# Legislative responses to recommendations of the Lockhart Review

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## (A) Key Issues for Stem Cell Research

1. 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 (see Reference 5 - recent key therapeutic publications using embryonic stem cells). 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.

2. Adult stem cells do not appear to share the same degree of plasticity and expansion capacity as embryonic stem cells. Also, the eventual therapeutic applications for adult and embryonic stem cells may be very different. Knowledge about one or other cell type will in all probability enhance the breadth and efficacy of the applications of the other. More research is needed with both adult and embryonic stem cells before clinical trials are contemplated. We strongly support adherence to the principles of evidence based medicine that require proof of concept and sufficient preclinical data to ensure the safety and efficacy of all new stem cell based treatments.

3. New embryonic stem cell lines are needed for research and specific clinical applications, because many of those currently available vary in their functional capacity for directed differentiation (for reasons not well understood) and have been exposed to animal proteins rendering them unsuitable for direct clinical translation. The availability of fresh and frozen embryos, excess to patients' needs and donated with informed consent, for deriving these cell lines is very important. Furthermore, 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. Such genetically affected embryos are always discarded by the couples and not frozen. It is important to access these embryos without the customary requirement to have a 2 week “cooling-off” period because this makes such embryos unsuitable for research purposes.

4. 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. Denial of access to this technology will severely hamper Australian medical research and the ability to collaborate globally to develop new therapeutic strategies, pharmaceuticals, and early diagnostics. Research in many therapeutic disciplines would benefit from access to disease specific stem cells. It is important for Australian scientists to be able to derive disease specific stem cells from patients with diseases defined by clinical criteria of Australian standards and to allow access to SCNT stem cell lines from overseas, derived by the global scientific effort. SCNT also provides a potential route to generating immunocompatible grafts for the clinical application of stem cell therapies. It is important to emphasize 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.

5. Alternative methods for deriving pluripotential stem cell lines (equivalent to embryonic stem cells) are needed and should be pursued. These alternatives should include cell fusion techniques involving adult somatic cells and embryonic stem cells, and cell extracts or cytoplasm from sources other than human eggs (eg. frog/animal egg and stem cell extracts). This research may enable the identification and synthesis of the active factors that are present in eggs which are able to reprogram pluripotentiality in adult cells. This may improve the efficiency of SCNT, reduce, or avoid the need for the use of human eggs and the embryonic phase for deriving pluripotential cells. Development of these techniques for the derivation of pluripotential cells is anticipated in the near future and access to these techniques may be needed by Australian scientists for future research. The reprogrammed cells resulting from the use of these techniques would only be used for research to study the cause of diseases and could lead to new drug discoveries that might ameliorate such diseases. Changes to legislation should enable such research to proceed in Australia.

6. Recent research has shown that non-embryonic pluripotential stem cells can be made by chemically activating unfertilized human eggs. These cells may become a new and significant source of pluripotential stem cells for research and for use in clinical medicine. Such cells could be a very close match for the donating woman and her children, and could be used clinically. The legislation should be amended to enable these cells to be derived from unfertilized eggs of consenting women.

7. 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.

8. A National Stem Cell Bank could be recognized as part of the Federal and State Government funded Australian Stem Cell Centre, at Monash University. Both adult and embryonic stem cells are being banked at this facility which provides national access to banked cell lines for all Australian scientists and importantly, training to grow and differentiate these stem cells.

# (B) Legislation Review Committee Reports

Note: Our responses in **BOLD TYPE**

# Recommendations

### *National legislation*

1. Clinical practice and scientific research involving assisted reproductive technologies (ART) and the creation and use of human embryos for research purposes should continue to be subject to specific national legislation.

### *Reproductive cloning*

2. Reproductive cloning should continue to be prohibited. **Agree**

### *Prohibitions on developing and implanting embryos*

3. Implantation into the reproductive tract of a woman of a human embryo created by any means other than fertilisation of an egg by a sperm should continue to be prohibited. **Agree**
4. Development of a human embryo created by any means beyond 14 days gestation in any external culture or device should continue to be prohibited. **Agree**
5. Implantation into the reproductive tract of a woman of a human–animal hybrid or chimeric embryo should continue be prohibited. **Agree**
6. Development of a human–animal hybrid or chimeric embryo should continue to be prohibited, except as indicated in Recommendation 17. **Agree**

7. Placing a human embryo into an animal or into the body of a human apart from into a woman's reproductive tract, or placing an animal embryo into the body of a human, for any period of gestation, should all remain prohibited. **Agree**
8. Implantation into the reproductive tract of a woman of an embryo created with genetic material provided by more than two people should continue to be prohibited. **We note the argument that serious mitochondrial diseases may be corrected using donor oocytes that contain mitochondrial DNA of a third person. There should be consideration given to placing this matter under regulatory review in the interests of assisting patients with such inheritable disease to have unaffected children.**
9. Implantation into the reproductive tract of a woman of an embryo created using precursor cells from a human embryo or a human fetus should continue to prohibited. **Agree**
10. Implantation into the reproductive tract of a woman of an embryo carrying heritable alterations to the genome should continue to prohibited. **Agree**
11. Collection of a viable human embryo from the body of a woman should continue to be prohibited. **Agree**

### *Creation of human embryos by fertilisation*

12. Creation of human embryos by fertilisation of human eggs by human sperm should remain restricted to ART treatment for the purposes of reproduction. **Agree**
13. Creation of human embryos by fertilisation of human eggs by human sperm to create embryos for the purposes of research should continue to be prohibited except in the situation described in Recommendation 15. **Agree**

### *Use of excess ART embryos in research*

14. Use of excess ART embryos in research should continue to be permitted, under licence, as under current legislation. **Agree**

### *ART clinical practice and ART research*

15. Research involving fertilisation of human eggs by human sperm up to, but not including, the first cell division should be permitted for research, training and improvements in clinical practice of ART. **Agree**
16. Testing of human oocytes for maturity by fertilisation up to, but not including, the first cell division or by parthenogenetic activation should be permitted for research, training and improvements in clinical practice of ART. **Agree. We note the recent report of pluripotential (=embryonic) stem cells formed from non-embryonic chemical activation of unfertilized human eggs. We recommend that this manner of forming pluripotential stem cells be permitted for research and clinical studies (see Reference 1).**
17. Certain interspecies fertilisation and development up to, but not including, the first cell division should be permitted for testing gamete viability to assist ART training and practice. **Agree**
18. The Licensing Committee should develop a simple proforma application for licences to undertake training and quality assurance activities for ART clinics. **Agree**
19. Consideration should be given to the use of cytoplasmic transfer (including transfer of mitochondrial DNA), under licence, for research on mitochondrial disease and other uses to improve ART treatment. **Agree – (see comment on 8)**

### *Use of fresh ART embryos*

20. An expert body should formulate objective criteria to define those embryos that are unsuitable for implantation. **Agree**

21. Fresh ART embryos that are unsuitable for implantation, as defined by the objective criteria, should be permitted to be used, under licence, for research, training and improvements in clinical practice. **Agree**
22. Fresh ART embryos that are diagnosed by preimplantation genetic diagnosis (according to the ART guidelines) as being unsuitable for implantation should be permitted to be used, under licence, for research, training and improvements in clinical practice. **Agree - It is noted that fresh (non-frozen) embryos with diagnosed genetic diseases are not available to establish disease specific stem cells (eg. cystic fibrosis, Huntington's Disease, Thalassaemia) because a 2 week cooling-off period is required for patients to consent to their use for such purpose. This makes such embryos unsuitable for establishing embryonic stem cells. This is a considerable handicap for Australian researchers wanting to study the causation, onset and development of these diseases in order to identify new candidate drugs to help treat such diseases. Patients never want such embryos, nor do they want them kept frozen.**

### *Use of human embryos created by somatic cell nuclear transfer*

23. Human somatic cell nuclear transfer should be permitted, under licence, to create and use human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days. **Agree – this is the only way to establish disease specific stem cells from complex diseases such as a range of cancers, neurodegenerative diseases such as Motor Neurone Disease, Parkinson's Disease, Alzheimer's Disease, Multiple Sclerosis. Research in animal models of some of these diseases show that this enables the identification of genetic, epigenetic, post-translation and environmental inducers, particularly conditions that require "two-hit" induction for phenotypic expression (malignancy, paralysis etc.) of the disease (see Reference 2).**
24. 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, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days. **Recent evidence from major overseas laboratories has shown that extracts of frog/animal eggs and embryonic stem cells can reprogram human adult cells into apparently pluripotential or pluripotent-like cells. Further research may show that exposure of adult cells to these egg extracts derived from these eggs or embryonic stem cells (stem cell fractions) will increase the efficiency of nuclear transfer, or even avoid the production of the embryonic stage necessary when using human eggs for nuclear transfer. The active molecules present in these egg or embryonic stem cell fractions could be synthesized in the future to reprogram adult stem cells into cells with characteristics that are similar or equivalent to pluripotential embryonic stem cells. These are very important developments that are expected to be confirmed in the near term and Australian scientists need to be able to participate in this research. Clearly, developments in this area may well address many of the ethical issues that currently exist with nuclear transfer using human eggs (see Reference 3).**

### *Use of human embryos created by activation methods not involving fertilisation of a human egg by a human sperm or somatic cell nuclear transfer*

25. Creation of human embryos and human embryo clones by means other than fertilisation of an egg by a sperm (such as nuclear or pronuclear transfer and parthenogenesis) should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria

outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days. **Agree**

26. Creation of human embryos using the genetic material from more than two people, or including heritable genetic alterations, should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days. **Agree**

27. Creation of embryos using precursor cells from a human embryo or a human fetus should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days. **Agree**

## *Definition of a human embryo*

28. The definition of a 'human embryo' in both Acts should be changed to: 'A human embryo is a discrete living entity that has a human genome or an altered human genome and that has arisen from either:
    (i) the first mitotic cell division when fertilisation of a human oocyte by a human sperm is complete; or
    (ii) 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, 14 days and has not yet reached eight weeks of development.'

    **Replace 28 with revised definition developed by NH&MRC and recommended in Patterson proposed bill 3 Subsection 8(1) (definition of human embryo):**

    **"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".**

## *Consent arrangements for the donation of embryos*

29. The National Health and Medical Research Council (NHMRC) should review its guidelines in relation to consent to research on excess ART embryos, in order to clarify the consent process in relation to the following issues:
    - the circumstances, if any, where those who choose to donate excess ART embryos to research may be able to choose not to be contacted at some later stage to give consent to a particular research proposal. **Agree**
    - the circumstances, if any, where a human research ethics committee can determine that the researcher need not ask for further consent to use embryos already declared 'excess'. **Agree**
    - the development of an appropriate form of consent that could be completed by the responsible persons for excess ART embryos shortly after the declaration that the embryos are excess. **Agree**
    - the manner in which those who donate embryos or gametes for the creation of ART embryos may express any preference for the type of research for which the tissue will be used, once the embryo is declared excess. **Agree to recommendations for**

**review enunciated by the Committee in section 17.6 Consent for embryo research, page 174-175 of Part C of the report. Note: this should not be restrictive as the type of research for which the tissue will be used may not be foreseen at the time of the consent.**

30. The NHMRC should develop ethical guidelines for the use of embryos that are unsuitable for implantation for research, training and improvements in clinical practice (see Recommendations 20–22).

### *Egg donation*

31. The current principles of consent for participation in medical research must apply to sperm, egg and embryo donors, so as to ensure that decisions are freely made. **Agree**
32. The NHMRC should develop guidelines for egg donation. **Agree**
33. The present prohibition of the sale of sperm, eggs and embryos should continue, but the reimbursement of reasonable expenses should continue to be permitted. **Agree**

### *Licensing arrangements*

34. The Embryo Research Licensing Committee of the NHMRC (the Licensing Committee) should continue to be the regulatory body responsible for assessing licence applications, issuing licences and monitoring compliance, as under current arrangements. **Agree**
35. The role of the Licensing Committee should be extended to include assessment of licensing applications and issuing licences for any additional activities permitted, under licence (see Recommendations 14–27). **Agree**
36. The Australian Parliament and the Council of Australian Governments should give urgent attention to the problem of delays in the filling of vacancies on the Licensing Committee. **Agree**
37. There should be no attempt to recover the cost of administration, licensing, monitoring and inspection activities associated with the legislation from researchers at this point in time. **Agree**

### *Monitoring powers*

38. The Licensing Committee should continue to perform its functions in relation to licences and databases for research permitted by licences under the Research Involving Human Embryos Act. **Agree**
39. Licensing Committee inspectors should be given powers, under the Prohibition of Human Cloning Act and the Research Involving Human Embryos Act, of entry, inspection and enforcement in relation to non-licensed facilities in the same manner and by the observance of the same procedures as applicable to search warrants under Commonwealth legislation, if such powers do not clearly exist. **Agree**

### *Oversight of ART clinical practice and research*

40. There should be a continuation of the role of the Reproductive Technology Accreditation Committee in the regulation of ART. **Agree**

### *Import and export of human reproductive materials for personal use*

41. The import or export of a patient's reproductive material, including ART embryos, for the purpose of that person's ongoing ART treatment should not require any regulation other than that required under existing quarantine regulation. **Agree**

### *Trade and international exchange of human reproductive materials and stem cells*

42. The import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority. **Agree - 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. Australian scientists should be part of this global initiative (see letter from the International Society of Stem Cell Research – Reference 4).**
43. The existing requirements for the import and export of human biological materials are satisfactory and, for ethically derived human embryonic stem cells, no further restrictions are necessary. **Agree**

### *Biotechnology and commercialisation*

44. Trade in human gametes or embryos, or any commodification of these items, should continue to be prohibited. **Agree**
45. Donors of tissue that is going to result in an immortal stem cell line should be informed by means of processes monitored by human research ethics committees about the potential use of that stem cell line, including the potential for commercial gain and the fact that they may not have any rights in potential stem cell developments. **Agree**
46. The development of biotechnology and pharmaceutical products arising from stem cell research should be supported. **Agree**

### *National stem cell bank*

47. A national stem cell bank should be established. **Agree**
48. Consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem cell bank. **Agree**
49. A national register of donated excess ART embryos should be established. **This needs to have the support of patients donating embryos and be subject to rigorous confidentiality processes.**

### *Regulatory approach to legislation*

50. The Licensing Committee should be authorised under the Prohibition of Human Cloning Act to give binding rulings on the interpretation of that Act, or the regulations made under that Act, on condition that it reports immediately and in detail to the NHMRC and to parliament on such rulings. **Agree**
51. The Licensing Committee should be authorised by the Research Involving Human Embryos Act to give binding rulings and to grant licences on the basis of those rulings for research that is not within the literal wording of the Act, or the regulations made under the Act, but is within their tenor, on condition that the Committee reports immediately and in detail to the NH&MRC and to parliament on any rulings it gives, or any licences it grants, in that way. **Agree**
52. A researcher who conducts research on the basis of a ruling or a licence should be protected from liability under the legislation, provided that they act in accordance with the relevant ruling or licence. **Agree**
53. In view of the fast-moving developments in the field, and the range of amendments proposed herein, the two Acts should be subject to a further review either six years after royal assent of the current Acts or three years after royal assent to any amended legislation. **Agree**

### *Public education*

54. There should be ongoing public education and consultation programs in the areas of science that are relevant to the Acts. **Agree**

## (C) References

**1.** Brevini TAL, et al. 2006. Derivation and characterization of parthenogenetic human embryonic stem cells. Hum Reprod Vol 21 Supplement 1: Abstracts Book of the 22nd ESHRE Annual Meeting, Prague, pp i93; O-238.

### 2. Key References on Nuclear Transfer

Blelloch RH, et al. 2004. Nuclear cloning of embryonal carcinoma cells. Proc Natl Acad Sci U S A 101(39):13985-13990.

Doss MX, et al. 2004. Embryonic stem cells: a promising tool for cell replacement therapy. J Cell Mol Med 8(4):465-473.

Hochedlinger K, et al. 2004. Reprogramming of a melanoma genome by nuclear transplantation. Genes Dev 18(15):1875-1885.

Hochedlinger K and Jaenisch R. 2006. Nuclear reprogramming and pluripotency. Nature 441(7097):1061-1067.

Hochedlinger K and Jaenisch R. 2003. Nuclear transplantation, embryonic stem cells, and the potential for cell therapy. N Engl J Med 349(3):275-286.

Lanza R, et al. 2004. Regeneration of the infarcted heart with stem cells derived by nuclear transplantation. Circ Res 94(6):820-827.

Lerou PH and Daley GQ. 2005. Therapeutic potential of embryonic stem cells. Blood Rev 19(6):321-331.

### 3. Key References on the Use of Animal Egg Cytoplasm to Reprogram Adult Cells

Lu C, et al. 2003. Reconstruction of human embryos derived from somatic cells. Chinese Science Bulletin 48:1840-1843.

Simonsson S and Gurdon J. 2004. DNA demethylation is necessary for the epigenetic reprogramming of somatic cell nuclei. Nature Cell Biol 6: 984-990.

Gurdon JB, et al. 2003. Nuclear reprogramming and stem cell creation. PNAS 100: 11819-11822.

Byrne JA, et al. 2003. Nuclei of adult mammalian somatic cells are directly reprogramming to oct-4 stem cell gene expression by amphibian oocytes. Current Biol. 13: 1206-1213.

Chen Y, et al. 2003. Embryonic stem cells generated by nuclear transfer of human somatic nuclei into rabbit oocytes. Cell Research 13: 251-263.

**4. Letter of support from ISSCR**

**5. Key publications on transplantation of human/primate embryonic stem cells into preclinical animal models of human disease and injury are:**

Ben-Hur T, et al. 2004. Transplantation of human embryonic stem cell-derived neural progenitors improves behavioral deficit in Parkinsonian rats. Stem Cells 22(7):1246-1255.

Kehat I, et al. 2004. Electromechanical integration of cardiomyocytes derived from human embryonic stem cells. Nat Biotechnol 22(10):1282-1289.

Keirstead HS, et al. 2005. Human embryonic stem cell-derived oligodendrocyte progenitor cell transplants remyelinate and restore locomotion after spinal cord injury. J Neurosci 25(19):4694-4705.

Banin E, et al. 2006. Retinal incorporation and differentiation of neural precursors derived from human embryonic stem cells. Stem Cells 24(2):246-257.

Takagi Y, et al. 2005. Dopaminergic neurons generated from monkey embryonic stem cells function in a Parkinson primate model. J Clin Invest 115(1):102-109.

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

# (D) Analysis of advice on developments in assisted reproductive technology and related medical and scientific research

A document prepared by mpconsulting for the Department of the Prime Minister and Cabinet

*Note: Our responses in italics*

The purpose of this report was to provide an analysis of any **"changes in the state of play"** in relation to assisted reproductive technology (ART) and related research since the passage of the *Prohibition of human cloning act (2002)* and *Research involving human embryos act (2002)*.

**"changes in the state of play"** was interpreted to mean the raising of new issues (scientific developments, unintended consequences of legislation or new ethical arguments)

The Department requested analysis of 8 particular issues that were the subject of recommendations by the recently commissioned legislative review, chaired by the late Justice John Lockhart. The issues analysed related to three areas:

**1) Developments in relation to the definition of a human embryo 2) Developments in ART research and 3) Stem Cell Research.**

***Comment:*** *It is relevant to point out that the Lockhart review panel included eminent scientists and lawyers, its review was conducted over a period of many months, it received numerous submissions and consulted widely with scientific and community groups before bringing down final recommendations.*

*In contrast, we are not told the composition nor the qualifications of the persons who generated the mpconsulting document. Therefore it is not possible to objectively assess whether this represents an equally valid alternate view to the Lockhart review.*

*Our comments on this analysis document will be confined to Chapter 4, dealing with this area, and specifically with respect to the recommendations related to Somatic Cell Nuclear Transfer (SCNT or Therapeutic Cloning).*

**Summary of mpconsulting analysis**
With respect to the creation and use of human embryos created by somatic cell nuclear transfer, Recommendation 23 of the recent legislative review suggested that SNCT should be permitted under licence with certain restrictions, most specifically that such SCNT derived embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

The *mpconsulting* analysis document indicates that the main arguments for the lifting of the ban on SCNT revolved around the potential of this technology to provide a range of benefits, including the generation of patient matched ES cells for modelling and other research into specific diseases and the generation of specific cellular therapies.

The *mpconsulting* document also presents opposing arguments centering on the perception that creating cloned embryos for the purpose of their destruction was contrary to community standards and the fear that permitting SCNT would "inevitably" lead to reproductive cloning.

The *mpconsulting* analysis summarised that the Lockhart committee's recommendation to lift the current ban on SNCT was based on
i) the conclusion that ongoing research in both adult and ES cells was necessary and likely to be beneficial
ii) that there was a different moral significance attributed to cloned embryos that were not implanted and
iii) the production and destruction of cloned embryos was not dissimilar to the production and destruction of ART embryos that was permitted.

Based on these analyses, *mpconsulting* concluded that "…the [Lockhart] Committee's considerations appeared to be based around the potential for SCNT for the treatment of illness and the Committee's own resolution of the ethical issues rather than an assessment of the state of science as at a certain point in time." (p22).

***Comment:*** *Under the existing legislation, SCNT research is prohibited in Australia, therefore one cannot expect relevant results based on local research. Despite the discreditation of the South Korean work, there is still considerable interest in SCNT in other parts of the world. The aim of SCNT is to reprogram a somatic cell nucleus to a more plastic "embryonic" state, thus allowing differentiation into the complete range of adult cell types. Currently, this reprogramming can only be achieved through the use oocyte cytoplasm. However, the ultimate aim of research is to replace the requirement for enucleated oocyte cytoplasm with known reprogramming factors. There has been very active research in this field. Particularly noteworthy is the recent publication of a scientific paper identifying a number of genes that facilitate somatic cell reprogramming towards embryonic stem cell states in the mouse* ***(Takahashi and Yamanaka, Cell 126: 1-14, August 25, 2006)****.*

*It is our opinion that it is necessary to actually permit SCNT research to proceed in order to demonstrate progress in reprogramming and eventually to evolve to the state that SCNT may be no longer required for reprogramming. Therefore, because scientific research requires long time frames for success (measurable in years) we believe that it is entirely appropriate for the Lockhart Committee to consider the 'potential' rather than the 'actuality' for SCNT for the treatment of illness in coming to its recommendations.*

## (E) DOCUMENTS TABLED IN THE SENATE BY SENATOR PATTERSON

We support the proposed ‘Amendment Bill 2006’ tabled in the Senate by Senator Patterson.

With reference to Schedule 1.23 Offence – creating or developing a human embryo containing genetic material provided by more than 2 persons:

*We note the argument that serious mitochondrial diseases may be corrected using donor oocytes that contain mitochondrial DNA of a third person. There should be consideration given to placing this matter under regulatory review in the interests of assisting patients with such inheritable disease to have unaffected children.*