>39</sup> The National Health and Medical Research Council (NHMRC) is the licensing body.

<sup>40</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 9.

<sup>41</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 10. It is permissible to import/export human embryonic stem cell lines derived from human embryo clones.

<sup>42</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 20. Couples wishing to take ART embryos from Australia to another country to continue treatment may do so, as these ART embryos are not "prohibited" embryos.

<sup>43</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 12.

<sup>44</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 13.

- developing a human embryo outside the body of a woman for more than 14 days;<sup>45</sup>
- making heritable alterations to a human genome;<sup>46</sup>
- collecting a viable human embryo from the body of a woman;<sup>47</sup>
- creating a chimeric embryo;<sup>48</sup>
- developing a hybrid embryo beyond 14 days;<sup>49</sup>
- placing a human embryo in an animal; in the body of a human other than a woman's reproductive tract; or an animal embryo in the body of a human;<sup>50</sup> and
- commercial trading in human eggs, human sperm or human embryos.<sup>51</sup>

In contrast to those practices for which there is an absolute ban, some practices are only prohibited if done without a licence, and carry a 10-year maximum term of imprisonment. These practices include the following:

- creating or developing a human embryo other than by fertilisation;<sup>52</sup>
- creating or developing a human embryo containing genetic material of more than two persons;<sup>53</sup>
- using precursor cells from a human embryo or a human fetus to create or develop a human embryo,<sup>54</sup> and
- creating or developing a hybrid embryo for any purpose other than testing sperm quality in an accredited ART centre.<sup>55</sup>

Section 8 defines various terms such as human embryo, human embryo clone, hybrid embryo and chimeric embryo. A chimeric embryo is a human embryo into which animal DNA has been introduced, and for which no licence can be issued. The creation of such an entity is absolutely prohibited. A hybrid embryo is created by mixing human egg with animal sperm or animal DNA or by mixing an animal egg with human sperm or human DNA. Unlike the provision which makes it an absolute offence to create a chimeric embryo,<sup>56</sup> it is not an offence per se to create a hybrid embryo if a licence has been granted.<sup>57</sup>

Section 23B contains a curious anomaly. Section 23B(3) stipulates that it is not an offence to create or develop a hybrid embryo if authorised to do so under licence. A note added to the section further stipulates that a licence may be issued either (a) for the purpose of testing sperm quality but only up to the first mitotic division<sup>58</sup> or (b) if the hybrid is created by introducing human cells into animal eggs "for not longer than 14 days". This would suggest that there are two possible purposes for which a licence may be granted to create a hybrid embryo. The first would be where the intention is to test sperm quality, in which case the hybrid embryo should be destroyed at the first mitotic division.

<sup>45</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 14. This prohibition covers a human embryo created by parthenogenesis, embryo splitting or SCNT.

<sup>46</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 15.

<sup>47</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 16.

<sup>48</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 17. A chimeric embryo is a human embryo into which animal DNA is introduced.

<sup>49</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 18.

<sup>50</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 19.

<sup>51</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 21. The buyer and seller are both liable. However, the reimbursement of reasonable expenses is permitted, eg a woman is permitted to pay for the cost of retrieval of donated eggs from a donor. This section does not preclude altruistic donations of gametes, provided no consideration is involved.

<sup>52</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 22.

<sup>53</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 23.

<sup>54</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 23A.

<sup>55</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 23B.

<sup>56</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 17.

<sup>57</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 23B.

<sup>58</sup> About 48 hours.

The second purpose for granting a licence, ie in the case of introducing a human cell into an animal egg, for unspecified reasons, suggests that the embryo should be destroyed by the 14th day. Section 23B(3)(b) does not prescribe any limitations on the purpose for creating such a hybrid embryo, suggesting that these types of hybrid embryos may be created as an alternative to human embryo clones using human oocytes.

The Lockhart Committee recommended that:

in order to reduce the need for human oocytes, transfer of human somatic cell nuclei into animal oocytes should be allowed, under licence, for the creation and use of human embryo clones for research, ... and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.<sup>59</sup>

This recommendation is represented in the amended *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) as s 23B(3)(b).

The NHMRC, the licensing authority, can only grant a licence for the purposes stipulated in s 20(1) of the RIHE Act, and although s 20(1) in the draft Act originally contained subss (a) – (g), the final amended Act contains only subss (a) – (f). Subsection (g) corresponded with s 23B(3)(b) of the PHC Act. A few hours before the vote was taken in the Senate, one Senator whose vote could have prevented the Bill passing, moved an amendment to remove subs (g). Due to this last-minute amendment in the Senate<sup>60</sup> subs (g) was deleted from s 20(1), resulting in the licensing authority *not* having the power to issue a licence for the creation of animal-human embryos for the purposes of research, other than for the very limited purpose of testing sperm quality.

The Lockhart Review's Recommendation 24 did not survive the debates and has not been adopted in the legislation. Section 23B(3)(b) thus remains in the PHC Act, but in an impotent state, as it is not possible for any licence to be granted to activate this section. It would have been preferable to delete subs (b) of s 23B(3) from the PHC Act, to make it absolutely clear that animal-human hybrid embryos may not be created for the extraction of stem cell lines. The result of this anomaly is that the PHC Act appears to permit the creation of human-animal embryos for research purposes, under licence, but the RIHE Act does not permit such a licence to be granted.

It is interesting to note that only three months after the Australian legislation came into force, the United Kingdom licensing authority gave the green light for applications to be made for the creation of animal-human hybrid embryos. It is regrettable that this last-minute amendment in Australia has created a situation whereby Australian researchers' efforts could be stymied through a shortage of human donor eggs, while their United Kingdom counterparts may have the possibility of making greater progress through availability of research material.

One argument in the Australian Federal Parliament which carried the yes vote was the fact that if therapeutic cloning was not permitted, Australia risked being left behind in this ground-breaking research. It was argued that passing the legislation would put Australia into a category of more permissive nations where advances could be made through cloning research. The Lockhart Committee was sensitive to the issue of human donor egg shortages when it presented its batch of recommendations. By not adopting the recommendation for using animal eggs, the Australian Parliament has placed a very real obstacle in the way of medical progress, and possibly created a situation where this very new legislation is already becoming an anachronism.

Such is the speed of scientific advance in the biomedical arena that legislative provisions which are not flexible and forward thinking can impede scientific breakthroughs. In December 2006 Australia looked set to join the United Kingdom as a place where medical research could flourish. By April

<sup>59</sup> Lockhart Review, n 16, Recommendation 24.

<sup>60</sup> By Senator Andrew Bartlett on 7 November 2006. In his speech, Senator Bartlett referred to the then British bid by scientists to gain permission to use cow and rabbit eggs in place of human eggs, which are in short supply. He further referred to the fact that such research is likely to be distorted in the media which then creates panic about the possible creation of part cow-part human creatures. By removing the subsection authorising the NHMRC to issue licences for the use of animal eggs, he said it would remove the potential apprehension about what is involved.

2008, this early optimism appeared to be premature, as United Kingdom scientists are progressing with the creation of “cytoplasmic” hybrid embryos.

### Effect of the legislation

The most significant effect of the amended PHC Act and RIHE Act is the opportunity for scientists in Australia to create human embryo SCNT clones for research purposes. This has not previously been possible. Reproductive cloning continues to be absolutely prohibited. Egg donors cannot receive any payment, discount or priority on services,<sup>61</sup> other than reasonable expenses such as storage and transport costs. Therefore, scientists working in Australia must create human embryo clones in Australia, although there is no prohibition on the importation of stem cell lines derived from human clones originating elsewhere.<sup>62</sup>

The NHMRC has issued revised guidelines, and will change its administrative, monitoring and compliance activities surrounding the licensing of research involving human embryos.<sup>63</sup>

Although the passing of the legislation is a significant breakthrough for Australia, and will certainly keep Australian scientists at the forefront of this ground-breaking research,<sup>64</sup> there remain a number of unresolved issues. These issues will need to be debated in the future, either when the legislation comes up for review or if scientific discoveries mandate immediate consideration by policy-makers. Some of these issues are considered below.

## UNRESOLVED ISSUES

### Ethical/religious questions

The most difficult objections to counter in regulating human embryonic stem cell research are those grounded in ethics and religion, for they are not always responsive to logic and to material considerations. The basis of the religious objection to SCNT is the fact that a human embryo is created and then destroyed. It is the destruction of the human embryo which is objectionable. According to this view, all human life should be protected and a SCNT embryo is as worthy of protection as any other human embryo, since it is a potential life. According to Father Frank Brennan, “I am happy to view a human embryo respectfully as a human being in the earliest stages of development”.<sup>65</sup>

Would an embryo created without the combination of the DNA from two donors be any less objectionable to a religious absolutist? What if a human egg could be activated to develop into an embryo which could never grow into a human being? The destruction of these embryos after obtaining stem cells may possibly be free of religious and ethical concerns. Recent advances in parthenogenesis may make it possible to create embryos for the extraction of stem cells by activating either eggs (or theoretically sperm) or any somatic stem cell.

In June 2007, scientists from Roslin Cells, a subsidiary of the Roslin Institute,<sup>66</sup> reported that they were successful in creating a stem cell line from a human egg, without the necessity of introducing any sperm or DNA from another donor. Dr Paul De Sousa reported that his team were able to

<sup>61</sup> Buyer and seller are both liable.

<sup>62</sup> Subject to respecting any policies in the originating country: see the National Health and Medical Research Council, *National Statement on Ethical Conduct in Human Research* (2007) at [3.4.4] (National Statement).

<sup>63</sup> National Statement, n 62.

<sup>64</sup> Within the confines of what is actually permitted. As mentioned, the parameters of Australia’s research possibilities are narrower than in the United Kingdom. An additional restrictive mechanism in Australia is the level of funding for embryonic stem cell research, which is significantly less than eg in California, where over US\$3 billion has been set aside for stem cell research.

<sup>65</sup> Brennan F, “It’s Time to Engage the ‘Conscience of the Nation’ on Bioethics” (2006) *Eureka Street* 19, <http://www.eurekastreet.com.au> viewed 20 February 2007.

<sup>66</sup> Which created Dolly the sheep.

stimulate the human eggs so as to cause the cells to divide and develop.<sup>67</sup> If this process were found to be successful, it would obviate the need to create and destroy human embryo clones, a major stumbling block for many opponents of SCNT.

However, this process could present a new ethical dilemma. If the process became successful, infertile men or women may be able to produce an embryo, “from which embryonic stem cells would then be extracted. These could then be coaxed into producing viable eggs or sperm.”<sup>68</sup> Such developments might eventually offer the possibility of procreation without the involvement of two people.

In a landmark breakthrough, two teams of scientists have recently made a significant advance in stem cell research, which suggests that many of these ethical issues may become obsolete in the not too distant future. A team of scientists in Japan, headed by Shinya Yamanaka, and a team in the United States, headed by James Thomson, have each reported that they have been successful in reprogramming human skin cells into pluripotent cells (iPS cells), without the involvement of human eggs or embryos.<sup>69</sup> While the efficiency of this new methodology is still low, and safety concerns remain, the rate at which the science is developing suggests that the need for human eggs and the creation and destruction of human embryos may soon cease to be relevant. Of course, in solving one ethical dilemma, a new one may be created. Since iPS cells may develop into any cell types, there is no reason why they could not theoretically also develop into human gametes, ie eggs and sperm. Such a development raises the spectre of a different set of ethical issues.

The essence of the moral/ethical considerations concerns the question of what it means to be human. For example, is an embryo created by mixing human DNA with an enucleated animal egg still a human embryo? Definitions are extremely important if legislative provisions are to remain relevant. Ambiguities in definitions can lead to uncertainties in the law, resulting in litigation<sup>70</sup> and the necessity to pass further legislation.<sup>71</sup>

### Source of eggs

Now that it is possible in Australia for scientists to be granted a licence to create human embryo clones by SCNT, and to extract stem cell lines for research, the most pressing question is where the human eggs (oocytes) will come from. There is a high attrition rate, as the majority of eggs used do not result in an embryo. Scientists therefore need many more eggs than are currently available.<sup>72</sup>

<sup>67</sup> “Scientist Finds New Source of Stem Cells”, *The Scotsman* (20 June 2007), <http://www.news.scotsman.com/latestnews/Scientists-find-new-source-of-3296548.jp> viewed 10 June 2008. It seems that the disgraced Korean scientist, Dr Hwang Woo-suk, who was found to have fabricated data, did in fact produce stem cells in 2004, not through cloning, as he claimed, but rather through the process of parthenogenesis. It is possible that Dr Hwang may have been unaware that parthenogenesis had occurred, although he had considered, and discounted, that possibility. See Ritter M, “New Riddle in Scandal of Korean Who ‘Faked’ Clone Research”, *The Scotsman* (3 August 2007), <http://www.news.scotsman.com/topics.sfm?tid=10&id=1212492007> viewed 27 August 2007.

<sup>68</sup> *Stem Cells Coaxed to Produce Both Eggs and Sperms*, <http://www.spiritindia.com/health-care-news-articles-2614.html> viewed 17 September 2007.

<sup>69</sup> Takahashi K et al, “Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors” (2007) 131 *Cell* 861, <http://www.images.cell.com/images/Edimages/Cell/IEPs/3661.pdf> viewed 10 December 2007; Yu J et al, “Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells” (2007) *Science Express*, <http://www.sciencemag.org/cgi/rapidpdf/1151526.pdf> viewed 10 December 2007.

<sup>70</sup> The Pro-Life Alliance in the United Kingdom challenged the power of HFEA to issue licences for the creation of a SCNT embryo, claiming that the *Human Fertilisation and Embryology Act 1990* (UK) did not cover SCNT embryos in its definition of embryo, which only included a “live embryo where fertilisation was complete” and thus the process was unregulated in the United Kingdom. The United Kingdom Government argued that the definition of embryo was formulated prior to the developments of SCNT technology and that if known, Parliament would have included this technology. See *R (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687.

<sup>71</sup> The *Human Reproductive Cloning Act 2001* (UK).

<sup>72</sup> In research published in *Nature* in November 2007, Dr Shoukrat Mitalipov, from the Oregon National Primate Research Centre, announced that his team had produced dozens of cloned embryos from an adult primate, a 10-year-old male rhesus

Since it is illegal to buy, sell or import human eggs into Australia,<sup>73</sup> the research is reliant on altruistic egg donations, usually from women undergoing IVF or from women who have a family member suffering from a debilitating disease. Surplus IVF eggs have been used for some time. It is unlikely that altruistic egg donations will yield sufficient eggs to meet the demands of scientific research. There are significant risks to women donors associated with the necessary hormonal stimulation and surgical egg retrieval. The procedure is invasive and possible complications include breast tenderness, headaches, insomnia, bloating, Ovarian Hyper-Stimulation Syndrome (OHSS), and an increased risk of ovarian cancer.<sup>74</sup> Allied to the question of donated eggs is the issue of informed consent by donors. Can a woman donating eggs stipulate limits on what her eggs can be used for? Women who donated eggs during an IVF process may not have given consent to specific procedures which were not even thought of at the time of donation. Can those eggs be used for research, despite the consent not addressing the exact nature of the research? Can a woman change her mind once the eggs are donated?

Should women be paid to donate eggs? This is generally considered to be ethically undesirable as women in financial need may feel pressured to donate eggs, and the practice could result in the exploitation of certain groups of women, particularly the more economically disadvantaged. In Australia, women are only permitted to receive compensation for reasonable expenses associated with the collection, storage or transport of the egg.<sup>75</sup> In the United Kingdom, it is illegal to offer payment to egg donors, but fertility clinics can offer discounts on IVF treatment to women who donate eggs for research. Women who donate eggs outside of fertility treatment can claim reasonable expenses up to a limit of £250.<sup>76</sup>

In the United States, women can sell their eggs to infertile couples, and some clinics offer \$10,000, although some private arrangements to sell can attract up to \$50,000. However, even in the United States, payment for research donations has been prohibited in 2005 in Massachusetts and, in 2004, under the stem cell research initiative in California.<sup>77</sup>

There is no uniform set of rules, and differences exist among States in the United States. In Canada, since 2004, payment for eggs is prohibited.<sup>78</sup>

In December 2006, the ISSCR Guidelines set up a two-tier system whereby women who were egg donors (donating eggs while undergoing fertility treatment) were not permitted to be paid, while women who were egg providers (providing eggs outside of fertility treatment) were permitted to be

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macaque monkey. They were successful in extracting stem cells from these embryos. Although cloned embryos had previously been produced from mice, it was thought too difficult to do the same thing in primates. Mitalipov said that his team is also working on the possibility of getting stem cells from eggs, not embryos, although the work has not yet been published: see Hitti M, *Embryonic Stem Cells Made from Monkeys*, <http://www.webmd.com/news/20071114/embryonic-stem-cells-made-from-monkeys?> viewed 10 December 2007.

<sup>73</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 21.

<sup>74</sup> Reid L et al, "Compensation for Gamete Donation: The Analogy with Jury Duty" (2007) 16 *Cambridge Quarterly of Healthcare Ethics* 35; Bernier L and Gregoire D, "Reproductive and Therapeutic Cloning, Germline Therapy, and Purchase of Gametes and Embryos: Comments on Canadian Legislation Governing Reproductive Technologies" (2004) 30 *Journal of Medical Ethics* 527.

<sup>75</sup> *Prohibition of Human Cloning Act 2002* (Cth), s 21(3).

<sup>76</sup> United Kingdom Human Fertilisation and Embryology Authority, *FAQs about Donating Eggs for Research* (2007), <http://www.hfea.gov.uk/en/1496.html> viewed 5 December 2007.

<sup>77</sup> Steinbrook R, "Egg Donation and Human Embryonic Stem-Cell Research" (2006) 354 *NEJM* 324.

<sup>78</sup> It is the purchase, not the sale, of gametes which is prohibited in Canada (see s 7(1), (2) of the *Assisted Human Reproduction Act 2004* (Can). Section 12 allows for reimbursement of receipted expenditures.)

paid.<sup>79</sup> Scientists report that it is extremely rare to find women who are prepared to supply their eggs for stem cell research outside of fertility treatment.<sup>80</sup>

Alternative potential sources of eggs include other mammals' eggs, harvested eggs from the ovaries of aborted female fetuses<sup>81</sup> and from adult ovaries which have been removed for medical reasons. The PHC Act prohibits the use of animal eggs to create SCNT embryos, while the harvesting of eggs from aborted fetuses and removed ovaries raises a number of ethical issues. With advances in technology, it may become possible at some future time to extract human eggs from stem cell lines. An additional, and still experimental process, is the process of parthenogenesis,<sup>82</sup> which may circumvent the need for eggs altogether, if somatic cells can be triggered to produce an embryo.<sup>83</sup>

While there are a number of alternative sources of eggs which can be utilised in SCNT, at the present time in Australia, under the current legislative regime, the only practical source of eggs is altruistic egg donation. This limited source of eggs could present a significant impediment to scientific progress in Australia.

One option already tried in the United States is to take a spare fertilised egg, remove the nucleus and attempt to fuse the rest of the fertilised egg with the patient's cell. Kevin Eggan's group at the Harvard Stem Cell Institute used mouse zygotes "temporarily arrested in mitosis" rather than unfertilised eggs.<sup>84</sup> They were able to demonstrate that it may be possible to produce stem cells by using fertilised eggs, rather than unfertilised eggs. The point at which the cell cycle is interrupted holds the key to whether viable stem cell lines can be generated. Although a similar method using human fertilised eggs in Australia is currently outside NHMRC approval guidelines, it remains as one avenue worth reconsidering when the legislation comes up for review. There are myriad frozen fertilised eggs in storage which are surplus to needs for IVF, which could be used for therapeutic cloning research, without the problematic ethical, practical and medical issues surrounding altruistic egg donation.

### Animal-human chimeras/hybrids

Currently Australian law does not permit creating a hybrid embryo for research purposes by introducing the nucleus of a human cell into an animal egg. Many other countries either do not have specific legislation on the creation of human-animal cloning, or prohibit it directly. Australia, Canada and the United States have all considered it.<sup>85</sup>

On 5 September 2007 the HFEA in the United Kingdom issued a statement announcing that, "[H]aving looked at all the evidence the Authority has decided that there is no fundamental reason to

<sup>79</sup> Bayliss F and McLeod C, "The Stem Cell Debate Continues: The Buying and Selling of Eggs for Research" (2007) 33 *Journal of Medical Ethics* 726. The ISSCR Guidelines stipulate (at [11.5a]): "Except when specifically authorised by the SCRO (Stem Cell Research Oversight) process, no reimbursement of direct expenses or financial considerations of any kind may be provided for donating embryos or gametes that have been generated in the course of clinical treatment and are in excess of clinical need or deemed of insufficient quality for clinical use."

<sup>80</sup> Bayliss and McLeod, n 79.

<sup>81</sup> Harvesting eggs from aborted female fetuses is prohibited in Australia, the United Kingdom and the United States. In 2003, a team of scientists, from Israel and the Netherlands, found that ovarian tissue taken from second and third trimester aborted fetuses could be kept alive in the laboratory for weeks. This tissue could potentially mature to release eggs. There are a number of practical and ethical issues associated with such a development.

<sup>82</sup> Parthenogenesis is a process whereby an unfertilised egg is stimulated to begin going through the very early stages of human development. Stem cells that arise from parthenogenesis would be genetically matched to the person who provided the unfertilised egg. See ISSCR sample research consent form; see also De Sousa PA and Wilmot I, "Human Parthenogenetic Embryo Stem Cells: Appreciating What You Have When You Have It" (2007) 1 *Cell Stem Cell* 243.

<sup>83</sup> See n 70.

<sup>84</sup> Eggan K, "Developmental Reprogramming After Chromosome Transfer into Mitotic Mouse Zygotes" (2007) 447 *Nature* 679.

<sup>85</sup> United Kingdom Human Fertilisation and Embryology Authority, *HFEA Statement on Its Decision Regarding Hybrid Embryos*, App C – International Perspective, <http://www.hfea.gov.uk/en/1581.html> viewed 14 September 2007. In Canada, the *Assisted Human Reproduction Act 2004* (Can) prohibits the creation of chimera embryos for research (s 5(1)(i)). In the United States the *Draft Human Chimera Prohibition Act 2005* (§ 1373) prohibits the creation of a human chimera (some human-nonhuman hybrids would come under the definition of a chimera).

prevent cytoplasmic hybrid research".<sup>86</sup> The HFEA will consider each application on its merits to determine whether the research project is both necessary and desirable, and whether it meets strict ethical guidelines. Two licence applications have been lodged to date. Although scientists have been creating animal cytoplasmic hybrid embryos for over a century,<sup>87</sup> the creation of human-animal hybrids using SCNT of human nucleus into animal eggs and grown to the blastocyst stage is novel. This technique is so novel that there is insufficient evidence to predict whether the technique will be successful in deriving stem cells.<sup>88</sup> It may be that since humans and other mammals (such as cows and rabbits) are so far removed from each other in terms of evolutionary distance, they may be incompatible for the purposes of extracting functional stem cell lines.

Prior to making its decision, the HFEA conducted extensive public consultations, and considered the ethical issues which were raised by the public regarding the creation of animal-human hybrids. Many of these ethical issues are the same issues which arise in the general public perception surrounding SCNT. A brief consideration of these is discussed here.

The first issue is what the HFEA has termed the intuitive responses. These are comprised as objections based on the "yuk" factor, playing God or being against nature. A second group of objections come under the rubric of moral considerations and pertain to the essential quality of what it means to be human, with the potential for moral ambiguity between humans and animals. Religious objections based on biblical texts underscore the prohibition as coming from God. A third, and common, objection is based on the notion of "human dignity" and that it is vital to keep animals and humans distinct so as not to undermine human dignity. As pointed out by the HFEA, this last objection confuses the entity which is proposed to be created with a full-term being. The research proposals are limited to the creation of an embryo which would be destroyed by the 14th day, and would have no possibility of developing into a full-term being.

Policy-makers are often uncomfortable with engaging in arguments based on intuitive and moral objections because these arguments are not easily countered with empirical evidence. However, these morality-based arguments should not be too easily discounted as they serve an important bulwark against a totally rationalist approach to developing technologies. An intuitive response can serve as a reliable indicator of shared community views, or shared value systems. What is often referred to as the "yuk" factor may warrant serious consideration.

One way that scientists can quell emotional objections is to present cogent and accurate information about what is actually being proposed. Evidence suggests that when accurate information is presented, the public responds in a rational way. This has been the experience in the United Kingdom in the recent animal-human hybrid consultation process.

In Australia the creation of human embryo clones is already permitted. Animals are already used extensively in medical research. The main objections to extending the law will relate to the ethical/intuitive issues outlined above. As mentioned earlier, altruistic egg donations are unlikely to produce sufficient eggs to carry out the permissible research. In addition, using animal eggs reduces the dangers associated with egg extraction, so it poses less risk to humans.

The public needs to be reassured that scientists currently have no desire to develop a hybrid into a living being, nor do they wish to create human chimeric embryos, ie animal embryos into which human cells are transferred. What is proposed in the United Kingdom is to transfer a nucleus from a human somatic cell into an enucleated animal egg, one that has been stripped of all but the external mitochondria. These embryos, which are 99.9% human and .1% animal, and contain 46 chromosomes, would be allowed to develop for no more than 14 days, by which time embryonic stem cells would be

<sup>86</sup> Under current United Kingdom legislation, the *Human Fertilisation and Embryology Act 1990* (UK), it seems that the enabling language is broad enough to give the HFEA the remit to decide this issue.

<sup>87</sup> *HFEA Statement on Its Decision Regarding Hybrid Embryos*, Authority Paper, [http://www.hfea.gov.uk/docs/2007-09-05\\_Authority\\_Paper\\_-\\_Delegated\\_Decision\\_Making\\_for\\_Code\\_of\\_Practice\\_-\\_395.pdf](http://www.hfea.gov.uk/docs/2007-09-05_Authority_Paper_-_Delegated_Decision_Making_for_Code_of_Practice_-_395.pdf) viewed 18 September 2007.

<sup>88</sup> To date, there has been only one documented report of a hybrid embryo being created using SCNT. See *HFEA Statement on Its Decision Regarding Hybrid Embryos*, Authority Paper, [http://www.hfea.gov.uk/docs/2007-09-05\\_Authority\\_Paper\\_-\\_Delegated\\_Decision\\_Making\\_for\\_Code\\_of\\_Practice\\_-\\_395.pdf](http://www.hfea.gov.uk/docs/2007-09-05_Authority_Paper_-_Delegated_Decision_Making_for_Code_of_Practice_-_395.pdf) viewed 18 September 2007.

extracted. The embryo would then be destroyed. If successful, the embryonic stem cells could be used “to model diseases, by observing molecular changes, and screen for drug therapies”,<sup>89</sup> among other things.

It is too early to predict if this technique will be successful. There are still many obstacles to overcome for the successful derivation of a stem cell line. It is unknown whether the hybrid would survive long enough to elicit embryonic stem (ES) cell lines. However, in order to understand how the process works, and whether it is even feasible to pursue this line of research, scientists need to try it out before they can provide answers to these vital questions.

If Australia retains the prohibition on animal-human embryos, it will place a significant impediment to potential medical developments in alleviating diseases. The United Kingdom experience shows that it is possible to enact a flexible regulatory scheme without sliding onto a slippery slope. The HFEA decision comes after a most rigorous and comprehensive public consultation process. Scientists in the United Kingdom do not have an automatic right to create animal-human embryos, but there is the possibility of doing so, subject to strict ethical and scientific oversight. It is regrettable that the Australian Parliament chose to introduce an absolute ban on this research, ignoring both the recommendation in the Lockhart Review as well as the original draft legislation presented to the Senate by Kay Patterson.

### The legal/moral status of a cloned embryo

The embryo is not recognised as a human being in Australia and therefore has no inherent right to life.<sup>90</sup> Neither the PHC Act nor the RIHE Act contains a definition of “human”. As scientific and reproductive technology advances further, the law will need to develop what it means to be human according to law. Opponents of SCNT view the human embryo clone as a form of human life which deserves the same right to be protected as a human being. This is a similar argument to the one made against abortion laws. Proponents of SCNT see the embryo clone as tissue and matter, which may potentially be capable of further development, but which is at too early a stage to be considered as human.<sup>91</sup>

It is likely that in the not too distant future, there will be a variety of contexts in which human embryos are formed. These may include, inter alia, human egg and human sperm, as in traditional reproduction, or via ART, or human egg fused with human cells via SCNT, or animal egg fused with human cells, via SCNT, or a number of other processes not yet developed. If the law is to regulate embryonic research in a comprehensive manner, it must be able to accommodate these different life forms within its definitional boundaries so that decisions made about the legal and moral status of any particular life form are informed by a thorough understanding of what is meant by “human”.

Does the cloned embryo enjoy some legal protection? This is a question which will need to be fully explored, in the event of a scientist who fails to destroy the SCNT embryo by the 14th day. The PHC Act stipulates the penalty that such a scientist would incur. However, penalties are not a guarantee that breaches will not occur. Murder and drug importation in Australia carry maximum penalties of life in prison, yet these offences continue to occur. So it is possible that a scientist will at some time fail to destroy the developing embryo by the 14th day. The PHC Act is silent on what should then happen to the resulting embryo.

A number of complex questions arise. Suppose the failure to destroy is only discovered after the 40th day, and the embryo has been kept alive.<sup>92</sup> What should now happen to the embryo? Does it attract an independent right to continue to thrive, or should it be destroyed? Who owns the embryo, and who should make this decision? To add further complexity, suppose the developing embryo is one which began its existence not as a human clone but as a human-animal embryo clone. While such

<sup>89</sup> HFEA Authority Paper (5 September 2007) App B.

<sup>90</sup> See eg s 9 of the *Human Rights Act 2004* (ACT) which confers a right to life only on a person from the time of birth.

<sup>91</sup> Habermas sees no purpose in trying to find the legal point at which life begins, since the continuum of development makes such an inquiry arbitrary: see Habermas J, *The Future of Human Nature* (Polity, Cambridge, 2003) p 32.

<sup>92</sup> Perhaps by means not yet available.

questions may still seem the stuff of science fiction, they are not so speculative when one considers that less than 10 years ago, the whole concept of SCNT was not yet a reality either. Scientific discoveries do not always wait for legislative provisions to be settled. The time to be dealing with difficult moral and ethical questions is well before necessity sets in. The law may be a blunt instrument with which to regulate science and technology, but it is the only method currently available. It is therefore of greater importance to draft legislation carefully and prospectively.

### **Is the legislation flexible enough to accommodate future developments in scientific advances?**

Every jurisdiction around the world which has considered the issue of therapeutic cloning, whether the regulatory regime is permissive or restrictive, has an absolute prohibition on implanting a cloned embryo in a human body. Even the most permissive schemes do not permit cloning to be used for reproductive purposes. Australia's PHC Act prohibits the placing of a "human embryo clone in the body of a human or the body of an animal".<sup>93</sup> However, the legislation does not proscribe implanting a cloned embryo in an artificial womb. The legislation is silent on this issue. What if such a womb was developed? Does this mean that the activity might be unregulated? Under the current provisions, that is not the case, since it is also prohibited to allow a human embryo clone to develop beyond the 14th day,<sup>94</sup> but this example illustrates the possible lacuna in a legislative framework where future developments are not fully anticipated.

The concept of an artificial womb is not as implausible as might appear at first glance. While such an idea might initially be met with distaste, there may be therapeutic reasons for the artificial womb to be utilised in an IVF environment. For example, a woman who is able to fall pregnant naturally but is unable to carry the fetus to term<sup>95</sup> may utilise an artificial womb to gestate the developing fetus to full term. This process is known as ectogenesis. The fetus grows in an artificial womb separate from the mother's body.<sup>96</sup> Ectogenesis raises a number of moral and ethical objections, although many of these do not move beyond the purely emotional and intuitive.

Is an artificial womb so legally different to a surrogate womb – or to an incubator in a neonatal intensive care unit? It is now possible for premature babies as young as 24 weeks gestation to survive by completing their development in an incubator. The conditions in an incubator try to replicate those of the human womb. Imagine if the incubator came to replicate more and more a human womb, so that eventually a baby could spend all its time in such a womb. IVF technology may one day be able to offer an infertile couple the possibility of not only the creation, but also full gestation, of a genetically related offspring, with minimal, or even without any, physiological involvement of the couple. As medical advances to keep premature babies alive improve, so it may be possible one day to guarantee the survival of babies who have spent their whole period of gestation in an artificial womb.

Ectogenesis has implications beyond the medical sphere. There are also significant social and economic implications. If developed and perfected, the artificial womb would offer the possibility of a viable alternative to pregnancy. Women who fear losing their jobs, or suffering career disadvantage, may one day be freed from the inconvenience of pregnancy.<sup>97</sup> Homosexual males who wish to be genetically related to their offspring may be able to combine cloning technology with an artificial womb.<sup>98</sup> Furthermore, there may be implications for abortion rights, which are often based on viability outside the womb.

While such scenarios may appear to be in the realm of "science fiction", policy-makers who ignore the speed of scientific and technological change do so at their peril. They need to decide

<sup>93</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 9.

<sup>94</sup> *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 14.

<sup>95</sup> As in the case of a woman with a damaged uterus.

<sup>96</sup> Ectogenesis is a further development of already existing neonatal intensive care units.

<sup>97</sup> *Scientific Advancements in Neonatal Medicine May One Day Lead to the Development of a Fetus Outside the Womb*, The Osgood File, <http://www.acfnnews.org/science/ectogenesis.html> viewed 17 September 2007.

<sup>98</sup> See n 97.

whether what is possible is also desirable. Legislative provisions should be framed in such a way that future practices and technologies, not yet available, are covered by the legislation. Otherwise legislative gaps may cause the legislation to quickly lose its impact.

### Will scientists demand more liberal laws in future?

A common objection to the passing of permissive laws is that not long after new laws are enacted, scientists will be agitating for yet more liberalisation in order to push the boundaries of science further. This is a reasonably accurate claim. However, on its own the claim is value neutral in that it does not offer an argument either in favour of or against further liberalisation of laws. If scientists can support the request for further liberalisation by persuasive evidence of the benefit to mankind, it can then be left up to the community, via elected representatives, to decide whether further changes to the law are warranted. Scientific progress would grind to a halt if the scientific community were to desist from exploring the environment because it might offend the public's sensibilities. Those who favour the slippery slope argument against cloning research regularly cite the threats posed by maverick scientists. Almost every endeavour with potential benefits also carries the potential threat of abuse. Motor vehicle accidents account for more deaths than deaths during combat, not to mention the damage they do to the environment – yet motor vehicles are not illegal. The manner in which they are operated is regulated by legislation, so as to minimise the risks while recognising the potential benefits to the general community. Users acknowledge that breaches will occur and penalties are set to deter such breaches.

Similarly, scientists who contravene the ethical guidelines and strict legal prohibitions of cloning legislation are subject to heavy prison penalties. The recent Australian experience with the PHC Act shows that in 2002 therapeutic cloning was prohibited, yet in 2006 the prohibition was overturned. The scientific community was partly responsible for this change. In May 2007, the United Kingdom government published a draft *Human Tissue and Embryos Bill* in which it changed its position of one year earlier, on animal-human embryos. The Draft Bill allows the creation of “cybrid” embryos<sup>99</sup> and animal-human chimeras.

No doubt the scientific community will continue to explore and investigate ways of finding treatments and cures for debilitating diseases. Some of these may necessitate further changes to the regulatory scheme. If so, it is the role of Parliament to debate and ultimately vote on the issues. The threat of further changes is not a sufficient reason to enact restrictive legislation.

### Research tourism

One way of avoiding or minimising a scientific brain drain is to encourage collaboration between scientists in different jurisdictions. Despite the fact that many nations have enacted different and inconsistent laws in relation to hESC research, the possibility of collaboration is strong.

The PHC Act and the RIHE Act do not specifically prohibit collaboration with scientists in other countries where the regulatory regime may be more permissive. As a result, there is no legal impediment to Australian researchers collaborating with researchers in other countries. They may even use the outcomes of this research in Australia unless the Australian law intends to exert extra-territorial jurisdiction. Australian law currently does exert extra-territorial jurisdiction in areas such as paedophilia, female genital mutilation and chemical weapons production.<sup>100</sup> There are very few national laws<sup>101</sup> regarding stem cell research which purport to exert extra-territorial jurisdiction, and any international Conventions prohibiting therapeutic cloning only operate as guidelines, unless

<sup>99</sup> Enucleated cow or rabbit eggs mixed with human DNA.

<sup>100</sup> Skene L, “Undertaking Research in Other Countries: National Ethico-Legal Barometers and International Ethical Consensus Statements” (2007) 4(2) *PLoS Medicine* 243. Germany is one country which does seem to exert extra-territorial jurisdiction on its scientists: see Mathews DJH et al, “Science and Law: Integrity in International Stem Cell Research Collaborations” (2006) 313 *Science* 921.

<sup>101</sup> Germany does purport to exert extra-territorial jurisdiction on its strict laws in this area.

they have been ratified by member states.<sup>102</sup> Italy, which restricts egg and embryo donation, does permit hESCs to be imported from overseas.<sup>103</sup> Collaborative endeavours could therefore be used to overcome individual nations' restrictive legislative obstacles.

By analogy, the regulation of internet content has raised similar issues in relation to different regulatory schemes. For example, certain online hate speech is illegal in jurisdictions such as Germany and France, while quite permissible in the United States.<sup>104</sup> It is relatively easy to bypass the German and French restrictive laws by creating mirror sites in the United States, where such material can be accessed from around the world.<sup>105</sup>

In order to assist and encourage international collaboration, the International Society for Stem Cell Research (ISSCR) has developed a set of guidelines for human embryonic stem cell research.<sup>106</sup> These uniform guidelines include the prohibition of human reproductive cloning, the development of human embryos beyond 14 days and the interbreeding of animals likely to harbour human gametes.<sup>107</sup> Australia's current laws are consistent with these guidelines.

Universal guidelines encourage researchers from countries with diverse regulations to work together in achieving better outcomes. The potential benefits of stem cell research will accrue to the human race generally, rather than to any one nation or a group of nations. So it seems desirable for researchers to combine their knowledge, rather than for researchers to move their expertise to other nations with better regulatory schemes.<sup>108</sup>

In an effort to facilitate collaboration, a group calling itself the "Hinxton" group has drafted ethical principles for collaborative research. The "Hinxton" group recommends that countries with restrictive laws should allow its scientists to collaborate with their peers in countries with permissive laws without risk of prosecution in their home countries, in the interest of scientific advance.<sup>109</sup> They further recommend that stem cell lines should be deposited in international repositories such as the United Kingdom Stem Cell Bank, to be publicly available.<sup>110</sup>

The HFEA has granted a licence to two groups that wish to create hybrid human-animal embryos for research purposes. This type of activity is prohibited in Australia. Could an Australian scientist collaborate in the United Kingdom research by importing the resultant stem cell lines into Australia for research? There seems to be no reason why this could not occur, as Australian legislation does not prohibit the importation of stem cell lines.<sup>111</sup> So, although a last-minute amendment in the Senate

<sup>102</sup> Skene, n 100. For example, the General Assembly of the United Nations' *Declaration on Human Cloning* which has no enforceable legal status.

<sup>103</sup> Winston, n 38.

<sup>104</sup> The First Amendment protects online speech, subject to some limited exceptions, such as those that pose a "clear and present danger" or are "obscene".

<sup>105</sup> However, once downloaded in a restrictive jurisdiction, the end user would still be liable to the laws of the jurisdiction.

<sup>106</sup> These were developed by scientists, ethicists and legal experts from 14 countries: see Daley G, "The ISSCR Guidelines for Human Embryonic Stem Cell Research" (2007) 315 *Science* 603.

<sup>107</sup> Daley, n 106.

<sup>108</sup> Of course, funding remains a powerful incentive for researchers to move to other countries. One example of such a move is that of Professor Alan Trounson who has left Australia to take up the presidency of the US\$3 billion California Institute for Regenerative Medicine.

<sup>109</sup> Mathews et al, n 100 at 921.

<sup>110</sup> In March 2007, the European Commission announced it will provide €1 million for the establishment of a European registry for human embryonic stem cell lines, with publicly accessible information available via the internet to researchers around the world. Australia will also be involved in the project.

<sup>111</sup> The NHMRC's *National Statement on Ethical Conduct in Human Research* (2007) stipulates (at [3.6.8]) that where stem cell lines have been created in another country, their use in research in Australia is subject to a general provision on all imported tissue, that "researchers should try to establish whether there are ethical and professional policies in that country ... governing the collection of tissue for use in research" and if so, and if it appears that the collection of the tissue has not contravened that policy, the NHMRC "may consider waiving consent for the use of this tissue". But if it seems that the tissue collection contravened the ethical policy of the originating country, "the tissue should not be used in research in Australia" (at [3.4.4]).

removed the possibility of hybrid clones being created for research in Australia, the product of such research could still be used in Australia to make further advances. Such is the power of scientific collaboration that legislative attempts to restrict scientific advance may prove futile.

### Commercialisation of results and property rights

In the United Kingdom all stem cell lines must be deposited with the Stem Cell Bank.<sup>112</sup> Due to the shortage of tissue which is likely to result from insufficient human eggs, an international embryonic stem cell bank would obviate the need for replication of results in different jurisdictions. Lott<sup>113</sup> suggests that a global human embryonic stem cell (hESC) bank could store stem cell lines and make them available to other researchers, thus utilising economies of scale to maximise the benefits while minimising duplication.

Cloning research raises a number of commercial considerations, such as who benefits from the results which are produced, what is the position regarding patents<sup>114</sup> and how to divide the fruits of the labour fairly. Will research groups claim patents over stem cell discoveries? Who owns the property rights in the physical cells? Can they be sold for profit by those deriving them? Do the current laws protect ownership rights of the cells? Will transfer of cell lines for profit offend against legislative provisions prohibiting commercial arrangements? The scope of this article does not allow for a comprehensive examination of these issues, other than to raise them here briefly. Parliament will need to decide whether to introduce amendments to the *Patents Act 1900* (Cth) to accommodate changes in stem cell technology or to protect intellectual property by other means.

### A global approach?

Stem cell research is a costly, slow and invasive process. Human oocytes are in short supply, and so it makes sense to use a scarce resource prudently. Stem cell research is an area where replication is best avoided, and universal cooperation is to be encouraged.

There are already precedents where universal cooperation works well, eg the *Warsaw Convention*, which limits liability for airline crashes.<sup>115</sup> This cooperative effort by 31 nations occurred in 1929, to create a legal framework which is still binding in international aviation.<sup>116</sup> The Human Genome Project is another example of a cooperative effort which produced significant results through a combined effort which could not have occurred without that cooperation.

In the area of stem cell research, it may be too optimistic to expect a uniform set of regulatory provisions across all jurisdictions. There are too many cultural, religious and historical differences between nations for each of them to share common values in relation to hESC research. However, this does not mean that scientists have no choice but to continue to work in isolated groups replicating one another's work.

There are now enough international societies which have well-developed ethical guidelines for stem cell research<sup>117</sup> so that scientific collaboration is a reality. This may involve some strategic planning so as to exploit each country's most permissive regulations. It may also require sacrificing individual commercial interests. Stem cell research is still in its infancy and vulnerable to a number of practical and ethical obstacles.

Early tangible benefits of cooperative efforts are likely to garner public support for the research and to quell opposition based on fear. Each year more and more nations around the world are

<sup>112</sup> The world's first Stem Cell Bank was opened in the United Kingdom in May 2004. See Lott JP et al, "Towards a Global Human Embryonic Stem Cell Bank" (2007) 7(8) *American Journal of Bioethics* 37.

<sup>113</sup> Lott et al, n 112.

<sup>114</sup> Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99 (2004) at [15.61]. Section 18(2) of the *Patents Act 1990* (Cth) stipulates that "Human beings, and the biological processes for their generation, are not patentable inventions".

<sup>115</sup> The *Warsaw Convention 1929*.

<sup>116</sup> With modification in 1955 at The Hague and 1999 in Montreal.

<sup>117</sup> Such as the International Society for Stem Cell Research.

introducing more permissive laws to allow scientists to conduct embryonic stem cell research, although the parameters of what is permitted vary between countries.<sup>118</sup> As the number of nations permitting stem cell research increases, and the researchers agree to abide by universal guidelines, it is likely that public and legislative support for hESC research will also increase universally.

### The last frontier: Reproductive cloning?

One objection by those who are opposed to therapeutic cloning<sup>119</sup> is that this will inevitably lead to reproductive cloning. And that may be the case. It is possible that reproductive cloning may in the future become simply another option in the vast array of IVF procedures for procreation. It may offer a viable option for gay and lesbian couples, or infertile couples who wish to have genetically related children.

Currently even permissive regimes<sup>120</sup> prohibit reproductive cloning.<sup>121</sup> Yet they fail to thoroughly explain why this should be so, other than basing their arguments on vague moral and ethical concerns, which are intended to be self evident. It is a practice that is considered to be so extreme that very little time is dedicated to considering the reasons why reproductive cloning must be prohibited.

More rational objections pertain to physical risks for the clone<sup>122</sup> rather than the more elusive risks to society. A common claim is that cloned humans would be discriminated against and treated with less respect than non-cloned humans. Another objection is that cloning humans is an affront to human dignity. But the most persuasive argument against reproductive cloning is one based on the risks attendant on the practice, ie the risk of abnormalities. This risk is currently too serious and the technology is in too early a stage of development to offer any viable hope for people wishing to use the technology. But that should not mean that regulators around the world should not discuss these issues in preparation for a time when the science is closer to becoming a reality. The law is generally quite slow in keeping up with scientific advances. It would be unfortunate for the law to be found wanting when the science is ready to move ahead. Now is the time to evaluate whether there is a role to play for reproductive cloning, and whether the reasons for retaining a total prohibition are compelling. It is inadequate to simply assert that the whole idea is immoral and therefore should be prohibited. Morality-based arguments have in the past been responsible for repressive and discriminatory laws in the areas of homosexuality, female sexuality<sup>123</sup> and divorce, to name just a few. Since belief systems about morals are not standardised throughout the community, this area of science deserves to be given serious attention with cogent reasons for prohibition.

Reasons cited for a prohibition on reproductive cloning include concerns that cloning would:

- xerox a person;<sup>124</sup>
- make children into commodities;
- reduce biological diversity;

<sup>118</sup> Currently there are about 33 nations with permissive legislation: see Winston, n 38.

<sup>119</sup> See Pence GE, *The Top Ten Myths about Human Cloning*, the Reproductive Cloning Network, <http://www.reproductivecloning.net/open/myths.html> viewed 23 August 2007.

<sup>120</sup> Those which currently permit therapeutic cloning, such as the United Kingdom and Australia.

<sup>121</sup> In Australia the *Commonwealth Gene Technology Act 2000* (Cth) prohibits cloning of whole human beings. The *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) prohibits placing a human embryo clone in the human body or the body of an animal (s 9). In the United Kingdom the *Human Reproductive Cloning Act 2001* (UK), s 1(1), has a similar provision. The European Parliament, UNESCO and WHO have all denounced reproductive cloning as “an affront to human dignity”. See also United Nations General Assembly, *Resolution Adopted by the General Assembly: United Nations Declaration on Human Cloning*, Fifty-ninth session, Distr: General, 23 March 2005. See also UNESCO, *Human Cloning: Ethical Issues* (2005). The UNESCO declaration does not have the force of law as it comes from a non-government organisation, but it does indicate a widely held world view.

<sup>122</sup> For a thoughtful consideration of the issues surrounding reproductive technology, see Elsner D, “Just Another Reproductive Technology? The Ethics of Human Reproductive Cloning as an Experimental Medical Procedure” (2006) 32 *Journal of Medical Ethics* 596.

<sup>123</sup> Such as “uncontrollable behaviour” charges against adolescent girls.

<sup>124</sup> As stated by the German Prime Minister when Dolly the sheep was cloned.

- create an organ donor group;
- be inherently evil and would be used to create a master race;
- be playing God; and
- reduce autonomy and individuality.<sup>125</sup>

One powerful objection is that the technology is currently unsafe to be used in humans. The scientists who cloned Dolly the sheep<sup>126</sup> have repeatedly stated that the technology is much too dangerous to be used in humans, in view of the possibility of developmental abnormalities in the human clones, large offspring syndrome (LOS) and a variety of other serious problems.<sup>127</sup> The current level of risk, as well as the inordinately high failure rate of cloning a mammal,<sup>128</sup> makes any discussion of human reproductive cloning speculative at the current time. In addition to the high failure rate in animals, the risks of potential deformity of the clone<sup>129</sup> provide a strong argument against proceeding with the technology until similar occurrences in humans could be ruled out, even if the moral issues could be resolved.

However dangerous the practice may be at present, it is likely that with time and the refinement of the technology, the danger will be diminished, as it has been with most other human developments. The science and the success rate may improve through trial and error. The fact that a current practice in an undeveloped state is too dangerous to be accepted by the scientific community is not sufficient reason, on its own, to prohibit it for all eternity.

Arguments against human cloning based on morality are difficult to sustain when one considers that similar arguments were made around the time of the first heart transplant.<sup>130</sup> The “yuk” factor also played a prominent role when it was considered unnatural that doctors should take a heart from one person and put it into the chest of another person. The heart was imbued with all manner of metaphysical elements. Far from being seen as just a physical organ of the body, the heart has throughout history been considered as a repository for strong feelings such as love and affection.<sup>131</sup> Children conceived through IVF were initially referred to as test tube babies, and many considered this method of conception unnatural and immoral.<sup>132</sup> Now that IVF is such a commonplace technology, it is of no consequence that a particular child is an “IVF baby”. The manner of one’s beginnings has become unexceptional. There is no empirical evidence that parents behave differently towards children born after IVF, except maybe to value them more because of the strong desire to have a child, and the gratitude that their wish has finally been achieved. Hordes of people do not flock to IVF clinics as a substitute for traditional ways of making babies.

Even if reproductive cloning could be made safe and was eventually legalised, it is unlikely that the majority of people would choose this method of making babies over the traditional methods. Claims that parents are being selfish to wish to procreate in this way, or that the resulting children will lead different lives to those children who commence life through fertilisation, are baseless. Parents who procreate through traditional methods have children for a variety of reasons, some selfish, some

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<sup>125</sup> Gogarty B, “What Exactly is an Exact Copy? And Why It Matters When Trying to Ban Human Reproductive Cloning in Australia” (2003) 29 *Journal of Medical Ethics* 84.

<sup>126</sup> Ian Wilmut and Rudolph Jaenisch at the Roslin Institute in Scotland.

<sup>127</sup> But there are those who argue that the developmental problems identified in animals may not necessarily be replicated in humans. See Zavos P and Antinori S, *Human Cloning Commentary*, the Reproductive Cloning Network, [http://www.reproductivecloning.net/open/zavos\\_antinori.html](http://www.reproductivecloning.net/open/zavos_antinori.html) viewed 10 June 2008.

<sup>128</sup> To produce Dolly, the researchers made 277 attempts. Of these only 29 embryos were implanted, of which only one developed successfully, producing Dolly.

<sup>129</sup> Dolly was euthanised in 2003, at the age of six and a half years, due to premature ageing of her organs.

<sup>130</sup> Bostrom N, *Human Reproductive Cloning from the Perspective of the Future*, the Reproductive Cloning Network, <http://www.reproductivecloning.net/bostrom.html> viewed 23 August 2007.

<sup>131</sup> For example, “he is heartless”; “she has a heart of gold”.

<sup>132</sup> The technique took many years of failed attempts before a successful birth resulted. See Elsner, n 122.

not.<sup>133</sup> It is beyond the scope of the scientific community and government to examine the motives of potential parents in deciding whether to make technologies available to them. It should not be the role of government to make such value judgments.

Savulescu has considered whether reproductive cloning may, in fact, be one of the greatest scientific advances in history,<sup>134</sup> capable of offering options for people with mitochondrial disease or infertile couples who wish to produce a genetically related child.<sup>135</sup> Savulescu has written extensively on the ethics of cloning and has considered the arguments against reproductive cloning and offered counter arguments to sometimes flawed and specious theories.<sup>136</sup>

Savulescu cites many reasons why reproductive cloning may be an asset to humanity, including the following:

- infertile couples could produce a genetically related offspring;
- where a pandemic threatens to wipe out humanity, individuals with disease-resistant genomes could replace those who perished; and
- cloning could be used to produce a source of stem cells for a sick sibling or relative.<sup>137</sup>

It is highly unlikely that reproductive cloning will be successful initially.<sup>138</sup> However, if the process does become successful in time, the “yuk” factor may lose its impact, much like people’s feelings in relation to heart transplants changed over time. Just as no-one pays any attention now to the manner in which an IVF baby started its life, but rather concentrates on the person it becomes, so a cloned baby who is wanted and loved will cease to be anything but a wanted and loved baby. Its origins will be less important the more that reproductive cloning occurs and becomes unexceptional.

Objections to cloning usually refer to an identical copy of another human being, either dead or alive. But this puts too much emphasis on genetics, and ignores environment. Just as identical twins do not have identical personalities or identical fingerprints,<sup>139</sup> but merely identical genes, so it is unlikely that humans who commenced life as a genetic clone of another human would be an exact replica of another human. In all likelihood, they will share the same genetic material but the way they experience their environmental influences will determine how their genes become modified. It is most unlikely that cloning Hitler or Mozart would produce another Hitler or Mozart.<sup>140</sup> Rather than raise hysterical and science-fiction type arguments about the spectre of hordes of human clones inhabiting the earth, ethicists, lawyers and scientists should consider a rational and ethical system of regulating human cloning for the future, so as to be prepared for the science when it occurs.

It is better to have a responsible and ethical framework in place in advance of scientific and technological change than try to deal with it as a matter of urgency. It is questionable whether it is the

<sup>133</sup> For example, to look after us in old age, to provide a brother or sister for a sibling, someone to love, to obtain government assistance etc.

<sup>134</sup> Julian Savulescu, Uehiro Chair in Practical Ethics, University of Oxford. See eg Savulescu J et al, “Behavioural Genetics: Why Eugenic Selection is Preferable to Enhancement” (2006) 23(2) *Journal of Applied Philosophy* 157; Savulescu J, “Should We Clone Human Beings? Cloning as a Source of Tissue for Transplantation” (1999) 25(2) *Journal of Medical Ethics* 87; Savulescu J, “Reproductive Technology, Efficiency and Equality” (1999) 171 MJA 668, [http://www.mja.com.au/public/issues/171\\_11\\_061299/savulescu/savulescu.html](http://www.mja.com.au/public/issues/171_11_061299/savulescu/savulescu.html) viewed 10 June 2008; Savulescu J, *Equality, Cloning and Clonism: Why We Must Clone*, the Reproductive Cloning Network, <http://www.reproductivecloning.net/savulescu.html> viewed 10 June 2008.

<sup>135</sup> Some commentators have criticised the desire of parents to produce genetically related offspring as part of a fanatical social trend: Kahn A, “Clone Mammals ... Clone Man?” (1997) 386 *Nature* 119.

<sup>136</sup> See eg Savulescu J, “The Ethics of Cloning” (2005) 33(2) *Ethics* 18.

<sup>137</sup> Savulescu J, [http://www.bep.ox.ac.uk/Cloning%20and%20stem%20cell%20articles/Cloning%20\(THES\).pdf](http://www.bep.ox.ac.uk/Cloning%20and%20stem%20cell%20articles/Cloning%20(THES).pdf) viewed 18 September 2007.

<sup>138</sup> There have been claims in the past that human cloning has already been achieved but this has never been supported by evidence. In 2002, Dr Brigitte Boissellier, scientific director of Clonaid, claimed to have cloned a human being. This claim has been discounted by the scientific community as being unlikely. Dr Panos Zavos and Professor Servino Antinori have indicated that they intend to clone a human.

<sup>139</sup> McLachlan H, *Ignore the Boys from Brazil – Say Yes to Cloning*, the Reproductive Cloning Network <http://www.reproductivecloning.net/mclachlan.html> viewed 10 June 2008.

<sup>140</sup> McLachlan, n 139; Savulescu, n 134.

place of regulators to draw up a plan of who should become parents and who should miss out on parenthood, particularly when the technology becomes available.

Parents who wish to clone a dead child may put unrealistic expectations onto that cloned child and if so, that may be regrettable. But it is not more regrettable than parents who constantly compare a child with less ability to another child with greater ability. Many parents do damage to children's psyche, but parents of a cloned baby are not necessarily more likely to do this than other parents. By the time human cloning technology becomes safe, there may exist far more significant developments, such as reversing the aging process.<sup>141</sup>

Strong opposition was also voiced when other new biotechnology breakthroughs were discovered, such as smallpox inoculations, contraception, heart transplants and IVF.<sup>142</sup> None of these has caused catastrophic outcomes. It is unlikely that human cloning, which would be strictly regulated within an IVF environment, will result in any catastrophic outcomes.

## CONCLUSION

It is obvious to anyone who has an interest in stem cell research that the advances in this field in the last 10 years have been revolutionary. From the birth of Dolly the cloned sheep in 1997, to the discovery of the first human embryonic stem cells in 1998, to the announcement in 2007 that pluripotent stem cells can be created from reprogrammed skin cells, it is impossible to predict where this science will be in another 10 years.

In contrast to the speed of scientific discovery, legislation generally moves quite slowly. The history of legislative reform in Australian stem cell research illustrates how cautious the approach has been to enabling scientists to create new techniques for curing diseases. From a total prohibition on human somatic cell nuclear transfer in 2002, the Australian Government eased its restriction in 2006, so as to allow therapeutic cloning, under the strict oversight of the NHMRC. The current legislation is relatively narrow in scope, and will be reviewed in 2009-2010. It is likely that by the time of the next review, many of the 2006 legislative provisions may become obsolete, and Parliament will need to grapple with novel issues, not yet apparent.

By the time of the next review, not only will the issues be novel, but the Parliament will be comprised of some new members, resulting from the federal election results of November 2007.

Whether these factors will result in a more permissive legislative framework is difficult to predict, as three years is a lifetime in this fast-moving field of science. What is most likely is that scientists around the world will continue to expand their knowledge in stem cell research, and will not be obstructed by one country's legislative restrictions. The choice for Australia will be whether to be at the forefront of this ground-breaking and historic scientific work or to be observers as others claim these victories, watching a brain drain in the process.

The debates prior to the passing of the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth) demonstrated the best of Australia's system of parliamentary democracy. The issues were examined in a rigorous, respectful and conscientious manner. Ultimately, most of the Lockhart Committee's recommendations were approved. It remains to be seen whether the issues which are relevant in 2009-2010 create new controversies. Those who are charged with making the decisions would be well advised to put prejudice and fear to one side and concentrate on the long-term outcomes of stem cell research. Even the spectre of human cloning, which may raise an intuitive gasp, should be rationally considered. Things which may seem extreme at first instinct may become less so upon further careful reflection. The possibility of finding cures for diabetes and similar diseases demands a visionary perspective by our Parliament.

<sup>141</sup> Bostrom, n 130.

<sup>142</sup> Epstein A, *Cloning is Moral*, the Reproductive Cloning Network, <http://www.reproductivecloning.net/epstein.html> viewed 10 June 2008.