CAMRA

Coalition for the Advancement of Medical Research Australia

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Monash Institute of Reproduction and Development

Motor Neurone Disease Association of NSW Inc.

Paraplegic and Quadriplegic Association of NSW

Prince of Wales Medical Research Institute

Rett Syndrome Association of Australia

Submission to Joint Senate Committee on Research Involving Embryos Bill 2002

Submitted by

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Introduction

The Coalition for the Advancement of Medical Research Australia supports the move to introduce national legislation allowing human embryonic stem (ES) cell research using excess IVF embryos that, by law, would otherwise be destroyed.

We believe embryonic stem cell research offers the greatest hope of finding a cure for many of the diseases and disabilities suffered by hundreds and thousands of Australians. We urge you, on behalf of the sufferers and their families, not to shut off this precious avenue of research.

A denial of this kind of research, which is already occurring in other developed countries, would mean our internationally recognised scientists will be forced to continue their leading edge research elsewhere. We want Australians to be some of the first to benefit from this exciting research. Losing our scientists to countries like Singapore or the UK, may not only prolong the suffering of Australians but will also cause a loss of intellectual capital in a field where currently Australia is taking a leading position.

CAMRA – The Patient Advocacy Group

The Coalition for the Advancement of Medical Research Australia (CAMRA) comprises nationally-recognized patient organizations, universities, scientific societies, foundations, and individuals with life-threatening illnesses and disorders for which there are currently no cures, advocating for the advancement of breakthrough research in regenerative medicine - in order to cure disease and alleviate suffering.

We support Australian embryonic stem cell research with the hope that therapies can be developed to help the hundreds of thousands of Australians who suffer from the array of diseases, disorders and disabilities.

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Coalition for the Advancement of Medical Research Australia

Diseases and Disabilities in Australia – the Grim Facts

Motor Neurone Disease

- 1 person dies every day in Australia from Motor Neurone Disease
- More than three times as many deaths in 1999 were attributed to Motor Neurone Disease than HIV/AIDS in Australia
- 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 18, 2002

Spinal Cord Injury

- 20,000 people have spinal cord injury
- 1 person is confined to life in a wheelchair every day in Australia

Breakthrough research - *Scientists at Washington University School of Medicine (2000)have successfully turned embryonic stem cells into nervous system cells which, when injected into the spinal cord of injured rats, reinstated the nerve axioms that carry messages up and down the spinal cord, allowing some movement to be reinstated in the animal.*
Source: Proceedings of the National Academy of Sciences (US), May 23, 2000

Type 1 (juvenile) diabetes

- 100,000 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 that is never outgrown.
- Insulin allows a person with type 1 diabetes to stay alive but it does not cure diabetes nor does it prevent its eventual and devastating effects: kidney failure, blindness, nerve damage, amputations, heart attack and stroke.

Breakthrough research - *A research team from the Universidad Miguel Hernadez 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

Parkinson's disease

- An estimated 25,000 people in Australia have Parkinson's disease

Breakthrough research - *The American Institute of Neurological Disorders and Stroke directed mouse embryonic stem cells to develop into large quantities of nerve cells (neurons) that produce dopamine, a critical brain chemical that is lost in Parkinson's disease. When transplanted into laboratory rats with damaged dopamine neurons (modelling Parkinson's), the neurons functioned normally and the rats showed signs of recovery in behavioural tests.*
Source: Nature AOP, published online 20 June 2002

CAMRA supports both Adult and Embryonic Stem Cell Research

There have been some exciting breakthroughs in both adult and embryonic stem cell research over the last two - three years. CAMRA believes it is way too premature to determine which of these fields will yield the therapies that we are seeking.

The argument that adult stem cells can provide all the scientific solutions is contradictory to the judgements of most world respected researchers, including many funded by CAMRA organisations. These scientists believe it is likely that both adult and embryonic stem cell research will yield therapies, each being appropriate for particular diseases or disabilities, and neither one being the solution to all.

These researchers include leading 'adult' stem cell advocate Catherine Verfaillie who recently announced her exciting breakthroughs in adult stem cell research. Catherine suggests that embryonic cells may be better for some types of work and adult cells for others. In addition, the American National Institute of Health claims that research in stem cells derived from human embryos and adult tissues promises 'a dazzling array of treatment for various diseases,' but for some purposes, it acknowledges that the embryonic stem cells are clearly superior.

The potential of embryonic stem cells is grounded in an accepted opinion within the scientific community that human embryonic stem cells have:

- a greater ability to be coaxed to become any cell in the body (pluripotent), and
- can replicate easily outside the body, making them easier to obtain.

This distinctive characteristic of ES cells may prove to be crucial in therapeutic and preventative treatment, providing, for example, a good supply of tissues and cells suitable for transplantation. One of the current primary challenges is the lack of donor tissues to cure diseases and disabilities. Using embryonic stem cell research to create this tissue will be an exciting breakthrough for thousands of people with life threatening illnesses.

A preliminary recent study done by Stanford University, found that adult blood stem cells were unable to transform themselves into other types of tissues, raising doubts about whether they can be used to reinvigorate ailing organs. Similarly, scientists at the University of Toronto have reported they have developed a new method for growing specialized cells out of embryonic stem cells that can produce far greater numbers of the specialized cells for research and clinical purposes.

As these research breakthroughs demonstrate, there are many hundreds of scientific and medical questions to be answered about both adult and embryonic stem cell research before we can find therapies for these diseases and disabilities. CAMRA asks that Senate not eliminate an encouraging area of research prematurely, when there are so many questions yet to be answered.

Ethical Choices

CAMRA recognises that the moral and ethical debate surrounding embryonic stem cell research is a challenging one for some individuals. In our communications, we aim to respect the opinions of some religious groups and individuals who believe that it is morally wrong to destroy embryos.

Representing patient groups, however, we believe that it should be the choice of the parents to decide whether they wish their excess IVF embryos to be discarded, or whether to allow them to potentially save the lives and improve the quality of life of others less fortunate. In a recent survey carried out by ASSESS Infertility Network, that was reported in the national press, it was found that almost 60% of IVF couples are willing to donate their excess embryos for research. Allowing individuals this choice provides them the opportunity to make their own moral decisions.

CAMRA believes that in arriving at their decision about the bill, members and senators are faced with an essentially simple choice. Either agree that all of those excessive embryos ought to be destroyed, as, by law, they eventually must be. Or enable these excess IVF embryos to be used in research that could eventually help hundreds of thousands of Australians recover from what, currently, are incurable diseases or injuries.

Keeping Medical Research in Australia

Medical Research in Australia directly contributes to Australia's intellectual capital and ensures that Australians are the first to benefit from any therapies developed.

Australia has positioned itself well in the emerging biotechnology arena with world respected scientists currently working in Australia, particularly in the field of Stem Cell research. For example, the Juvenile Diabetes Research Foundation International (JDRF) annually funds over $200 million of the best and most promising research wherever it may be in the world. On a per capita basis, JDRF funds more diabetes research in Australia than any other country. This is something to be proud of.

We feel strongly that continuing with medical research in this country is vital in ensuring that Australian citizens can be the first to benefit from this leading edge research. CAMRA is concerned that our current advantage will be lost if we do not support embryonic stem cell research in line with the UK and other Western countries.

CAMRA is concerned that Australian researchers will be forced to continue their research in places such as Singapore or the UK, where the environment is more supportive to researchers pursuing careers in stem cell research.

A number of respected international experts have already warned that Australia risks being left behind in the race to find cures for cancer and other diseases if the Federal Government refuses approval for the expanded embryonic tissue. Associate professor at Harvard Medical School, Dr Lim, recently said Australian researchers had been at the forefront of developing stem cell research technologies, but that advantage –and potential multibillion dollar industry spin-offs, could be lost unless regulatory constraints were eased.

Community Sentiment

Independent surveys in Australia by Roy Morgan International have shown in June and November 2001 that 72% and 70% of Australians approve of research using excess IVF embryos for the development of therapies, assuming the informed consent of donors.

Attitude of other Western Countries

CAMRA would also like to reiterate that Australian Parliamentarians are not alone in making a decision on this subject. Following the most rigorous and comprehensive debate and consultation, legislation in the UK and Sweden has given embryonic stem cell research the go-ahead, with Singapore close behind.

Provisions of the Bill

CAMRA is comfortable that the legislation in its current form includes tight ethical guidelines for scientists, and severe penalties for those who do not adhere to the legislation.

We agree with the Prime Minister in urging that the provisions, "*the totality of the legislative elements of this bill*", that "*represent the delivery of the COAG agreement*", not be amended.

CAMRA is concerned that any change to the current bill may lead to delays. These delays may
a) increase the likely loss of our scientists overseas
b) delay the pursuit of research which may lead to a cure

One member of CAMRA, Paul Brock, has Motor Neurone disease. Typical life expectancy for Motor Neurone disease is 2–3 years, although Paul is fortunate to have a longer acting form of the disease. Paul, like many others in a similar position urge politicians to make their informed decision as quickly as possible to allow the scientists to explore this area of research with a hope of prolonging or saving lives.

Obviously we cannot guarantee that successful therapies for all of diseases will be produced from either adult or embryonic stem cell research. However, we urge you to pass the legislation expeditiously and allow our scientists the opportunity to see whether this area of research really can yield the benefits we expect it can.

How Can Stem Cell Research Help Australians?

Motor Neurone Disease or Amyotrophic lateral sclerosis (ALS)

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. Eventually, stem cells may help the body to grow new connections between nerves and muscles, enable sufferers to walk again, feed themselves, breath 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.

Rett syndrome

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. Stem cells could potentially be used to transport a genetically modified MECP2 gene to replace the mutated one.

Spinal Cord Injury

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 life in a wheelchair without the hope of promising research.

Type 1 (juvenile) diabetes

Juvenile diabetes is a disease that strikes children and adults suddenly, makes them insulin dependent for life, and carries the constant threat of devastating complications such as blindness, amputations, kidney failure, heart attack, and stroke. 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 known, 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.

PRESS ARTICLE

I have attached on the following page an article which was published in the New York Times in 2001. It provides a useful overview of the progress of the research as determined by the NIH study.

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June 27, 2001 - New York Times

U.S. Study Hails Stem Cells' Promise

By ROBERT PEAR

June 26 — A new report from the National Institutes of Health says research on stem cells derived from both human embryos and adult tissue promises "a dazzling array" of treatments for various diseases, but for some purposes, it says, the embryonic cells are clearly superior.

The confidential study was prepared as part of the Bush administration's review of federal policy on embryonic stem cells. Officials within the administration are split over whether to prohibit federal spending on experiments using such cells, which have the ability to develop into almost any cells or tissues in the human body and thus may be useful in replacing or repairing failed tissues and organs.

The report, while emphasizing the limitless potential of embryonic stem cells, also suggests that the government should support research on adult stem cells. The adult cells "are capable of developing into more kinds of cells than previously imagined," it says, noting how blood stem cells can develop into brain cells, liver cells and heart muscle cells.

"All avenues of research should be exhaustively investigated, including both adult and embryonic sources of tissue," the report says.

The report, based in part on an exhaustive survey of scientific journals, affirms the scientific consensus, with an immense amount of detail obtained from interviews with researchers around the world. But it does not analyze ethical, legal or social issues of stem cell research.

While advocates of federal spending for such research point to the promise of new treatments or cures for ills like Parkinson's disease and diabetes, anti-abortion groups, conservatives and the Roman Catholic Church object on moral grounds to using stem cells extracted from embryos, even those at fertility clinics that might otherwise be discarded.

Some Bush advisers, led by Karl Rove, fear that federal support for the research will alienate these groups at a time when President Bush seeks to solidify his support among conservatives and Catholic voters.

Mr. Bush has said he opposes federal spending on stem cell research that involves the destruction of living human embryos. But he says he supports "promising research on stem cells from adult tissue."

The embryonic stem cells are typically derived from five-day-old embryos consisting of 200 to 250 cells, says the report, titled, "Stem Cells: Scientific Progress and Future Research Directions."

The report notes some of the limitations of research with adult cells.

"Adult stem cells are rare," the report says. "One of the advantages of using embryonic stem cells as compared with adult stem cells is that the embryonic cells have an unlimited ability to proliferate" in the laboratory.

But for this very reason, the report says, the embryonic cells carry a special risk: their ability to proliferate means that they are more likely to induce the formation of tumors, particularly benign tumors.

White House officials said they were not familiar with the institutes' study, which was requested by the secretary of health and human services, Tommy G. Thompson. Mr. Thompson was evidently planning to share the study with the White House, but an aide to Mr. Bush asked the department for details today after The New York Times obtained a copy of the document and asked the administration for comment.

Lawyers at the Department of Health and Human Services are studying whether the government can pay for experiments with embryonic stem cells in view of a law that says no federal money can be used for "the creation of a human embryo or embryos for research purposes."

Under guidelines issued by the Clinton administration last August, scientists can use federal money to conduct research with embryonic stem cells created in the course of fertility treatments. But scientists cannot use federal money to extract the stem cells from human embryos.

The National Conference of Catholic Bishops and other critics denounce this distinction as sophistry. In the process of obtaining embryonic stem cells, they say, scientists destroy the embryos, thus killing human life.

The study describes the potential uses of stem cells in treating Alzheimer's disease, Parkinson's disease, heart disease and diabetes, among other illnesses. It may soon be possible, the report says, to coax human embryonic stem cells into forming pancreatic cells that produce insulin and reverse the symptoms of diabetes.

Likewise, the report said, scientists have developed a technique to induce stem cells from mouse embryos to develop into nerve cell precursors that secrete a chemical messenger known as dopamine, and unpublished research suggests that these nerve cells may be able to eliminate symptoms of Parkinson's disease in rats.

Dopamine helps the nervous system control muscle activity. In patients with Parkinson's disease, dopamine-producing nerve cells degenerate for unknown reasons.

With heart disease, the report says, both embryonic and adult stem cells may be able to replace damaged heart muscle, and to develop new blood vessels that supply the heart muscle. Adult stem cells are "viable candidates for heart repair" work, the study said, but the embryonic cells have an advantage because they produce a larger supply of cells for transplants.

The report also cites evidence that embryonic stem cells can restore nerves and mobility in rats paralyzed with a condition similar to Lou Gehrig's disease.

Within three months of receiving injections of cells derived from embryonic stem cells, it said, "many of the treated rats were able to move their hind limbs and walk, albeit clumsily, while rats that did not receive cell injections remained paralyzed."

The study also examined possible treatments for heart disease. The repair of a damaged human heart , it said, would probably require millions of heart muscle cells. The capacity of embryonic stem cells to replicate in the laboratory "may give them an advantage over adult stem cells by providing large numbers of replacement cells in tissue culture for transplantation purposes," the report said. But it is unclear how adult stem cells could generate sufficient heart muscle to meet patients' demand, the study said.

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