



the Australian Society for Medical Research

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Mailed to:

Hon John Howard, MP	Prime Minister
Senator Kay Patterson	Minister for Health and Ageing
Hon John Anderson, MP	Deputy Prime Minister
Hon Dr Brendan Nelson	Minister for Education, Science and Training
Hon Peter McGauran, MP	Minister for Science
Hon Kevin Andrews, MP	Minister for Ageing
Hon Ian Macfarlane, MP	Minister for Industry, Tourism and Resources
Dr Robin Batterham	Chief Scientist
Mr Craig Knowles	Minister for Health (NSW)
Hon Robert Carr	Premier of NSW

Dear

Re: Human Stem Cell Research

The Australian Society for Medical Research (ASMR) understands that the meeting of Cabinet on February 25th discussed the possibility of a ban on human embryonic stem (ES) cell research and that carriage of this matter has been given to the Prime Minister.

The ASMR considers that stem cell research carries significant benefits for Australia and Australians and that these benefits should not be blocked by legislation to prevent use of existing human ES cells or the derivation of further ES cell lines from unused *in vitro* fertilisation (IVF) embryos. ASMR does however, support the establishment of a national regulatory two-tier approval process to ensure public and scientific scrutiny of any proposed work.

In this rapidly evolving area, factual information is critical and we draw your attention in particular to the document "Human Stem Cell Research" dated 18 April 2001 produced by the Australian Academy of Science (www.science.org.au/academy/media/stemcell.pdf).

Human Stem Cell Research Undertaken in Australia

There are at least three Australian companies whose R&D is focussed in the area. These include Stem Cell Sciences Ltd, ESI Pty Ltd and Bresagen Ltd. The primary academic groups who are currently using human ES cells, derived in Singapore, are based at Monash University in the Institute for Reproduction and Development. In addition, a Major National Research Facility, "The National Centre for Advanced Cell Engineering" is heavily focussed on human stem cell research, including ES cell research, as are components of at least two bids for the National Biotechnology Centre of Excellence Program.

The Juvenile Diabetes Research Foundation (JDRF) currently spend \$230 million on research internationally and a considerable portion is spent on stem cell research. JDRF currently spends \$10 million on research in

Australia and \$0.5 million of this is on stem cell research, an area which they are planning to expand considerably.

At present, research in this area is still limited because most, if not all, human ES cell lines are encumbered by commercial interests. There is a strong demand for ES cells in academic research and in industry for development of the potentially large market in therapeutic cloning.

Human Stem Cell Research Workforce

At present, ASMR estimates there are in the order of 50 researchers working directly on human stem cells. However, with greater access, there would be an immediate influx of some additional 200 researchers from nearly all states into the research area. In time, and with development of the technology, this number would become much larger and would involve researchers interested in almost all body organs and diseases.

Importantly, Australia hosts three of the world's leading companies in this area. This provides an important point of leadership in the global biotechnology revolution.

Effects of a Ban on Human Embryonic Stem (ES) Cell Research

Human ES cell research offers significant potential to improve or cure diseases and conditions which will affect up to half of the Australian population.

ES cells have the capacity to develop into any mature adult cell. Some adult stem cells may also have this capacity. However, we still do not understand the cellular and development processes that control stem cell differentiation. Work on adult stem cells should be encouraged, but since we do not understand the mechanisms of reprogramming, etc, adult stem cells cannot adequately substitute for ES cells. For example, in diabetes research, efforts to reprogram adult stem cells to differentiate into insulin secreting islet cells have not been successful.

A ban or moratorium would limit the development of this new area of science which holds great promise for the development of new disease treatments, discovery of new drugs and development of biomaterials.

There are already legislative powers in place to control certain practises. Thus, the Gene Technology Act and complementary State Bills already prohibit reproductive cloning to produce human (and human/animal hybrid) fetuses. The ASMR and all other national bodies agree with this position to prohibit this unethical and unsafe area.

The field of stem cell research is newly emerging and it is difficult to predict where the next advances will come. What is clear, however, is that inflexible regulations, bans or moratoriums won't help the appropriate development of this field. Rather systems involving flexible oversight, public scrutiny and expert opinion are needed.

The ASMR, along with other peak scientific bodies including FASTS and the Academy of Science, as well as the majority of direct proponents in academia and industry, support the need for uniform national regulation. However, at present, the NHMRC (AHEC) interim guidelines place an excessive burden on local Institutional Ethics Committees (IECs). We support the establishment of a national advisory committee (as suggested previously by the Academy of Sciences), under the auspices of the NHMRC to provide a means to achieve appropriate scientific review and public scrutiny of this work. This committee would function in a similar manner to the Gene Therapy and Related Procedures (GTRAP) committee of NHMRC, which provides national oversight and input to IECs on human gene therapy trials.

Incompatibility of a Ban with Government Policy

i Designated priority areas of research

The recent release of designated priority areas of research for the ARC specifically supported areas of current research work being undertaken with human ES cells. Human stem cell research is one of the areas that is leading to the

“heightened expectation that gene therapies ... will lead, among other things, to the eradication of inherited disease... However, the connection between an organism’s genes (its genome) and its physical appearance and behaviour (its phenotype) is exceptionally complex and, at present, highly elusive.”

Four of the seven key areas of study to be supported by the Genome/Phenome designated priority area are the focus of human stem cell research and include 1) cell differentiation, 2) control of gene expression, 3) cell signalling pathways, and 4) multigene control of phenotypic traits.

In the second designated priority area of research on Nanomaterials and Biomaterials, the policy document states

“Australia has extensive research strengths ... in biotechnology. Priority funded research ... would build on this existing base, in these areas of internationally recognised importance.”

Likewise two of the four key areas of study in this designated priority area of research include 1) development of novel devices and sensors and 2) “revolutionary new ways to produce implants for medical applications, and the production of replacement organs”. Both of these areas would be strongly served by research advances resulting from human ES cell research.

ii Backing Australia’s Ability

Backing Australia’s Ability, the Federal Government’s Innovation Statement, also provides strong support for research into human stem cells. In particular,

Major National Research Facilities

The recent award of a MNRF grant to “The National Centre for Advanced Cell Engineering” which is focussed on human stem cell research, including ES cell research, would potentially be incompatible with a government ban or moratorium on human ES cell research.

Biotechnology Development

At least two bids for the Biotechnology Centre of Excellence would have portions of their research plans impacted by a government ban or moratorium on human ES cell research.

R&D Start and Tax Concession

With several companies active in the area, it is likely that Start grants and other government business incentives for the future development of these and other new companies would be constrained by a government ban or moratorium on human ES cell research.

Lost Scientific and Commercial Opportunities

In this newly developing field, Australia is already home to three biotechnology companies which focus on the use of human stem cells and human ES cells. These companies, ESI, Stem Cell Sciences and Bresagen each have strong overseas linkages (Singapore, Scotland and US, respectively) and without an environment conducive to development of their technologies, all are potentially able to relocate offshore with ease. Such a loss, were it to happen, would severely impede any further biotechnology investments and commercial

development in this area. Moreover, this would likely impact other areas of Australian biotechnology development as investors may be wary about other potential government constraints on Australian research.

Major academic research groups based in Melbourne, Adelaide, Sydney and Brisbane are currently working on existing human ES cells, animal stem cells or on potential applications of human stem cell research. Thus, a ban or moratorium on ES cell research would limit the development of these areas of research, and the potential therapeutic applications being studied. These include treatments for diabetes, neurodegenerative diseases, cardiovascular diseases, bone diseases, kidney and skin diseases.

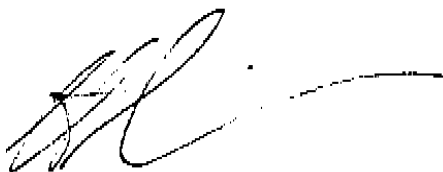
As stated above, the recently funded MNRF “The National Centre for Advanced Cell Engineering” would have its entire research plan placed in jeopardy or severely constrained by any ban or moratorium. Likewise, at least two bids for the National Biotechnology Centre of Excellence Program would have their work plans negatively impacted.

Summary

A ban or moratorium on the use of existing human ES cells and/or the creation of new ones from surplus IVF embryos, as outlined by the Interim Guidelines of the NHMRC (AHEC) and the recommendation of the Andrews Report, is not supported by the ASMR. A ban or moratorium would result in the Australian public being denied the potential health benefits and Australia losing the economic benefits that are likely to arise from research into and the use of stem cells. In addition, a ban or moratorium would be inconsistent with recent government policy announcements and funding commitments.

The ASMR supports the establishment of a national regulatory two-tier approval process to ensure public and scientific scrutiny of any proposed work. We suggest that a national advisory committee, under the auspices of the NHMRC, is established to provide a means to achieve appropriate scientific review and public scrutiny of ES cell research and development. This committee would function in a similar manner to the Gene Therapy and Related Procedures (GTRAP) committee of NHMRC, which provides national oversight and input to IECs on human gene therapy trials.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'PS', with a long horizontal line extending to the right.

Professor Peter R Schofield
President

CC: Professor Sue Sarjeantson (Australian Academy of Science), Mr Toss Gascoigne (FASTS)