To: community.affairs@aph.gov.au

Committee Secretary
Community Affairs Committee
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Dear Sir/Madam

Thank you for the opportunity of making comment on the legislative responses to recommendations to the Lockhart Report.

CAMRA is the Coalition for the Advancement of Medical Research in Australia, and is a nationally recognised peak patient advocacy group representing over 500,000 Australians with life threatening disorders and illnesses that may benefit from stem cell research.

A summary of CAMRA's position is as follows, complemented with additional information provided as a separate document:

- We are in support of the recommendations of the recent Lockhart Review.
- We believe that the current ban on stem cells through nuclear transfer (SCNT) – does not reflect community sentiment and is not in the best interests of Australia, Australian science, or Australians.
- The diverse range of personal opinions on this issue can only be justly translated into representative policy through an open discussion in Parliament – and a conscience vote.

Why?

1. **The majority (80%) of the Australian community supports SCNT**
   - A Roy Morgan poll conducted on 14/15 June[1] showed that 80% of Australians support embryonic stem cell research with stem cells made by merging an unfertilised egg with a skin cell (SCNT), where no fertilisation with sperm takes place.
   - A separate ACNielsen poll taken for *The Age* on 7/9 September 2006 found that 62 per cent of respondents were in favour of legislation allowing the cloning of stem cells for medical research.
2. **SCNT is not cloning, and Australia already allows research like this for infertility purposes**
   - Research is already allowed under licence in Australia on embryonic stem cells from fertilised eggs excess to those required for use in IVF treatments
   - SCNT involves creating embryonic stem cells using unfertilized eggs, but not sperm. The advantage of cells produced in this manner is that they are genetically identical to potential recipients, and hence will not be rejected when transplanted.

[1] See www.roymorgan.com/news/polls/2006/4036/

- 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

3. **Maintaining a ban will see Australia fall further behind international researchers and we will lose more of our best scientific brains 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.
   - We will also be prevented from sharing in the international collaborations, research knowledge, and intellectual property that will accompany this science.
4. **Over 500,000 Australians with debilitating diseases and conditions will need to look overseas for hope for a cure**
   - One person dies from Motor Neurone Disease in Australia every day.
   - One person suffers a severe spinal cord injury every day.
   - Over 140,000 Australian children and adults have type 1 diabetes.
   - One person in 100 over the age of 60 will develop Alzheimers.
   - 100,000 people in Australia have Parkinson's Disease.
   - Stem cell research holds hope for all of these conditions and many more.

We are happy to expand on the material provided either by submission or in person.

Yours sincerely

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CAMRA

Coalition for the Advancement of Medical Research Australia

Submission to Senate Community Affairs Committee in relation to the Legislative Response to the Recommendations of the Lockhart Review

Members of CAMRA

SpinalCure Australia

Juvenile Diabetes Research Foundation

Australian & NZ Society for Cell and Developmental Biology

Australian Society of Medical Research

Diabetes Transplant Unit of the Prince of Wales Hospital/ University of New South Wales

Monash Immunology and Stem Cell Laboratories, Monash University

Motor Neurone Disease Association of NSW Inc.

Neural Injury Research Unit,

University of New South Wales

Parkinson's NSW

Prince of Wales Medical Research Institute

Queensland Brain Institute,

The University of Queensland

Rett Syndrome Association of Australia

Submitted on behalf of CAMRA members by Joanna Knott, Spinal Cure Australia,

Graham Opie, Motor Neurone Disease Association of New South Wales,

Mike Wilson, Juvenile Diabetes Research Foundation

Submission to the Senate Community Affairs Committee

CAMRA

Coalition for the Advancement of Medical Research Australia

Summary of Submission

CAMRA is the Coalition for the Advancement of Medical Research Australia. CAMRA represents over 500,000 Australians with a variety of diseases and injuries.

In this role, CAMRA has prepared a submission which documents changes in community understanding and standards in Australia and globally, which in turn require some amendments to the legislation under review.

In relation to the **Prohibition of Human Cloning Act 2002** CAMRA supports:

- **NO CHANGE to reproductive cloning or human cloning**
- **CHANGE to allow for therapeutic cloning** (Somatic Cell Nuclear Transfer or "patient specific stem cell" research)

The production of stem cells compatible with a patient's condition would help develop new drugs for treatment of these conditions, and overcome many of the challenges associated with tissue rejection. It is possible to pursue these opportunities with legislation that retains clear prohibition of human reproductive cloning***. To ensure that thousands of Australians can benefit from potential life saving treatments at the earliest opportunity the Government needs to allow SCNT research to take place in Australia.***

In relation to the **Research Involving Human Embryos Act 2002** CAMRA supports **NO CHANGE** because**:**

- It is too premature to determine which field of stem cell research (embryonic or adult) will yield the therapies we are seeking into the causes, treatments and preventions of diseases and injuries
- Embryonic stem cell research is in its infancy with much yet to learn having only commenced around seven years ago while adult stem cell research has a history going back forty years.
- At this stage adult stem cells have not demonstrated the same plasticity (pluripotency and potential applications) to form other tissue types that embryonic stem cells have.
- Community standards indicate that the destruction of excess embryos (the alternative) is unconscionable if there are potential benefits from research use and the donors are in agreement.

Global community standards have changed. Legislation supporting the ability to conduct this type of research has been enacted in many other countries, including Canada, the UK, Belgium, Finland, Singapore, Japan, New Zealand, and China.

These positions and the associated rationale are defined further in this paper.

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APPENDIX 1

Diseases and Disabilities in Australia

Facts & the Hope from Emerging Research Directions

Stem cell research could potentially help:

Spinal cord injury	Rheumatoid arthritis	Deafness
Diabetes	Birth Defects	Macular Degeneration
Motor Neurone Disease	Infertility	Retinitis Pigmentosa
Parkinson's	Pregnancy Loss	Organ donation
Alzheimers	Leukaemia	Sickle Cell Anaemia
Stroke	Brain Cancer	Brain Trauma/Damage
Burns	Muscular Dystrophy	Liver Disease
Heart disease	Metabolic Disorders	Osteoarthritis

Further details are below:

Motor Neurone Disease

Key Statistics	➢ 10 people die each week in Australia from Motor Neurone Disease ➢ Almost five times as many deaths in 2003 were attributed to Motor Neurone Disease than HIV/AIDS in Australia (OR Almost twice as many deaths were attributed to Motor Neurone Disease than the combined total for HIV/AIDS, MS & Huntington's disease in Australia in 2003.) ➢ The average life expectancy of someone diagnosed with Motor Neurone Disease is 2-3 years
Breakthrough Research	Researchers at the Howard Hughes Medical Institute have produced motor neurons from mouse embryonic stem cells. Source: Howard Hughes Medical Institute News, July, 2002

Motor Neurone Disease progressively destroys the neurones (nerves) that provide the stimulus to our muscles through which we move, breathe, eat and drink. The disease is given different names depending upon how the symptoms present themselves. The most common form is characterised by muscle weakness and stiffness, over-active reflexes and rapidly changing emotions: upper and lower motor neurones are affected and the limbs cease to work. All forms of the disease are ultimately fatal. There is a real hope that stem cells can provide a supportive environment to nurture motor neurones and stop them from dying. Eventually, stem cells may help the body to grow new connections between nerves and muscles, enable sufferers to walk again, feed themselves, breathe and give them the chance to live a better quality of life and to survive beyond the average life expectancy of 2-3 years after diagnosis.

Spinal Cord Injury

Key Statistics	➢ 20,000 people have a spinal cord injury ➢ 1 person is confined to life in a wheelchair every day in Australia
Breakthrough Research	Oligodendrite cells (which build the myelin sheath around nerves) derived from human embryonic stem cells were injected into rats with spinal cord damage. Rates injected 7 days after injury showed improved mobility within 2 months of treatment. Source: Kierstead H et al., Neuroscience, May 2005

People with spinal cord injury would benefit greatly from even limited restoration of lost functions: gaining partial use of a limb such as a hand, or restoring bladder control, or being freed from pain. It may be possible for someone with spinal cord damage to walk again. In many spinal injuries, at least some of the signal-carrying neuronal axons remain intact. But the surviving axons no longer carry messages because cells called oligodendrocytes, which produce the myelin sheath that insulates the axons, are lost. More than 20,000 Australians live with a severe spinal cord injury and most are young people facing a life in wheelchair without the hope of promising research.

Type 1 (Juvenile) Diabetes

Key Statistics	➢ 140,000 Australians have type 1 diabetes ➢ Even with insulin, type 1 usually results in a drastic reduction in quality of life and shortens the average life span by 15 years ➢ Type 1 diabetes is one of the most costly, chronic diseases of childhood and one you never outgrow ➢ Insulin allows a person with type 1 diabetes to stay alive but it does not cure diabetes nor prevent its eventual devastating effects: kidney failure, blindness, nerve damage, amputations, heart attack and stroke
Breakthrough Research	A research team from the Universidad Miguel Hernandez in Spain isolated insulin-secreting cells from a culture of mouse embryonic stem cells. These cells restored normal glucose metabolism when transplanted into diabetic mice. This work is now being extended using human embryonic stem cells. Source: Diabetes, February 2000 In a recently published study using mice, Harvard researchers determined that new ß-cells in the pancreas are formed through the replication of pre-existing ß-cells, rather than adult stem cells creating new ß-cells. These are the very cells being attacked and therefore their numbers are limited. This result means that in order to cure juvenile diabetes, scientists must rely on another source of ß-cells such as embryonic stem cells to generate new ß-cells.

Juvenile or type 1 diabetes is a disease that strikes children and adults suddenly, makes them insulin dependent for life, and carries the constant threat of devastating complications. In type 1 diabetes, a person's pancreas produces little or no insulin, a hormone necessary to sustain life. Although the causes are not entirely know, scientists believe the body's own immune system attacks and destroys insulin-producing cells in the pancreas. Embryonic stem cell research could help cure juvenile diabetes by turning embryonic stem cells into healthy insulin-producing islets that could be transplanted into people with the disease.

Parkinson's Disease

Key Statistics	➢ An estimated 100,000 people in Australia have Parkinson's disease ➢ It is caused by deficiency of the chemical dopamine in the brain ➢ It is the second most common degenerative neurological condition ➢ Despite its gradual progression, people can live for decades with the illness ➢ Current medications may only be effective in the short term and are likely to produce debilitating side effects
Breakthrough Research	Reports the development of a method for producing high yields of dopamine producing nerve cells. The authors state that this method results in the production of unlimited numbers of mid brain dopamine neurons is a major step towards pre clinical models in Parkinson's disease. Source: Proc. National Acad. Sci. August 2004

Rett syndrome

Key Statistics	➢ An estimated 1 in 14000 people in Australia suffer from Rett syndrome ➢ It affects mainly girls, typically diagnosed between the ages of 6-18 months ➢ It is a neurodevelopmental disorder that deprives people of communication and motor skills and often shortens their life severely
Breakthrough Research	Stem cells could potentially be used to transport a genetically modified MECP2 gene to replace the mutated one.

Rett syndrome (RS) is a debilitating neurodevelopmental disorder that deprives affected individuals (most of whom are female) of communication and motor skills, leaving them completely dependent on others. Although a gene that causes Rett syndrome is known (MECP2), the neurobiology of the disorder is not understood. Stem cell research will help explain how mutations in the gene cause the array of symptoms.

APPENDIX 2

Examples of Global Community Understanding and Legislation

United Kingdom

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- Therapeutic cloning is regulated by Human Fertilization and Embryology Authority (HFEA) in order to understand the development of embryos and to develop treatments for serious disease.
- HFEA gave the first license to Newcastle Centre for Life (Aug 2004), where therapeutic cloning will be used
- A case study follows

United States

- Officially, embryonic stem cell research, therapeutic cloning and reproductive cloning are legal as there is currently no federal regulation or policies overseeing it.
- Reproductive and therapeutic cloning are specifically not federally funded. However, research on human embryonic stem cells is federally funded if these cell lines were created before August 9, 2001. Private industry research is not affected by these policies and is allowed to proceed with the creation of new stem cell lines.

Canada

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- Researchers can use an embryo from IVF if it is no longer needed for reproductive purposes and consent is given by the donor. Creating a human clone is restricted to improving or providing instruction in assisted reproduction procedures.
- In 2003, the Canadian House of Commons passed a bill allowing the Assisted Human Reproductive Agency the ability to grant permission for embryonic stem cell research and therapeutic cloning.

Mexico

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned (the laws were amended in 2004).

Belgium

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned as of May 2003.

Finland

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- Research done for the purposes of curing or preventing serious hereditary disease is allowed, but reproductive cloning is prohibited (Medical Research Act of 1999).

Spain

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- The law was passed in 1998 and amended in 2003 and 2004 and 2006.

China

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- "Guidelines for Research on Human Embryonic Stem Cells" released in 2004 by China's Ministry of Science and Technology, and Ministry of Health.

Japan

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- Production of cloned human embryos will be limited to basic research or regenerative medicine only (Bioethics Committee of the Council for Science and Technology Policy).

Singapore

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- The law allows the harvesting of stem cells from cloned human embryos, but it prohibits cloned embryos from developing more than two weeks.

South Korea

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- As of January 2004, reproductive cloning is banned.

New Zealand

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- In 2004, the Human Assisted Reproductive Technology Bill was amended to ban reproductive cloning and genetically engineered babies.

A more comprehensive review of the global legislative landscape is available for the Committee if desired.

APPENDIX 3

Advances in Stem Cell Research Since the Current Legislation Was Framed.

This appendix provides additional background information for CAMRA's submission to support changes in the legislation to enhance research aimed at using stem cells to treat debilitating diseases such as Parkinson's disease, Diabetes, MS, spinal cord damage, MND and Alzheimer's Disease caused by the death or degeneration of cells vital to the body's function.

Research Publications.

There has been significant progress in stem cell research since the Australia legislation was framed, both in the level of research activity and in the advance towards using stem cell therapy in some major diseases.

Stem cells are being used clinically to treat a number of blood disorders and have been shown to effect repairs to damaged heart muscles. Parkinson's disease, diabetes and spinal cord injuries are areas where the research results are very encouraging. A few of the recent publications are listed below.

New data on how stem cells can be multiplied and the factors that affect survival	Human embryonic stem cells derived without feeder cells Klimanskaya I et al., *The Lancet* - May 2005.	This paper describes the new ways of growing human embryonic stem cells without using other animal cells as feeder or support cells. This eliminates the danger of transferring animal viruses or diseases through the cells if they are used in therapy in humans.
	Mass production of embryonic stem cells. Yang S T. Proceedings of the American Chemical Society. March 2005.	Embryonic stem cells were grown in a bioreactor developed at Ohio State University. The number of cells grown after 15 days was 10 – 100 times greater than by normal flask incubation and cost were reduced by 80%.
Types of stem cells and how they can be induced to form different tissues	Pluripotent neural crest cells in the adult hair follicle.Sieber-Blum, M et al. Development Dynamics. October 2004	A type of embryonic stem cell found in mice called a neural crest cell, that persists into adulthood in hair follicles is described. They can develop into neurons, nerve supporting cells, cartilage/bone and pigment cells. No information is give on their ability to multiply in culture. There is evidence that similar cells exist in humans
	Stem cell characteristics in amniotic epithelial cells. Strom, S. and Miki. Y, Stem Cell Express, August 2005	Epithelial cells found in the human placenta (AE cells) which researchers believe can develop into a number of cell types in a similar way to embryonic stem cells. AE cells cannot 'live forever' like embryonic so would depend on regular placental harvest

Progress towards the use of stem cells therapy in specific diseases.	Stem cell treatment improves mobility after spinal cord injury. Kierstead H et al., Neuroscience, May 2005.	Oligodendrite cells (which build the myelin sheath around nerves) derived from human embryonic stem cells were injected into rats with spinal cord damage. Rats injected 7 days after injury showed improved mobility within 2 months of treatment. Rats injected 10 months after injury showed no improvement.
	Derivation of midbrain dopamine neurons from human embryonic stem cells. Proc. National Acad. Sci. August 2004	Reports the development of a method for producing high yields of dopamine producing nerve cells. The authors state that this method results in the production of unlimited numbers of mid brain dopamine neurons is a major step towards pre clinical models in Parkinson's disease.
	Human embryonic stem cells become beating heart cells**.** J, Itskovitz-et al. Nature Biotechnology 2004 Oct	Scientists isolated embryonic stem cells spontaneously developing into heart cells amongst masses of stem cells growing in laboratory dishes. These cells were pulsing in unison. The team made a small burn in the area that regulates the heart beat of 13 pigs, causing a permanent severe slowing of those animals' heart rates. The injury mimicked a human heart rhythm disorder that could be caused by disease or a small heart attack. Then they injected about 100,000 human embryo-derived heart cells into the damaged pig hearts. Eleven of the 13 returned to faster heart rates. There was no improvement in control animals that did not receive the cells.
	Generation of human retinal cells in the laboratory from human embryonic stem cells Klimanskaya, I. et al. Cloning and Stem Cells. 2005	Retinal pigment epithelial cells scavenge the retinal area for cellular debris and secrete substances that aid in tissue repair within the eye. The loss of RPE affecting 30 million people worldwide. Experiment with RPE cell transplants into people's eyes have begun, but the approach has been plagued by lack of supply . This paper reports that Human embryonic stem cells grown in lab dishes under certain conditions spontaneously became RPE cells, offering a supply of RPEH cells for transplant.

Information on stem cell stability and potential to replace cells in the body	Epigenic status of human embryonic stem cells. Rugg-Gunn, P. et al. Nature Genetics, May 2005	This study demonstrates that the genes in hES cell lines were stable at imprinted regions after 65 passages in cell culture. The stem cells should remain genetically stable and suggests that genetic stability should not be a barrier to the use of these cells for therapeutic purposes.

Progress towards the use of stem cells therapy in specific diseases	'Dopaminergic stem cells generated from monkey embryonic stem cells function in a Parkinson model'. *Yasushi Takagi et al.* (2005) Journal of Clinical Investigation 115: 102 – 109.	The authors generated nerve cells capable of producing dopamine from monkey embryonic stem cells. They injected these neurones into the brains of monkeys treated with MPTP to induce Parkinson's disease. Treated animals showed marked improvement in posture and mobility and neuro-imaging showed that dopamine synthesis was increased in the brains of treated animals.