CHAPTER 3

THE MAJORITY REPORT

THE CASE FOR THE LOCKHART RECOMMENDATIONS

Introduction

3.1 The Committee was divided on acceptance of the two bills, which were based on the Lockhart Recommendations. However a majority of the committee agreed emphatically to support, and to recommend that Senators vote for, the Patterson Bill. The majority of the Committee also acknowledge the excellent contribution to the deliberations from Senators Stott Despoja and Webber through their draft exposure bill.

3.2 This chapter provides a brief scientific overview of the issues involved in the Lockhart Recommendations and the arguments provided in evidence which supported the Lockhart Recommendations, and the two bills prepared in response to the recommendations.

Overview of the science relevant to this Bill

A. Assisted Reproductive Technology:

3.3 Assisted Reproductive Technology (ART) is the application of laboratory or clinical technology to gametes and/or embryos for the purposes of reproduction. ART services are overseen by the NHMRC. Further information about ART and the NHMRC's role can be found on the NHMRC website www.nhmrc.gov.au.

3.4 The information given on the NHMRC website is written in the context of the current legislation.

B. Stem Cell Science:

3.5 There are many explanations of stem cell science available in scientific literature, lay press and online. Some sources communicate the science in a clear non-emotive fashion; others are biased, confusing or simply wrong. Rather than adding to the array of information already available, the Committee has decided to write a brief overview and defer to the NHMRC online educational resource for detailed information on the matter. This can be found in hard copy in Appendix 4 or online as "Stem Cells, cloning and related issues" at
http://www.nhmrc.gov.au/embryos/stemcells/index.htm

3.6 The information given on the NHMRC website is written in the context of the current legislation.

3.7 The Lockhart Committee also gives a description of the science which can be found on pages 39 – 40 as 5.1 'Background to Stem Cell Sciences' www.lockhartreview.com.au

3.8 Stem cells are ‘unspecialised’ cells that have the unique potential to develop into ‘specialised’ cell types in the body (for example blood cells, muscle cells or nerve cells). This can be either for growth and development, or for replenishment and repair. They occur at all stages of human development, from embryo to adult—but their versatility and numbers tend to decrease with age. Given the right conditions in the body or the laboratory, stem cells (unlike muscle cells, nerve cells and or blood cells) can replicate themselves many times over. When a stem cell replicates, the resulting cells can either remain as stem cells or can become specialised cells.

3.9 Stem cells are commonly described as 'adult' and 'embryonic' because of the tissue from which they are derived but they can also be defined by their potential as 'totipotent', 'pluripotent' and 'multipotent'. Totipotent cells are those stem cells which have the capacity to become any cell of the body as well as the capacity to form a whole being. These are only found in the first days of embryo development before the differentiation process begins.

3.10 Pluripotent cells have the potential to become any cell in the body but have no capacity to form a whole being. Under the current legislation human embryonic stem cells may only be obtained from donated surplus IVF embryos, and then only under special licence. These are what we commonly refer to as embryonic stem cells.

3.11 Multipotent stem cells are those that have entered a more specialised stage and can only develop into a certain range of cell types. Human adult stem cells, which generally fall into this category, are donated by people who have given informed consent for their use in research.

3.12 Another source of human embryonic stem cells could be Somatic Cell Nuclear Transfer (SCNT). This is a process commonly called cloning. It is important to remember that the word cloning is used to describe replication of single cells, genetic material as well as whole beings. It is vital that the different outcomes are clearly acknowledged. The SCNT process is where the nucleus of an egg is removed and replaced by one taken from a donor adult cell eg. a skin cell. This is then stimulated and it behaves like an embryo produced by sperm and egg. While the basic SCNT technique is the same as that used to clone whole animals, this cannot happen in humans for several reasons:

1) There has been and shall remain, if the Patterson Bill is passed, a strict prohibition on SCNT embryos being implanted in the body of an animal or human.

2) They are also prohibited from developing beyond 14 days.

3) Under the proposed legislation attempting to do either of these things whether with intent or otherwise will attract a penalty of up to 15 years imprisonment for the person or persons who tried to do it.

4) Scientists believe that the current indications are that the chances of these SCNT embryos developing beyond the blastocyst stage are very remote.

3.13 The representatives of Do No Harm tabled at the hearing on Tuesday 25th November an Editorial from Nature which says 'Whether taken from a fertility clinic or made through cloning, a blastocyst embryo has the potential to become a full functional organism'.[1] This is exactly what the Lockhart Committee addressed in ensuring that an embryo created by SCNT is encompassed by the definition of embryo.

3.14 This technique is widely used in animal research but is currently prohibited in Australia using human cells. However it is not illegal in, for example, the United Kingdom, USA, Singapore, and Sweden. As yet, researchers have not been able to successfully produce human embryonic stem cells using SCNT however this technique is less than 10 years old.

3.15 SCNT requires a source of ova. The bills propose these can be donated human ova or animal ova. Concern has been raised about the potential for exploitation of women as egg donors and also the ethics of using animal eggs in the research. It is important to stress that both bills prohibit the commercialisation of human egg donation and insertion of any cloned human embryo into the body of an animal or human. The notion of informed consent is an integral part of any medical procedure.

3.16 There is research that has pointed to the possibility that some multipotent cells possess plasticity and may be able to develop into more than one cell type making them more like pluripotent cells.[2] Other research has recently shown that it is possible to re-program specialised cells to behave like pluripotent cells.[3] This is promising new research, as if proven it could remove the need to use human ova. However SCNT research using ova remains pivotal to advancing this new research which winds back the cellular clock because we need to understand what it is in the cytoplasm of the egg that causes the donor nucleus in SCNT to behave like that of an embryo formed by sperm and egg.

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1 Nature, Vol 436, 7th July, 2005

2 Multipotent stem cells from adult olfactory mucosa. Murrell et al Dev Dyn 2005 Jun;233(2):496-515.

3 Takahashi and Yamanaka (2006). Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors. Cell 126: 663-676.

The Lockhart Review Committee

The Lockhart Committee Membership

3.17 The Lockhart Committee was appointed by the then Minister for Ageing, the Hon. Julie Bishop, and the membership was agreed to by the States and Territories.

3.18 The membership comprised a group of six eminent Australians. It was chaired by the late Hon. John Lockhart and included Professor Barry Marshall whose work, undertaken with Dr Warren, discovering the link between the bacteria Helicobactor pylori and gastric ulcers, was recognised in October 2005 when they shared the Nobel Prize in Physiology or Medicine.

3.19 The Committee in the Reports and in the Executive Summary detail the process of the extensive Review they undertook.

3.20 It was of concern to the majority of the Committee that a description such as 'a poorly outfitted group'[4] was used by those opposed to the recommendations of the Review to describe the members of the Lockhart review and their work.

3.21 Professor Sherley's attack on the credibility of the members was rejected outright by the majority of witnesses appearing before the Committee. The members of the Lockhart Committee also rejected this unwarranted criticism.

3.22 In his evidence to the Melbourne Inquiry, Professor Graham Jenkin from Monash Immunology and Stem Cell Laboratories cited an interview with Bob Klein, Chairman, California Institute for Regenerative Medicine:

> The American Medical Association, the California Medical Association and a group of 80 Nobel Laureates each independently reviewed the potential stem cell science and reached similar conclusions. What is more, these independent reviewers fully agreed with the Lockhart Committee's key position.[5]

What did the Lockhart Committee consider?

3.23 The Terms of Reference for the Lockhart Review were prescribed in the the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*. They were that the persons undertaking the review must consider and report on the scope and operation of these Acts taking into account the following:

1) developments in technology in relation to assisted reproductive technology;

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4 Professor James Sherley, *Submission 181*, p. 2.

5 'Inquirer', *Weekend Australian*, October 21-22 2006, p.28.

2) developments in medical research and scientific research and the potential therapeutic applications of such research;

3) community standards; and

4) the applicability of establishing a National Stem Cell Bank.

3.24 The Acts required that the Lockhart Committee report must contain recommendations about amendments that should be made to this Act, having regard to the matters mentioned above.

3.25 They also required that the Lockhart Committee must consult:

(a) the Commonwealth and the States; and

(b) a broad range of persons with expertise in or experience of relevant disciplines; and the views of the Commonwealth, the States and the persons mentioned in paragraph (b) must be set out in the report to the extent that it is reasonably practicable to do so.

What impact do the Lockhart recommendations as proposed in the Patterson Bill have on the application of the existing legislation?

3.26 The Lockhart recommendations and explanations for these can be found on pages 162-183 of the Lockhart Report and are in Appendix 5.

3.27 In summary, the proposed amendments to the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*:

- **retain** existing prohibitions on activities such as:
    - placing a human embryo clone in the human body or the body of an animal;
    - importing or exporting a human embryo clone;
    - creating a human embryo by fertilisation of a human egg by human sperm, for a purpose other than achieving pregnancy in a woman;
    - creating or developing a human embryo by fertilisation of human egg by human sperm which contains genetic material provided by more than 2 persons;
    - developing a human embryo outside the body of a woman for more than 14 days;
    - making heritable alterations to a human genome;
    - collecting a viable human embryo from the body of a woman for the purposes of research;
    - creating or developing a chimeric embryo;
    - developing a hybrid embryo beyond 14 days;

  - placing a human embryo in an animal, a human embryo into the body of a human other than into the female reproductive tract or an animal embryo in a human; and
  - importing, exporting or placing in the body of a woman, a prohibited embryo.

- **enable** certain types of research involving embryos to be permitted provided that the research is approved by the NHMRC Licensing Committee (in accordance with legislated criteria) and that the activity is undertaken in accordance with a licence issued by the NHMRC Licensing Committee. In summary, a person may apply for a licence to:
  - use excess ART embryos;
  - create human embryos other than by fertilisation of a human egg by a human sperm, and use such embryos;
  - create human embryos (by a process other than fertilisation of human egg by human sperm) containing genetic material provided by more than 2 persons, and use such embryos;
  - create human embryos using precursor cells from a human embryo or a human fetus, and use such embryos;
  - undertake research and training involving the fertilisation of a human egg, up to but not including the first mitotic division, outside the body of a woman for the purposes of research or training;
  - create hybrid embryos by the fertilisation of an animal egg by human sperm, and develop such embryos up to, but not including, the first mitotic division provided that the creation or use is for the purposes of testing sperm quality and will occur in an accredited ART centre; and
  - create hybrid embryos by introducing the nucleus of a human cell into an animal egg, and use of such embryos.

3.28 Unless a shorter time is specified, the uses of embryos that may be authorised by a licence may **only** be authorised for development up to 14 days (excluding any period during which development is suspended). In **no** circumstances can any embryo be developed, outside the body of a woman, beyond 14 days.

3.29 The Patterson Bill gives effect to the recommendations of the Lockhart Committee by either maintaining recommended prohibitions or making alterations to the legislation where needed to reflect the recommendations.

The science

3.30 It is important to note that the main area of controversy is not the merits or otherwise of embryonic stem cell research. This research has been legal and widely accepted in Australia since the 2002 using donated surplus human IVF embryos. The

major disagreement is the permitting of SCNT as a potential additional source of human embryonic stem cells. Many of those who argued against this aspect of the recommendations object to using any stem cells derived from an embryo that is destroyed in the process. That is, their objections go beyond SCNT to procedures that are already lawful.

3.31 Overwhelmingly Lockhart members, contributors and the majority members of this committee in favour of the Patterson Bill acknowledged that an SCNT embryo is defined as a human embryo. While respecting the individual's right to see the SCNT embryo as equal in status to that of an embryo produced by egg and sperm, it is intrinsic in the recommendations of Lockhart and the Patterson Bill that the continued prohibition of the creation of an embryo by egg and sperm for any purpose other than ART demonstrates the difference in the intrinsic value of the egg and sperm embryo.

3.32 Those in favour of the Patterson Bill argued that the central issue to consider is whether the value of the SCNT embryo outweighs the potential that SCNT research may offer living and future people for the prevention and treatments of disease.

3.33 Most evidence the committee received in support of the Lockhart Review and related bills focussed on the need and benefits of permitting somatic cell nuclear transfer (SCNT) to produce embryonic stem cells. People in favour of this bill were sensitive to those who believe that the intrinsic value of the SCNT embryo is equal to that of an embryo created through natural fertilization using egg and sperm. However they did not think that this belief should outweigh the potential to help living people with the possible understanding of disease process, therapies or drug testing the resultant SCNT ES cells may be used in finding.

3.34 In the lead up and during the course of these hearings some people accused scientists of 'peddling hope to vulnerable people' and misleading people using 'hype' by promising cures. The majority of the committee found those in favour of this research to be measured and candid about the uncertainty of the outcome of the research.

3.35 Interestingly upon perusal of a previous committee report on this same issue it appears that a simular view point was expressed by one of our colleagues in the House of Representatives. In 2001 the Standing Committee on Legal and Constitutional Affairs reported to the House of Representatives through its chair The Hon Kevin Andrews that:

> …the Committee has heard from many people. Scientists have shared their excitement about the discovery of techniques that could open future possibilities of cures for life threatening conditions. Families of people with disabilities have welcomed the prospect that some day relatives with Parkinson's or Alzheimer's disease might be restored to health. Yet researchers have cautioned also that such treatments remain speculative, and warned against raising hopes prematurely. In the case of Alzheimer's, the disease process has not even been identified.

3.36 It is the opinion of the majority of this committee that the claim that reputable scientists are hyping the potential of this research is inappropriate.

3.37 An overwhelming number of scientific contributors stressed that before we could expect to develop therapies we needed to understand how cells develop and differentiate and how disease processes occur at a cellular level. They also argued while this research remained prohibited any hope of finding therapies would be delayed and that stem cells derived by this technique would assist in our understanding of cell biology and in developing therapies for genetic disease. Many also argued that this knowledge would also provide greater potential for identifying adult stem cell treatments.

3.38 Supporters also suggested variously that:

- Existing legislation was being overtaken by scientific development;
- Legislative differences over SCNT amongst jurisdictions were causing leading researchers to leave Australia and was hampering collaborative work with overseas institutions;
- The proposed amendments reflect a plurality of views; and
- The current regulatory framework is inconsistent by allowing embryos created for ART to be used for stem cell research, but prohibits creating cloned embryos from being created for the same purpose.

3.39 The Lockhart Review sought to establish the equivalence of these two activities, saying in their report that:

> ...the production and destruction of such embryos is not dissimilar to the production and destruction of excess ART embryos, which is permitted by the legislation and widely accepted by society. Thus, to permit one (production and destruction of ART embryos) but not the other (production and destruction of nuclear transfer and other bioengineered embryos) is inconsistent and appears to attach more importance to the treatment of infertility than to the treatment of other serious diseases and conditions that could be helped as a result of this activity.[6]

3.40 Dr Paul Brock indicated that the implementation of the Lockhart recommendations would address legislative inconsistencies between the two acts:

> The Lockhart Review put the focus on a current anomaly which the proposed Bill will redress. The 2002 Australian legislation allowed for the creation of human embryonic stem cell lines from fertilised human eggs that have become surplus to the needs of IVF implantation – which means that they would never be implanted into the woman's uterus. But the 2002 legislation currently does not allow creation of such human embryonic stem cell lines derived from an unfertilised human egg in the SCNT process,

6 *Legislation Review*, p. 170.

> which would also never be implanted into the woman's uterus. This is a logically and ethically inconsistent situation.[7]

3.41 SpinalCure Australia also emphasised that allowing SCNT would be comparable with the current treatment of excess ART embryos:

> This type of embryo is not intended to be implanted, so the production and destruction of such an embryo is not dissimilar to the production and destruction of excess IVF embryos, which is permitted by legislation and accepted by society. Therefore denying SCNT but allowing IVF research implicitly values infertility treatment more than potential cures to chronic diseases.[8]

3.42 Likewise, Professor Melissa Little indicated that, in the context of already allowing research on excess ART embryos, the Lockhart Review's recommendation to allow SCNT presented the same ethical questions as those addressed in 2002. Referring to the current legislative arrangement, she stated:

> This acknowledges that, while not the opinion of all in our country, our society does not regard the blastocyst as having equivalent rights to an implanted embryo, fetus or a postnatal human being. A blastocyst is a ball of undifferentiated cells with no capacity to self-sustain or to differentiate without successful implantation into a womb. It is a seed. It has potential and no more. We condone the discard of such tissues as a part of IVF, hence there is no additional ethical dilemma in using these cells for some other purpose...
>
> The Lockhart committee reaffirms the acceptability of our existing legislation with respect to the regulated derivation of new human ES cell lines.[9]

The case for SCNT Research

3.43 While the obvious argument in favour of allowing human SCNT research to take place in Australia is the potential medical benefits human embryonic stem cells in general may bring, we are reminded that as yet no human ES cells been derived from this process. Scientists point out the catch-22 that until the ban is lifted research cannot progress in Australia. Many scientists who contributed to the debate pointed out that SCNT research in animals has shown that this technique has specific value over and above that of ES cell research using egg and sperm derived embryos.

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7 Dr Paul Brock, *Submission 2*, p. 6.

8 SpinalCure Australia, *Submission 29*, p. 2.

9 Professor Melissa Little, *Submission 167*, p. 2.

Creation of Disease-Specific Embryonic Stem Cell Lines

3.44 Because SCNT techniques involve cloning of donated adult cells we would have the opportunity to seek donations of cells from people with identified diseases. This could allow targeted research into particular diseases.

> …if we wish to generate pluripotent cell lines in order to gain insights into certain complex diseases, there is currently no alternative to the generation of disease-specific embryonic stem cell line [other than] via SCNT.[10]

3.45 These disease-specific stem cells lines would allow scientists in multiple laboratories to work on cells known to have genetic problems at the same time. These cloned cells could be used to gain better understanding of those disease processes at a cellular level, test drugs and hopefully derive therapies.

3.46 Professor Jack Martin, one of the few respected scientists who objected to this research, based his argument on the notion that there have been no therapies derived from ES cells and there was no 'proof of concept' to justify lifting the prohibition on SCNT. Other scientists disagreed, as well illustrated by Professor Martin Pera's comment to the committee where he stated:

> …with respect to the statement that there are no [human] therapies from cloned embryonic stem cells, of course there are not because research has not been done on a human yet that would enable it. However, there is proof of concept in animal studies that you can treat disease with such an approach.[11]

Better understanding of ageing process and cancer

3.47 It is known that as we age our genetic material deteriorates and SCNT technology allows exploration of the cellular ageing process which could lead to a better understanding of conditions such as cancer.

Understanding de-differentiation

3.48 Concern has been raised about the need to use donated human eggs in order to perform SCNT research. It has been pointed out that promising new research uses insertion of certain proteins into an adult cell to stimulate it to regress to a pluripotent stem cell-like state. This could mean that the need for human eggs may be reduced or even eliminated if this research can be replicated. However scientists point out that SCNT research is vital in advancing this new research as de-differentiation of the adult cell is an intrinsic part of the SCNT process and so SCNT research allows the ideal arena to further our understanding of de-differentiation.

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10 Professor Andrew Elafanty, *Committee Hansard*, 24 October 2006, p. 68.

11 *Committee Hansard*, 24 October 2006, p. 13.

3.49 Sir Gustav Nossal encapsulated the argument in support of lifting the prohibition on SCNT. He wrote:

> Embryonic stem cell research is rich in promise. It has already demonstrated its potential in the study of disease causation, in development of new diagnostic methods and in basic research. In the longer term, the possibility of new therapies for serious diseases is real, though this will be the work of decades rather than of years…
>
> Stem cell science has advanced to the point where it is pushing against the boundaries of current legislation. It is time for the next step.[12]

3.50 The Monash Immunology and Stem Cell Senior Researchers (The Monash Researchers) supported permitting SCNT on the basis of its potential to treat a number of incurable diseases:

> Access to somatic cell nuclear transfer (SCNT) technology is critical to study the causation and treatment of many common, yet complex human diseases, including many types of cancers and neurodegenerative diseases such as Motor Neurone Disease (Lou Gehrig's Disease or AML), Parkinson's Disease, Alzheimer's Disease, Multiple Sclerosis, Muscular Dystrophies, and numerous other debilitating conditions... It is important to emphasise that neither embryonic nor adult stem cells (as opposed to SCNT derived stem cells) are able to provide an adequate research platform for study of disease processes such as those listed above, neither are diseased cells derived from the lesions able to be expanded sufficiently in vitro for detailed analysis. The advent of SCNT circumvents these issues and provides a unique opportunity to examine such disease states.[13]

3.51 A number of disability support groups argued similarly with Kidney Health Australia submitting that:

> Embryonic stem cells offer great hope to patients with kidney disease, because potentially they can be induced to form any cell type of the human body, including any type of kidney cell. So if a cell type in the kidney (of which there are approximately 30 different types) is being lost due to disease, or parts of the kidney have been damaged or destroyed by disease, embryonic stem cells offer the promise of replacing these lost cell populations and/or repairing regions of the kidney.[14]

3.52 Professor Melissa Little, in discussing the potential for therapeutic applications, suggested that improvements in understanding cell biology and drug screening would constitute the main benefits. Professor Little is researching treatments for kidney disease at the University of Queensland and wrote:

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12 *Submission 74*, p. 1.

13 The Monash Researchers, *Submission 73*, p. 2.

14 Kidney Health Australia, *Submission 56*, p. 1.

> While the long-term objective is obviously some advancement in medical science, it is possibly more likely that research into stem cells will not lead to the cures that we currently imagine. I would argue that there is likely to be two often undiscussed outcomes of this research that may well have far greater implications for human health and a much greater chance of being delivered. The first of these is increased biological understanding. Our fundamental understanding of how a cell is directed to become a specific type of cell remains vague. The fact that there is an ability to change the fate of a cell such that it takes on another form is only just becoming accepted in cell biology and this has come out of recent advances in stem cell science. How and when and why this happens during normal processes of response to injury or disease can start to be addressed by investigating processes such as how a nucleus is reprogrammed during somatic cell nuclear transfer. This will have very broad implications for our understanding of biology and medicine. It may also ultimately allow us to avoid the derivation of a blastocyst at all, which would be a position morally acceptable to all. The second outcome of stem cell research that is often overlooked is the development of such cells as screening tools. To have a supply of potentially patient-specific human cells to screen compounds in development for human use is very likely to revolutionise the pharmaceutical and biotechnology industries and lead to increased safety in new products.[15]

3.53 The Australian Stem Cell Centre also stated that SCNT would assist in greater understanding of genetic diseases:

> SCNT offers a unique approach to the study of genetic disorders in humans. The availability of such cell lines would enable the study of the cellular basis of disease susceptibility, an understanding of the evolution or trigger for the emergence of a genetic disease in the very early human and the testing of hypotheses concerning the involvement of specific genes for patients suffering from a number of serious diseases. [16]

Adult and embryonic stem cell complementarity

3.54 There was no witness or submission where support for embryonic stem cell research was expressed that was not also in favour of concurrent adult stem cell research. These supporters spoke of the importance of both arms of stem cell research.

3.55 Many opponents of SCNT have argued that there is little justification for crossing ethical barriers to develop embryonic stem cells when adult stem cells offer greater therapeutic promise. However this is not an argument against SCNT per se but rather objection to the general notion of embryonic stem cell research.

3.56 Conversely, submitters supportive of the Lockhart recommendations argued that research on embryonic and adult stem cells should be undertaken

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15 Professor Melissa Little, *Submission 167*, pp. 1-2.

16 Australian Stem Cell Centre, *Submission 63*, p. 5.

contemporaneously, thereby improving the overall understanding of stem cell differentiation and the potential applications of stem cell therapies, from both adult and embryonic stem cells.[17]

3.57 Senator Stott Despoja emphasised this issue in her tabling speech:

> We should be wary of advocating one type of research over the other. Each has its strengths and weaknesses – such as the pluripotency (ability to differentiate into any body cell) of embryonic stem cells versus the more limited multipotency (restricted to certain cell types) of adult stem cells – although new research is challenging this idea. Embryonic stem cells also have the unlimited capacity to keep dividing.
>
> Most scientists agree that both forms of research must be pursued in the quest for knowledge of diseases and conditions and potentially treatments; that neither area of research can single-handedly provide all treatments.[18]

3.58 The Monash Researchers noted the complementary nature of research in this field commenting that: 'Knowledge about one or other cell type will in all probability enhance the breadth and efficacy of the applications of the other'.[19] Similarly, Professor Tuch and Dr Sidhu stated: 'only by encouraging research with all forms of stem cells will benefits result to the community, both of a scientific and therapeutic nature'.[20]

3.59 The Federation of Australian Scientific and Technological Societies also suggested that it would be 'premature' to give preference to one aspect of stem cell research over another:

> ...the rapidity and intensity of the field means that results in both adult and embryonic stem cell research in Australia and internationally, have, in many cases, not been replicated or confirmed (and this is to be expected given the time frames involved). Thus it is premature to make definitive statements about the efficacy of different research or potential clinical techniques. Indeed, the scientific evidence suggests it is highly desirable that a variety of techniques both within and across adult and embryonic stem cell research and other tissue regeneration research programs are supported.[21]

3.60 Professor Barry Rolfe argued that comparisons between the two types are needed to progress adult stem cell therapy:

> The advances being made in research into adult stem cells should in no way preclude research using embryonic stem cells. I am studying the concept of

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17 See for example Kidney Health Australia, *Submission 56*, p. 2.

18 Senator Stott Despoja, *Tabling speech*, 14 September 2006, p.5.

19 The Monash Researchers, *Submission 73*, p. 1.

20 Tuch and Sidhu, *Submission 1*, p. 2.

21 Federation of Australian Scientific and Technological Societies, *Submission 72*, p. 2.

> stem cell reprogramming and it is clear from the research to date that we need as many comparisons as possible to work out how to go forward from a totipotent stem cell to a defined pluripotent stem cell type and how one might progress "backwards" from a pluripotent cell to a true totipotent cell. Resolution of this question could help to bypass all the future fuss over embryonic stem cells. We cannot possibly know what such research may lead to, so a comparison is very valuable.[22]

3.61 Professor Bob Williamson from the Australian Academy of Science and who works with adult stem cells explained the need to research both embryonic and adult stem cells:

> We believe that stem cell science represents a real opportunity for better clinical care. I actually work exclusively with adult stem cells, and perhaps I will make the point around that: why do I as an adult stem cell scientist believe that somatic cell nuclear transfer and embryonic stem cell research is important? Embryonic stem cells have two very important properties that are positive. One is that they can differentiate; they can give any cell type in the body. Adult stem cells cannot transdifferentiate in general and, as you get older, they become less and less likely to transdifferentiate. So, although it is possible to get liver cells from an adult to form more liver cells, and bone marrow cells to form bone marrow cells, we cannot get those cells to form heart muscle, neurones and so on. Only embryonic stem cells can do that.
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> Only embryonic stem cells have the capacity to grow and grow and grow indefinitely—their second important property. Adult stem cells stop growing after 15, 20 or 25 generations. Because we need to understand these properties, we need to use research in ES cells to teach us how to use adult stem cells. Adult stem cells have two great advantages: one is that they are safe and the second is that they will not be immunologically rejected.
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> My personal view as an adult stem cell scientist is that we need to encourage this kind of research.[23]

3.62 Professor Phil Waite from UNSW stated that it was too early to predict the potential of embryonic stem cells as 'research on human embryonic cells has been underway for just 8 years, compared with 50 years for adult cells' and emphasised the need to better understand both types of stem cells:

> ...it is clear that adult and embryonic stem cells are fundamentally different. We need to understand the basic science of these cells and their differences before we can determine which would be most useful for the many disorders we seek to treat...Clearly we should not shut the door on any one type before we know its potential.[24]

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22 Professor Barry Rolfe, *Submission 6*, p. 4.

23 *Committee Hansard*, 20 October 2006, p.39.

24 Professor Phil Waite, *Submission 93*, p. 1.

3.63 Stem Cell Sciences Ltd contended that the focus should be on appropriate regulation, rather than the merits of adult over embryonic stem cells:

> As a Company actively exploring the therapeutic potential of different stem cell types, including both adult and embryonic stem cells, we believe that it is not yet clear which stem cell type will be of most value in certain therapeutic indications and that both must be pursued in order to deliver the most effective and safest medical outcomes. The debate surrounding the Lockhart Review recommendations should not be about which type of stem cell is superior but about how to regulate valuable and necessary research to advance regenerative medicine in Australia.[25]

3.64 The Australian Stem Cell Centre submitted that allowing SCNT research could improve adult stem cell therapies such that many of the ethical dilemmas central to this debate could be overcome:

> SCNT should be viewed as an important tool for reprogramming an adult cell genome in an experimental environment and not as a procedure related to reproductive biology to achieve a live birth.
>
> Understanding the reprogramming of an adult cell nucleus to achieve a more flexible or plastic state would have far-reaching beneficial implications for biology and medicine. Ultimately, SCNT may deliver an understanding of those unidentified factors within an egg cell that can reprogram the behaviour of a mature cell, these findings might eventually obviate the need to use eggs or produce embryos at all, because it could be applied directly to the reprogramming of adult cells. In addition, understanding reprogramming would also increase our knowledge of adult tissue stem cell plasticity (the conversion of one type of tissue stem cell into cells of another tissue). This important area of SCNT is currently entirely closed to Australian researchers.[26]

What has changed since 2002

3.65 Opponents of the Lockhart recommendations claim that nothing has changed to justify relaxing of the current legislation. Some scientists who gave evidence supported this view for example Professor James Sherley and Emeritus Professor John Martin. However the overwhelming majority of scientists who provided evidence to the inquiry refuted this claim. They provided a significant number of peer reviewed journal articles clearly demonstrating that the claim is baseless. In addition opponents referred to the report commissioned by the government by MP consulting. However this document has attracted controversy over the narrow terms of reference given to the consulting firm. It has been claimed that the scope was so limited that the findings were predictably in favour of the premise that there was little change in 'the state of play':

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25 Stem Cell Sciences Ltd, *Submission 104*, p. 1.

26 Australian Stem Cell Centre, *Submission 63*, p. 5.

> I have read the MP Consulting document...I genuinely do not believe that the MP Consulting document has any credibility. I say that first because the MP Consulting document was prepared in private, without taking any evidence, without inviting any evidence, without allowing any rebuttal; whereas Lockhart took evidence in public debate.[27]
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> I understand that the MP Consulting document had a much narrower range and brief and they were asked to assess the state of play. I was a little concerned that the state of play was almost to look at public announcements and commentary and not necessarily the scientific merit and justification.[28]
>
> Stem cell science is pushing up against the boundaries of the current legislation.[29]

3.66 Advocates of SCNT described the limitations of what can be achieved using stem cells derived from ART embryos, which usually do not have specific disease characteristics. Evidence was provided that there had been advances in embryonic stem cell research since the passage of the Acts, which give weight to the contention that the legislation was being overtaken by developments in the field.

3.67 The Victorian Government provided the Committee with a report titled 'Key Recent Advances in Human Embryonic Stem Cell Research: A Review of scientific literature commissioned by the Department of Innovation, Industry and Regional Development, Government of Victoria'. The Australian Academy of Science also referred to this review and provided a commentary prepared by Sir Gustav Nossal and Dr Graham Mitchell on technological developments over the past few years in the field of human stem cells in regenerative medicine. They concluded:

> In the opinion of these reviewers and in the current and appropriate cautious and regulated environment, a broad SCNT approach is required for stem-cell based regenerative medicine to achieve its undoubted promise. On the specific question of whether the field has actually progressed in a technological sense, we can respond unequivocally in the affirmative. Formidable challenges confronting the field have been addressed particularly around the generation of clinically-acceptable human ES cells and production of medically-relevant tissue cells from human ES cells (tested in animal systems). SCNT appears to be the best current approach to address the fundamental issue of rejection by the recipient of transplanted cells. Finally, very obvious progress has been made in the use of ES cells and their progeny in cell-based screening for new drugs, for toxicology assays, and for the identification of molecules involved in ES cell renewal and, conversely, differentiation into tissue cells.[30]

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27 Professor Williamson, Committee Hansard, 20 October 2006, p. 46.

28 Dr Munsie, Committee Hansard, 24 October 2006, p. 27.

29 Sir Gustav Nossal, *Submission 74*.

30 'Progress in Stem Cell R&D', GJV Nossal and GF Mitchell, 12 September 2006.

3.68 A Literature Review 'Human embryos, stem cells and cloning – developments in research and regulations since 2001' prepared for the Department of Health and Ageing in August 2005 noted that:

> Research on the growth and differentiation of stem cells for scientific investigations, development of cellular therapies and investigation of disease development has increased rapidly since 2001. Most work has focused on rodent, nonhuman primate and human embryonic and adult stem cells. The literature in this area is vast and we have only been able to include the most general reviews and summarise the main issues relating to embryonic and adult cell types.[31]

3.69 Professor Phil Waite, who is comparing embryonic stem cells, adult bone marrow stem cells and olfactory stem cells in spinal cord injury, listed the following recent advancements:

> ...research in the last few years has demonstrated that:
>
> - Human embryonic stem cells can be differentiated into myelin producing precursor cells and made in sufficient numbers and purity for human use.
> - Human embryonic stem cells can repair demyelinating lesions in mice.
> - Human embryonic stem cells can improve locomotor function in a rat model of spinal cord injury.
> - Adult stem cells migrated less well in the spinal cord and mature glial cells would not remyelinate.
> - Complications such as excessive growth of teratomas were never seen.[32]

3.70 Advocates of SCNT stressed that the benefits that may occur through SCNT were not available through excess ART embryos. According to Professor Little, having access to disease-specific embryonic stem cells is significant:

> ...the derivation of hES cell lines [by SCNT] will enable us to increase our understanding of normal development, abnormal development, nuclear activity and our ability to reprogram one cell type into another. This understanding will be of great importance to the development of new treatment techniques and the manipulation of cell type during disease. To be able to develop a human ES cell from a patient with a disease of development is likely to give us significant insight into what has gone wrong in embryonic patterning. Such understanding can never be gained by simply harvesting existing hES cells from an IVF blastocyst.[33]

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31 Human embryos, stem cells and cloning – developments in research and regulations since 2001: Literature Review, prepared for the Department of Health and Ageing by Biotext PL, August 2005, p.xvii.

32 Professor Phil Waite, *Submission 93*, p. 2.

33 Professor Melissa Little, *Submission 167*, p. 3.

3.71 Stem Cell Sciences Pty Ltd state in their submission that 'since 2002 there have been several major publications that demonstrate the advances in human embryonic stem cell research'.[34] These include:

1. Improvements in the quality of embryonic stem cell lines towards generation of cells that could be used for a clinical application;[35]
2. Numerous examples of differentiation and engraftment of cells derived from human and animal embryonic stem cells in animal models;[36]
3. Correction of genetic abnormalities in mouse embryonic stem cells;[37]
4. Value of embryonic stem cells in drug screening and toxicology;[38]
5. Demonstration that stem cells generated from SCNT share the same characteristics as those derived from a fertilised blastocyst in animal models;[39]

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34 *Submission 104*, Attachment, 'Advances in Human Embryonic stem cell research since 2002'.

35 Ludwig T et al (2006). Derivation of human embryonic stem cells in defined conditions. Nature Biotechnol. 24: 185 – 187; Liu Y et al (2006). A novel chemical-defined medium with bFGF and N2B27 supplements supports undifferentiated growth in human embryonic stem cells. Biochem. Biophys. Res. Comm. 346: 131 – 139; Ellerström et al (2006). Derivation of xeno-free human ES cell line. Stem Cells (published on-line June 1 2006).

36 Trounson (2006). The production and directed differentiation of human embryonic stem cells. Endocrine Rev 27: 208 – 219; Ben-Hur et al (2004). Transplantation of human embryonic stem cell-derived neural progenitors improves behavioural deficit in Parkinsonian rats. Stem Cells 22: 1246 – 1255; Takagi et al (2005). Dopaminergic neurons generated from monkey embryonic stem cells function in a Parkinson primate model. J Clin Invest 115: 102 – 109; Kehat et al (2004). Electromechanical integration of cardiomyocytes derived from human embryonic stem cells. Nature Biotech 22: 1282 – 1289; Faulkner and Keirstead (2005). Human embryonic stem cell-derived oligodendrocyte progenitors for the treatment of spinal cord injury. Transpl Immunol. 15: 131 – 142; Keirstead et al (2006). Human embryonic stem cell-derived oligodendrocyte progenitor cell transplants remyelinate and restore locomotion after spinal cord injury. J. Neurosci. 25 : 4694 – 4705; Fujikawa et al (2005). Teratoma formation leads to failure of treatment for type I diabetes using embryonic stem cell-derived insulin-producing cells. Am J Pathol 166: 1781 – 1791; Zheng et al (2006). Skeletal myogenesis by embryonic stem cells. Cell Res 16: 713 – 722.

37 Chang et al (2006). Correction of the sickle cell mutation in embryonic stem cells. Proc Natl Acad Sci USA 103: 1036 – 1040; Rideout et al (2002). Correction of a genetic defect by nuclear transplantation and combined cell and gene therapy. Cell 109: 17 - 27.

38 Gorba and Allsopp (2003). Pharmacological potential of embryonic stem cells. Pharmacol Res 47: 269 – 278; Davila et al (2004). Use and application of stem cells in toxicology. Toxicol Sci 79: 214 – 223; Gorba and Allsopp (2003). Pharmacological potential of embryonic stem cells. Pharmacol Res 47: 269 – 278; Kulkarni and Khanna (2006). Functional hepatocyte-like cells derived from mouse embryonic stem cells: a novel in vitro hepatotoxicity model for drug screening. Toxicology In Vitro 20: 1014 – 1022.

39 Brambrink et al (2006). ES cells derived from cloned and fertilized blastocysts are transcriptionally and functionally indistinguishable. Proc. Natl. Acad. Sci. USA 103: 933 – 938; Wakayama et al (2006). Equivalency of nuclear transfer-derived embryonic stem cells to those derived from fertilized mouse blastocysts. Stem Cells 24: 2023 – 2033.

6. Basic proof-of-concept that stem cells generated by SCNT could partially restore function in animal models;[40] and

7. Value of SCNT to investigate epigenetic factors including cancer characteristics in animal models.[41]

3.72 Monash Immunology submitted that recent advances in stem cell research provide unparalleled opportunities to explore cell and tissue development, to enable tissue repair, and to lead to new treatments and drug discoveries that could limit or ameliorate degenerative diseases. Research involving both adult and embryonic stem cells should be pursued with rigor and intensity to determine the efficacy and safety of new medical treatments based on cell therapy and associated discoveries.[42]

3.73 They cited many of the same publications that Stem Cell Sciences Pty Ltd did as the key publications on transplantation of human/primate embryonic stem cells into preclinical animal models of human disease and injury and also:

- Banin E, et al. 2006. Retinal incorporation and differentiation of neural precursors derived from human embryonic stem cells. Stem Cells 24(2):246-257; and
- Lund RD, et al. 2006. Human embryonic stem cell-derived cells rescue visual function in dystrophic RCS rats. Cloning and Stem Cells 8(3): 189-199, 2006

3.74 At the Melbourne Hearing they tabled another highly relevant article that had been published since the hearing commenced which highlighted the speed at which this research is moving forward:

- D'Amour et al, Production of pancreatic hormone-expressing endocrine cells from human embryonic stem cells. Nat Biotechnol. 2006 Oct 19; [Epub ahead of print] Jurisdictional implications for Australian research.

40 Rideout et al (2002). Correction of a genetic defect by nuclear transplantation and combined cell and gene therapy. Cell 109: 17 – 27; Barberi et al (2003). Neural subtype specification of fertilization and nuclear transfer embryonic stem cells and application in parkinsonian mice. Nature Biotech 21: 1200 – 1207.

41 Blelloch et al (2004). Nuclear cloning of embryonal carcinoma cells. Proc Natl Acad Sci USA 39: 13985 – 13990; Hochedlinger et al (2004). Reprogramming of a melanoma genome by nuclear transplantation. Genes and Dev 18: 1875 – 1885.

42 *Submission 73*.

Jurisdictional discrepancies

3.75 Somatic cell nuclear transfer is currently legal in the following countries: Belgium, China, Japan, Mexico, New Zealand, South Korea, Singapore, South Africa, Sweden, Thailand, United Kingdom and United States of America.[43]

3.76 The committee was warned of the implications of legislative differences on SCNT between Australia and these countries. First, Australian scientists working in the area of embryonic stem cell research would leave Australia, usually for the United States, to pursue their research. Secondly, a more restrictive regime in Australia would adversely affect collaborative projects being undertaken with overseas institutions operating in jurisdictions where the practice is legal.

3.77 The Coalition for the Advancement of Medical Research in Australia (CAMRA) argued that prohibiting SCNT was encouraging leading stem cell researchers to move overseas:

> Australia has been a leader in stem cell research. Earlier this year we lost our top human embryonic stem cell scientist, A/Professor Martin Pera, to California. Last month we lost one of our top adult stem cell scientists, A/Professor Paul Simmons, to Texas. This will continue.[44]

3.78 The Australian Stem Cell Centre confirmed this trend:

> Without the ability to perform SCNT, elite researchers remaining in Australia will always be behind the lead of the top researchers in the United States, United Kingdom and other countries where SCNT is lawful. Inevitably, without the ability to perform SCNT and collaborate on SCNT projects, the strategy and outlook for the Centre will also be hindered. A number of key senior scientists have this year left Australia for the United States where SCNT is permitted and considerable funds are available. The length of time the legislative review has taken to date and the uncertainty in the outcome is a significant deterrent to the Centre being able to attract leading scientists, from this field, to come to Australia. It is also a significant risk to the stability of the Australian scientists working in this field at present.[45]

3.79 Legislative differences between different jurisdictions where stem cell research is carried out also have implications for collaborative research. The

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43 There is no federal legislation covering this area of research in the U.S., though the federal government does not provide funding for research involving the destruction of embryos. Some states have legislated to allow SCNT. See Biotext Pty Ltd, *Human embryos, stem cells and cloning – developments in research and regulations since 2001: Literature review*, August 2005, http://www.lockhartreview.com.au/_files/Literature%20Review%20(Biotext).pdf, (accessed 17 October 2006).

44 CAMRA, *Submission 21*, p. 2. Also *Committee Hansard* 20.10.06, p.45 (Australian Academy of Science).

45 Australian Stem Cell Centre, *Submission 63*, p. 5.

Australian Stem Cell Centre indicated that unless the Lockhart recommendations were implemented, it would be impeded in:

> ...establish[ing] important scientific collaborations with highly regarded research groups in jurisdictions that allow activities that are not currently allowed in Australia under Australian law (particularly key groups in the UK and the US).[46]

Reflecting plurality in legislation

3.80 Another argument in support of the Lockhart Review and the bills was that a vociferous minority should not be able to force the prohibition of activities supported by a significant proportion of the community. This view holds that in a liberal society with a wide diversity of views, the moral and ethical opinions of one section of the community should not be imposed on another.

3.81 The Lockhart Committee contended that the arguments used to oppose embryo research and SCNT did not justify its legal prohibition:

> The Committee was acutely aware of the special moral status attached to embryos and the concerns that many groups, particularly Christian churches, had regarding their destruction. But the Committee also recognised that not all communities in Australia attach the same significance to the embryo, and that other concerns, such as the need to care for the sick and vulnerable and respect the wishes of individuals, are also morally important.[47]

3.82 Dr Paul Brock, who has motor neurone disease, agreed that in a pluralist society no one view should dictate ethical standards:

> In any multi-cultural, multi-faithed and non-faithed secular democratic society such as ours, the formulation of principles of ethical standards cannot be based exclusively upon any or only one religious creed, or denomination, or sub-denominations.[48]

Evidence supporting other specific Lockhart Recommendations

Amending the definition of an embryo

3.83 Presently, the Acts define a ***human embryo*** as 'a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.'[49] The definition proposed in both the Patterson Bill and Stott Despoja and Webber exposure draft bill is as follows:

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46 Australian Stem Cell Centre, *Submission 63*, p. 2.

47 Lockhart Review Committee, *Submission 20*, p. 3.

48 Dr Paul Brock, *Submission 2*, p. 2. Dr Brock's PhD is in English.

49 Section 7 of the RIHE Act; s. 8 of the PHC Act.

> ***human embryo*** means a discrete entity that has arisen from either:
>
> a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
>
> b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;
>
> and has not yet reached 8 weeks of development since the first mitotic division.

3.84 The Lockhart Committee advised Senators Patterson and Stott Despoja that it was their intention that this definition be consistent with the NHMRC discussion paper titled 'Human Embryo – A Biological Definition',[50] which was being prepared at the same time as the Lockhart Report was being finalised for publication. This is reflected in both bills.

3.85 The Lockhart Committee noted that while the 2002 legislation enabled scientists to continue ART research, the choice of definition for a 'human embryo' in the Acts:

> Has had the apparently unintended consequence of impeding valuable research and clinical practice in ART clinics. In particular, the legislation has stopped research on culture and maturation of immature eggs (called 'in vitro maturation of oocytes', or IVM), storage of frozen eggs, various aspects of IVF, and gamete (egg and sperm) development. Research on maturation of eggs has been further prevented by the prohibition on oocyte activation (also called 'parthenogenesis'). The ability to produce mature eggs in culture provides a way of reducing the treatment of woman with follicle stimulating hormone, which would benefit many women undergoing ART. It may also allow production of mature eggs from frozen ovarian tissue, thus allowing women who have undergone chemotherapy or other treatments that reduce ovarian function to have their own genetic children.[51]

3.86 Any attempt to define 'human embryo' will always be contentious. In their report the Lockhart Committee clearly explain their reasons for recommending change to the existing definition in the Acts. Professor Wendy Rogers emphasised the importance of achieving legislative clarity by referring to an observable marker:

> As fertilisation is a process which occurs over time, rather than a discrete event, any definition relating to embryos created by fertilisation of an egg by a sperm will be somewhat arbitrary in the sense that it selects one moment in the process as the marker to define when a human embryo begins to exist. The NHMRC definition uses a biologically observable

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50 The second part of the definition, part (b), proposed in the Lockhart Review refers to development up to fourteen days, rather than the primitive streak.

51 *Legislation Revie*w, Executive Summary, pp.xiv-xv.

> feature (first mitotic division) to anchor their definition for an embryo created for reproductive purposes, thereby clarifying what is and is not a human embryo in ways that can be verified, as opposed to using syngamy which is not as easily observable.[52]

3.87 With regard to the definition's treatment of embryos created by means other than fertilisation of an egg by a sperm, she commented:

> For entities created in other ways, the potential to develop to the point of appearance of the primitive streak indicates that a human being might ensue from the process, whilst excluding other entities that have no potential to develop into a human being. Recognition of potential is one of reasons often cited for giving moral regard to embryos, so that recognising this in the definition is consistent with widespread moral views.[53]

3.88 Professor Susan Dodds suggested that the legal definition of an embryo should seek to provide legal clarity, rather than resolve ethical differences. This, she stated, was achieved by the proposed definition:

> The ethical differences that exist in the community regarding the moral status of embryos cannot be resolved by legal artifice, and laws that depend on a particular ethical perspective for their interpretation are likely to be found to be unjustified. For that reason one of the most important features of both Bills is that they offer a noncircular definition of the human embryo that uses objective, observable, scientific features of the development of fertilised oocytes into embryos to establish the scope of the legal provisions... Researchers ought to be confident (at least so long as the science supports first mitotic division and development of the primitive streak as clear identifiers) that they can predict when and whether the laws apply to their research.[54]

3.89 Support for the proposed definition was provided by the Fertility Society of Australia which recognised the scientific justification for the proposed new definition:

> The inclusion of the revised definition of an embryo is useful in acknowledging that fertilisation is a dynamic process and cannot be defined until a physiological marker is observed.[55]

Obtaining fresh embryos for research

3.90 Lockhart Recommendations 20-22 and Schedule 2, Items 4 and 24 of the Patterson Bill seek to enable prior consent to be granted for the use of fresh embryos, regarded as 'unsuitable for implantation', for research. This unsuitability would be determined by being either diagnosed with a genetic abnormality prior to

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52 Professor Wendy Rogers, *Submission 67*, p. 1.

53 Professor Wendy Rogers, *Submission 67*, p. 1.

54 Professor Susan Dodds, *Submission 84*, p. 2.

55 Fertility Society of Australia, *Submission 40*, p. 1.

implantation, or by being deemed otherwise unsuitable against objective criteria. Support for allowing these categories of embryos to be obtained in a fresh state for research purposes focused mainly on the benefits of studying embryonic stem cells carrying known genetic deficiencies.

3.91 The Australian Stem Cell Centre wrote of the potential advances possible should this activity be permitted:

> Currently, scientists are unable to obtain IVF created embryos (created for the purpose of reproduction) affected by an inherited genetic disease, deemed unsuitable for implantation. ... The potential benefits for the study of disease by developing disease-affected stem cell lines, with appropriate consent from the donors, could have many uses from understanding the genetic triggers and processes during the onset of disease to using the cells for the development of new drugs and treatments for such diseases.

3.92 The Monash Researchers stressed the importance of creating stem cell lines with known genetic abnormalities:

> ...new embryonic stem cell lines need to be established from embryos with diagnosed genetic abnormality and inheritable genetic disease (eg. Huntington's Disease, Cystic Fibrosis, Thalassaemia, Muscular Dystrophy), donated by couples having IVF and preimplantation genetic diagnosis of such serious genetic disease. Collectively these will generate research tools that will be a new and unique resource for gaining improved understanding of these serious disease conditions and for development of potential new treatment strategies.[56]

3.93 Professor Wendy Rogers, a specialist in medical ethics and health law from Flinders University, expressed support for Lockhart's recommendation on unsuitable embryos identified through pre-implantation genetic diagnosis (PIGD). She wrote:

> I believe that couples can give informed consent to research with these embryos without the 2 week cooling off period on the grounds that they have spent considerable time and effort in reaching the point of PIGD, and are aware of the possibility of some of the embryos being unsuitable for implantation. In these circumstances, it is not wrong to allow discussion of the fate of the embryos that will not be used for attempting pregnancy prior to the results of tests which will identify any such embryos. Allowing donation of unsuitable embryos for research allows the donating couple to retrieve some good from the process, and also allows them to express agency in ways that we usually recognise in Australia. Other couples with ART embryos that are not required for reproductive purposes have the opportunity to donate their embryos for research if they so wish; making this change in the legislation will accord couples with PIGD-identified unsuitable embryos the same options.[57]

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56 The Monash Researchers, *Submission 73*, pp. 1-2.

57 Professor Wendy Rogers, *Submission 67*, p. 3.

3.94 Her support for the use of fresh ART embryos was, however, limited to those identified through PIGD. Professor Rogers submitted that identifying other embryos as 'unsuitable', by objective criteria, was more problematic:

> The process of judging the quality of embryos when choosing which to implant is a very inexact science, and any embryos judged as "less vigorous" on clinical grounds alone should not be considered for use in research when fresh if there is any chance that they might be considered for implantation at a later stage.[58]

3.95 The Authors of this Chapter noted that recommendation 32 calls for the NHMRC to develop guidelines for egg donation and considers that Professor Rogers' comments should be referred to the NHMRC to be considered when developing the guidelines.

Allowing the international exchange of genetic material

3.96 Lockhart Recommendation 41, Schedule 4 of the Patterson Bill and division 2, clause 19 of the Stott Despoja and Webber exposure draft bill seek to enable the import or export of a patient's reproductive material, including ART embryos, subject to quarantine regulation. ACCESS supported this measure to remove 'previously burdensome requirements for people needing to import or export embryos to continue their ART treatment in another country'.[59]

3.97 Also, Recommendation 42 of the Lockhart Review, Clause 23C of the Patterson Bill, and division 2, clause 18 of the Stott Despoja and Webber exposure draft bill would enable researchers to access embryonic stem cell lines from overseas provided they were derived in a manner consistent with Australian legislative requirements. The Monash Researchers submitted that the international exchange of stem cell resources should indeed be facilitated:

> It is a global research priority to derive pluripotent stem cells with a broad range of diseases for scientific study. Collaborations for this endeavour will minimize the duplication of effort and resources needed to derive these important cell lines.[60]

3.98 The Australian Stem Cell Centre also supported a relaxation of the regulations on exchanging such material. It suggested that this would improve collaboration and enable donated eggs to be used more efficiently:

> The Centre supports an amendment to the *Customs (Prohibited Imports) Regulations 1956* to allow Australian researchers access to stem cells and stem cell lines derived from SCNT embryos developed overseas. If SCNT becomes lawful in Australia as a result of this inquiry, co-extensive

58 Professor Wendy Rogers, *Submission 67*, p. 3.

59 ACCESS, *Submission 176*, p. 1.

60 The Monash Researchers, *Submission 73*, p. 8.

> amendments must be made to allow importation of SCNT-derived cell lines in order for researchers in Australia to effectively use this technology and collaborate with other international scientific groups. This would also ensure no duplication of unnecessary stem cell lines, effectively minimising the number of nuclear transfer embryos created and the number of human eggs used to create those cell lines.[61]

National stem cell bank

3.99 The legislation does not expressly deal with the question of establishing a national stem cell bank, as recommended by the Lockhart Review. Senator Stott Despoja commented:

> In this draft bill, I have not legislated for a national stem cell bank. This is partly because a stem cell bank does not necessarily require legislation. In fact, the UK has a national stem cell bank which does not have a legislative basis. There are options for such a framework including the possibility of establishing a stem cell bank along similar lines to that of blood bank.
>
> This bill requires the Attorney-General's Department and the Department of Health and Ageing to examine in some detail the issues surrounding a stem cell bank. The terms of reference are more detailed than those under which the Lockhart Review was operating.[62]

3.100 In the Patterson Bill the proposed clause of 47b of the RIHE Act requires the Minister to report to Parliament (within 6 months) regarding the establishment of a National Stem Cell Centre and a national register of donated excess ART embryos.

3.101 A number of submitters commented on this issue. Professor Tuch and Dr Sidhu suggested that the new stem cell bank should operate across several cities, using existing facilities, and perform the following functions:

- Storing stem cell lines;
- Distributing stem cell lines; and
- Acting as an official site to deposit cell lines.

3.102 They further suggested that a central steering committee could be established to maintain a registry of stem cell lines and make other decisions, such as on storage and IP issues.[63]

3.103 The Australian Stem Cell Centre suggested that it, in conjunction with the Major National Research Facility, is 'the logical organisation to oversee a national stem cell bank as it has an existing cell storage facility and trained staff'. Its submission outlined the following benefits of such a facility:

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61 Australian Stem Cell Centre, *Submission 63*, p. 6.

62 Senator Stott Despoja, tabling speech, 14 September 2006, p.7.

63 Tuch and Sidhu, *Submission 1*, p. 2.

> The formal implementation of an Australian stem cell bank would enhance Australia's reputation as a leading producer of high quality cell lines. A national stem cell bank would have many positive features including:
>
> 1. ensuring regulatory and ethical compliance of all cell lines deposited;
> 2. standardising the quality of all cell lines;
> 3. providing consistent complementary information and service advice with all cell lines;
> 4. conserving embryos; the Bank would reduce duplication of research to produce specific cell lines;
> 5. being a national (and eventually international) resource by requiring compulsory deposition of all Australian derived cell lines;
> 6. providing an independent assessment of the quality and standard of cell lines;
> 7. being a database of historical records of production and distribution of all cell lines;
> 8. monitoring the import and export of cell lines; and
> 9. providing a central body for the independent reporting requirement to licensing bodies.[64]

3.104 Professor Wendy Rogers insisted that stem cell resources remain in public hands:

> ...there is a serious ethical issue of equity that arises when tissues donated by Australians for the benefit of the Australian community (including both researchers and patients) are then used to develop commercial products for private enterprise. The products and profits from the research involving SCNT and the development of stem cell lines including a stem cell bank (should they proceed in Australia) should remain in public control, and equally available within the public healthcare system. The current climate of competition between the states for commercial biotechnology investment raises concerns that there will not be public ownership of many resources donated by Australian women for stem cell research. It is appropriate that any legislation recognises the interest of those groups who provide the basic resources for the development of potential therapeutic treatments in having access to those treatments.[65]

64 Australian Stem Cell Centre, *Submission 63*, p. 7.

65 Professor Wendy Rogers, *Submission 67*, p. 3.

Community Standards

3.105 Some of those opposed to the recommendations suggested the Lockhart Committee had not adequately taken into account community standards in making their recommendations. The majority of the Senate Committee are of the opinion that this is not a valid criticism of them. The Lockhart Committee undertook extensive consultation involving face-to-face meetings with key stakeholders, public hearings and some private meetings (at stakeholders' requests), facilitated stakeholder discussion forums, and selected site visits. In addition, the Committee reviewed the latest results of focus group and telephone survey research by the Public Awareness Program of Biotechnology Australia, and a literature review (commissioned by the NHMRC on behalf of the Minister for Ageing) of recent scientific and technological advances in human cloning, human embryo research and related matters, including stem cell technologies.

3.106 Witnesses referred to the number of surveys relating to community opinions on this research and questioned the independence of some, noting that the use of particular wording, without appropriate context or background information, could provide misleading results. Ms Joanna Knott from the Coalition for the Advancement of Medical Research in Australia questioned the independence of these surveys:

> I am aware of quite a lot of research that has come out, but I think that the Roy Morgan and ACNielsen research is truly independent. I am not convinced that some of the other research is as convincing, because it is not necessarily as independent.[66]

3.107 The majority of independent polls found consistently strong support for research. Professor John McNeil also considered that the Morgan and ACNielsen polls were more indicative of informed community opinion:

> Of the four Australian studies that have been published, two of them—the ACNielsen poll and the Morgan poll—have been conducted to what I would regard as a good scientific standard through random telephone dialling. They have come to quite remarkably similar conclusions.
>
> The key issue is that the percentage of individuals who have expressed opposition to the concept of stem cell research is roughly 11, 12 or 13 per cent—males and females—and the number that support research in these studies has been in the majority: over 50 and usually 60 per cent. Quite a few have not been able to offer an opinion.
>
> There have been somewhat contrary results provided by the Sexton Marketing study. But it is important to point out that it is recognised that in an area like this, where there is a large degree of community ignorance, the way a question is asked can have an enormous impact on the response that is given. For example, a simple bald question like, 'Do you support or oppose the cloning of human embryos as a source of stem cells?' would be regarded by me as a rather emotive way of putting a question. And it is not

66 CAMRA, *Committee Hansard*, 23 October 2006, p. 33.

> surprising that without a proper lead-in the results were somewhat different. The response to that poll suggested that 51 per cent opposed cloning.
>
> My attitude here is that without an introductory program that explains the context in which the word 'cloning' was used it is very unlikely that the majority of respondents actually understood what they were being asked about. Therefore, I would pay less attention to this result than I would to the ACNielsen and Morgan studies.[67]

Response to specific comments raised in opposition

3.108 This final section provides a response to some specific issues raised by those in opposition to the recommendations and bills that are discussed in the second part of this chapter.

Embryonic Stem cells and cancer risk

3.109 Concern was raised by some opponents of the bill that embryonic stem cells may, if injected into people, sometimes cause cancer, in particular teratoma. It is the opinion of the majority of the Committee that this concern, while important, does not require legislative change. These are the sorts of risks taken into consideration before any new clinical trial involving humans is permitted to proceed in this country. Also this issue applies to existing legal research and is adequately covered by standard risk benefit analysis for medical research and the current protocols under NHRMC and Therapeutic Goods Administration.

Slippery slope argument and future reviews

3.110 Opponents of the bills referred to the 'slippery slope' argument expressing scepticism that a line would be drawn at SCNT. The Lockhart Committee rejected the slippery slope view:

> Allowing SCNT under licence will not inevitably lead to reproductive cloning. The Australian community almost unanimously opposes it and it should remain prohibited. However, the best safeguard against reproductive cloning is restricting the degree to which embryos can be matured and prohibiting them being implanted [sic] into women. It is reassuring that there have been no instances of non-compliance with legislative and regulatory requirements in Australia (where embryo research is allowed under licence) or in the UK (where SCNT is allowed).[68]

3.111 Dr Paul Brock also rejected the proposition:

> ...the 'slippery slope' assertions of those claiming that embryonic stem cell research would lead to human reproductive cloning are as hollow as they are improperly alarmist. It's like saying that fertilizer production and

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67 Professor McNeil, *Committee Hansard,* 24 October 2006, p. 24

68 Lockhart Review Committee, *Submission 20*, p. 3.

> nuclear medical research should be banned because terrorists can use these processes and products to make bombs.[69]

3.112 Related to this argument were concerns that a future review of the Acts would create pressure for further concessions. The Monash researchers supported continuing legislative review to ensure that research developments were recognised:

> Since this field of research is developing rapidly, the Acts should remain under review from time to time (eg 3 yearly) to enable new unforeseen directions of research endeavour and benefits to be pursued for treatment of otherwise intractable pathologies and injuries. It is not always possible to predict the outcomes and direction of research and important new developments which could be severely hampered unintentionally by inflexible legislation.

3.113 Professor Susan Dodds also supported ongoing review of the Acts, but suggested the process needs refinement when assessing 'community standards':

> It is important that RIHE and PHC Acts and any amendments to them should be regularly reviewed in light of scientific developments, legal developments and evolving ethical attitudes (as is seen in the changes in attitudes towards IVF over the past 25 years), nonetheless any group responsible for such a review will need a tool or baseline or set of criteria to be able to assess "community standards", especially as it is accepted that the underlying ethical differences in attitude towards human embryos at various stages of development will very likely continue to exist.[70]
>
> The recommendations of the Review reflect that temporally compressed process and the critical reflection of the Review Committee on the expert advice it received, while clearly acknowledging that there does not exist a single set of community standards obtaining in these areas.[71]

3.114 Dr Megan Munsie from Stem Cell Sciences Ltd rejected the assertion that proponents of SCNT would seek to incrementally push the legislative boundaries each time a review occurs and explained that their position had not changed since the original legislation was passed:

> I think we are being consistent: three years ago we were asking for the same thing. Three years ago we were asking to do somatic cell nuclear transfer, and we have the bills we currently have. We have not changed our position.[72]

3.115 The Lockhart Committee submitted that they had sought middle ground in a highly polarised debate:

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69 Dr Paul Brock, *Submission 2*, p. 3.

70 Professor Susan Dodds, *Submission 84*, p. 3.

71 Professor Susan Dodds, *Submission 84*, p. 1.

72 Stem Cell Sciences Ltd, *Committee Hansard*, 24 October 2006, p. 23.

> The Committee found from its community consultations, conducted as part of the Review, that the views on this type of research are widely polarised and that they cannot always be reconciled. Our report and its recommendations proposed that a middle ground which reflected the values and priorities of the community would be supported by the majority of Australians, while recognising that some would consider that the recommendations went too far, and others would argue that they did not go far enough.[73]

Availability of ova

3.116 The Majority of the Committee was impressed by the high value placed on human ova by those working in the area of stem cell and ART research. They referred to the ova as 'precious' and conveyed to the committee a sense of responsibility in dealing with limited resource and the sensitivities surrounding their donation. They also indicated their commitment to develop techniques that could ultimately minimise the number required for research.

3.117 It should not be forgotten that any research must pass the vigorous scrutiny of an institute ethics committee and NHMRC licensing requirements and monitoring before it can take place. The Bill recommends guidelines for egg donation. The Majority of the Committee are comfortable, without minimising the significance of human ova, that the bill together with existing protocols for informed consent regarding medical procedures puts this type of donation on a par with any other human tissue donation.

3.118 There have been some exaggerated claims that thousands of eggs will be required to develop and provide treatment for disease using SCNT research. However these inflated figures were put in perspective by statements like those of Professor Marilyn Renfree from the Australian Academy of Science where she stated at the Canberra Hearing that it is hard to speculate on how many eggs would be needed to research Parkinson's disease, Alzheimer's disease and Motor Neurone disease because no-one has yet done it, particularly due to restrictions in Australia. However, Professor Renfree does state :

> ...that we can understand stem cell biology and cellular biology by using the surplus eggs from assisted reproductive technology treatments, because once you have a few of those you can make a stem cell bank. They are banks of stem cells that can, as Professor Williams said, be propagated indefinitely, so you can multiply them into as many as you wish and distribute them to various laboratories. Relatively few would be required.[74]

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73 Lockhart Committee, *Submission 20*, p. 2.

74 Senate Community Affairs Committee Inquiry into Legislative Responses to Recommendations of the Lockhart Review, Friday 20 October 2006, p. 41.

3.119 Claims were made that the demand for human eggs for use in SCNT research could lead to unethical sourcing and possible commodification of human eggs. Senator Stott Despoja refuted this idea in her tabling speech:

> Some opponents of SCNT have warned that legalisation of this technique may lead to the commodification of human eggs. It is important to note that this bill maintains the current prohibition of the sale of human eggs, sperm and embryos and clarifies "reasonable expenses" in relation to permitting reimbursement of expenses for the supply of human eggs, sperm and embryos.[75]

3.120 The Majority of the Committee notes that this is dealt with in a compatible way in the Patterson bill and is comfortable that this bill continues the strict prohibition of sale of eggs.

3.121 In his submission Emeritus Professor John Martin expresses concern that by permitting the use of animal eggs to be used in SCNT research as a means to conserve human eggs could lead to animal human hybrid clones being implanted in an animal.[76] This is absolutely not the case. He cites what he alleges as a deficiency in the bill with regard to the prohibition of implantation of this type of embryo into an animal or human body. With respect, Professor Martin has misinterpreted the intent and meaning of this bill. Notwithstanding the preposterous notion that any proposal for research of this nature would get approval from an institute ethics committee or be consistent with the stringent guidelines and protocols of the NHMRC, the bill clearly prohibits implantation of hybrid embryos into the body of human or animals.

3.122 The definition of a human embryo is defined in the bill under Schedule 1. Clause 3b includes:

> *any other process that initiates organised development of a biological entity of a human nuclear genome or altered human genome that has the potential to develop up to or beyond the stage at which the primitive streak appears.*

3.123 And if the Bill is passed the definition of a human embryo clone will remain consistent with the PHC Act in part 1 section 8 Definitions Clause (1)(2) where it states that:

> *For the purposes of establishing that a human embryo clone is a genetic copy of a living or dead human: (a) it is sufficient to establish that the set of genes in the nuclei of the cells of the living or dead human has been copied; and (b) it is not necessary to establish that the copy is an identical genetic copy.*

3.124 And so it follows that Part 2 division 1, 9 of the Bill applies to hybrid embryos where it is clearly stated that it is an offence to place *'a human embryo clone*

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75 Senator Stott Despoja, Tabling speech, 14 September 2006, p.4.

76 Submission 35, section 3(ii).

in the human body or body of an animal'. Such activity would attract a maximum 15 years in prison.

3.125 The majority of the Committee hopes that Emeritus Professor Martin is comfortable with this explanation as it is certainly the intent of the Committee that no such embryo clone should be placed in the body of a human or animal.

3.126 Some opponents of the bill have cited Dr Peacock, Chief Scientist of Australia as calling for the continued ban on using animal eggs in SCNT research. Dr Peacock made the following statement in a stem cell briefing session on 13 September 2006:

> In the Lockhart Review it was suggested that animal eggs could be used for some of the research so that fewer human eggs would be required. Many scientists think that using a nucleus and egg cell from different species complicates the research. Most scientists regard this particular recommendation to be of little importance.

3.127 Dr Peacock's statement is not about banning but about safety which is adequately covered by research and clinical protocols overseen by the NHMRC.

Conclusion

3.128 Australia has always enjoyed a leading role in biotechnology. We have been at the forefront of in vitro fertilization since the first break throughs in the 1970's. Australian researchers were amongst the first to isolate human embryonic stem cells in the late 1990s and the first to publish proof-of-principle of somatic cell nuclear transfer (SCNT) in the mouse in 2000.

3.129 The 2002 legislation enacted the three year moratorium on SCNT research as recommended by the 2001 report of the House of Representatives Standing Committee on Legal and Constitutional Affairs (Human Cloning: scientific ethical and regulatory aspects of human cloning and stem cell research) by prescribing the legislative review which has come to be known as the Lockhart review. It is the opinion of the majority of this committee that the Lockhart Committee discharged their duties with sensitivity and honesty as they carefully considered the risks and benefits to the Australian community as a whole. They consulted appropriately and were thoughtful and fair in their recommendation. They clearly explained every decision they made in language understandable to all.

3.130 Kevin Andrews who chaired the 2001 committee concluded the foreword of that report stating:

> These are not matters to be decided behind closed doors by scientists or lawyers, however expert and sincere, without widespread community consultation. Nor are they matters that can be resolved by doing nothing. As a society we are confronted with profound issues that require ongoing attention and discussion.

3.131 The new legislation, if enacted will require that a similar review be undertaken in a further three years in order to maintain appropriate public and parliamentary scrutiny of this very important and sensitive research area.

3.132 It is the opinion of the majority of this committee that the overwhelming weight of evidence presented before us must lead to the acceptance of the recommendations of the Lockhart Committee.

Senator the Hon Kay Patterson
LP, Victoria

Senator Natasha Stott Despoja
AD, South Australia

Senator Ruth Webber
ALP, Western Australia

Senator Claire Moore
ALP, Queensland

Senator Carol Brown
ALP, Tasmania

Senator Kerry Nettle
AG, New South Wales

Senator Judith Adams
LP, Western Australia

Senator Jeannie Ferris
LP, South Australia