Alzheimer’s Australia Policy Position on Stem Cell Research
Background Paper
September 2006

Background

The original Alzheimer’s Australia policy position on stem cell research was endorsed by the National Board in April 2002. In light of the Lockhart review and the current debate on the issue, it seems timely to review Alzheimer’s Australia’s position on the use of stem cells in research. Alzheimer’s Australia’s current policy position is supportive of stem cell research, within appropriate regulatory guidelines. It is important that Alzheimer’s Australia’s position continues to be based on an informed scientific view while recognising the range of personal viewpoints around this issue.

Definitions

There has been confusion around some stem cell research terminology. A good overview is presented by the National Health and Medical Research Council at: http://www.nhmrc.gov.au/embryos/stemcells/index.htm. In light of the current debate, it is important to understand the differences between somatic cell nuclear transfer, reproductive cloning and therapeutic cloning.

**Somatic Cell Nuclear Transfer (SCNT)** is a technique which involves obtaining an egg, removing the genetic material and replacing it with genetic material from an adult cell and triggering development into an embryo, which would have the same genome as the adult cell. The technique has been used to produce cloned animals, including Dolly the sheep (an example of animal reproductive cloning) and to develop embryonic cell lines (an example of therapeutic cloning).

**Human reproductive cloning** would result in the creation of a cloned person, whose DNA is identical to another person’s. There is widespread opposition to human reproductive cloning in both the scientific community and the general public and it is completely prohibited. Animal reproductive cloning has been attempted in the agricultural sector to produce livestock and as a research tool.

**Therapeutic cloning** is also known as research cloning or nuclear transfer. The process of somatic cell nuclear transfer, as described above, is used and the resultant embryo is allowed to develop for only a very short amount of time. Embryonic stem cells can be taken from the developing embryo to be used for further research. The cells produced via therapeutic cloning would have the same genome as the adult cell used in the nuclear transfer process. Therefore there may be the potential to develop embryonic stem cells that are matched to a particular individual for transplantation purposes or with known genetic mutations for disease modeling.
The Current Legislation

Stem cell research in Australia is currently regulated by the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*. Both acts were required to be independently reviewed by December 2005.

The purpose of the *Prohibition of Human Cloning Act 2002* is to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos, by prohibiting certain practices. These prohibited practices include reproductive cloning, the creation of a human embryo clone and the creation of a human embryo by a process other than fertilisation, among others.

The purpose of the *Research Involving Human Embryos Act 2002* is to address concerns, including ethical concerns, about the scientific developments in relation to human reproduction and the utilisation of human embryos by regulating activities that involve the use of certain human embryos created by Assistive Reproductive Technology (ART). The Act allows the use of excess ART embryos for research if authorised by a license and prohibits the use of human embryos that are not excess ART embryos for any purpose except for a woman to achieve pregnancy.

Lockhart Review

On 19th December 2005, the Lockhart Review committee delivered their recommendations for changes to the 2002 legislation to the Australian Government. Many of their recommendations maintain the current legislation, including continuing the prohibition on reproductive cloning, continuing to allow the use of excess ART embryos in research under license, and maintaining a strong regulatory framework for the use of embryos in research.

The main proposed changes to the legislation are:

- **Changing the definition of a human embryo**
  The definition would be restricted to the period of development between the first cell division and 8 weeks development, after which time it is considered to be a foetus. By the time of the first cell division (21 – 26 hours after initial fertilisation), the maternal and paternal genomes are fully combined and a new genetic entity is formed. Currently, the definition is set at 9 – 12 hours after initial fertilisation when the male and female pronuclei are visible but the genomes have not yet combined. This alteration of the definition would allow for research on fertilised eggs prior to the first cell division.

- **Assistive Reproductive Technology clinical practice and research**
  Several recommended changes aim to allow research and training into best practice in ART, including allowing research on fertilisation and certain interspecies fertilisation and development up to the first cell division, which will allow for tests of gamete viability that were routine practice prior to the 2002 Legislation.
**Human Somatic Cell Nuclear Transfer**

Somatic Cell Nuclear Transfer (SCNT) would be permitted under license to create and use human embryos for research, training and clinical applications, including the production of human embryonic stem cell lines, within regulatory criteria. Embryos created via SCNT would not be allowed to develop for more than 14 days or be implanted in the body of a woman. Similarly, transfer of human somatic cell nuclei into animal oocytes would be allowed under license for research applications as above, to reduce the need for human eggs in the developmental stages of SCNT research.

**Human embryos created by other means**

In addition to SCNT, changes would allow human embryos to be created by means other than fertilisation under license for research, training and clinical applications, as long as these embryos are not implanted or allowed to develop over 14 days. This would include creation of human embryos using genetic material from more than 2 people, with heritable genetic mutations and from precursor cells for research purposes.

**Establishment of a National Stem Cell Bank**

The Lockhart Review supported the establishment of an Australian National Stem Cell Bank as a means to facilitate research, improve access to stem cell lines and coordinate the stem cell research effort in Australia.

**Public Education**

Public education and consultation programs about stem cell research and the issues raised in the legislation were deemed necessary to address a lack of understanding in the wider community and foster more responsible reporting of this area of research by media and researchers.

The Lockhart Review received 1035 written submissions and employed a nationwide consultative strategy. The most controversial recommendation of the review is the decision to allow somatic cell nuclear transfer or therapeutic cloning. The Review determined that further research progress necessitated the use of therapeutic cloning to develop embryonic stem cells that could be matched to individuals for therapeutic purposes or with known genetic mutations for disease modeling and other research.

SCNT is controversial because it requires the creation and destruction of a very early stage embryo. However, the review noted that “the production and destruction of such an embryo is not dissimilar to the production and destruction of excess ART embryos, which is permitted by legislation and widely accepted by society”. Additionally, many respondents to the review felt that “the moral significance of such a cloned embryo is linked more closely to its potential for research to develop treatments for serious medical conditions, than to its potential as human life.”
Subsequent Developments

In June 2006, Cabinet decided against changing the legislation as proposed by the Lockhart Review. Subsequently many Members of Parliament have indicated their support for the Lockhart Review and several MPs have indicated that they will introduce Private Members’ bills on the issues raised by the Lockhart Review. In late August, the Department of the Prime Minister and Cabinet released a report into the decisions of the Lockhart Review which reported that there was no justification for the legislation changes proposed by the Review. The debate continues and it is anticipated that the issue will be further discussed in Parliament in late 2006.

Alzheimer’s Australia’s Current Policy Position

The current Alzheimer’s Australia Policy Position was endorsed by the National Board in April 2002. The position indicates that Alzheimer’s Australia:

• Supports stem cell research, provided that appropriate ethical guidelines and oversights are in place,
• Acknowledges ethical dilemmas raised by stem cell research for some,
• Supports the current legislation and the need for regulatory frameworks to avoid the deliberate creation of embryos for research purposes, and
• Believes that Australian researchers should be involved in stem cell research.

Rationale for Change

A review of Alzheimer’s Australia’s position is warranted in light of the current debate on the issue and the recommendations of the Lockhart review.

Alzheimer’s Australia’s vision is for a ‘society committed to the prevention of dementia, while valuing and supporting people living with dementia’. In this context, supporting research into all aspects of dementia is a high priority for the organisation.

While there is some consensus that Alzheimer’s disease will not be the first disease to benefit from stem cell based therapies and that the treatment of Alzheimer’s disease with stem cell therapies may be complicated, it is likely that stem cell research can assist in further understanding the mechanisms of Alzheimer’s disease and other forms of dementia. Possible areas of research include examining the development of Alzheimer’s disease and the disease process, as well as highlighting new approaches for drug development and drug screening systems. In particular, SCNT or therapeutic cloning may allow the development of cellular models of Alzheimer’s disease with specific genetic mutations and facilitate the drug development process.

Alzheimer’s Australia’s support for stem cell research should not be contingent upon breakthroughs but should recognise that research is an exploratory process. While it is unlikely, particularly in the short term, that stem cells will be used as therapy for Alzheimer’s disease, more research is needed to explore the potential of stem cells as a powerful research tool to examine mechanisms of human disease.
In addition, there are several related neurodegenerative disorders that are more promising candidates for stem cell based therapies. These include Parkinson’s disease, Huntington’s disease and Motor Neuron Disease, all of which can result in dementia. Motor Neuron Disease is currently being studied using therapeutic cloning techniques in the UK. Research into stem cell therapies and Parkinson’s disease is advancing, with researchers working on developing stem cells for transplantation.

Supporting legitimate scientific research with the potential to advance our knowledge about dementia fits well within Alzheimer’s Australia’s role in promoting the advancement of dementia research in Australia. Australian researchers are world class and should be allowed to contribute to this area of science and maximise benefits to all Australians. The changes proposed by the Lockhart Review will facilitate Australia’s role in the international stem cell research community while maintaining a strong National regulatory framework.

**Recommendations**

It is recommended that Alzheimer’s Australia support the recommendations of the Lockhart review in full.

In particular, Alzheimer’s Australia should support legislation that

- Maintains the strong National regulatory framework governing the use of stem cells and embryos in research,
- Continues to allow the use of excess ART embryos in research,
- Maintains the prohibition of reproductive cloning or any cloning resulting in the development of embryos beyond 14 days,
- Allows the technique somatic cell nuclear transfer to be used to further research,
- Establishes a National Stem Cell Bank, and
- Encourages public education about stem cell research.