Eskitis Institute for Cell and Molecular Therapies

Nathan Campus, Griffith University
170 Kessels Road
Nathan, Queensland 4111
Australia

Professor Alan Mackay-Sim
Deputy Director

Telephone + 61 (0)7 3735 7563
Fax + 61 (0)7 3735 7773
Email a.mackay-sim@griffith.edu.au

13 October 2006

Mr Elton Humphrey
Secretary
Senate Community Affairs Committee
Parliament House
Canberra, ACT 2600

Dear Mr Humphrey,

As a scientist involved in stem cell research I have observed to the public debate in the papers and on TV and I believe the public is being misled and misinformed about the issues and the relevant science. I recommend to the Committee my letter to the Lockhart Review which is applicable in the current debate.

The current debate should really be about whether to take the next ethical step and to allow "therapeutic cloning", the use of "somatic cell nuclear transfer" to make embryonic stem cells for clinical and research use. The media and commentators and "experts" often mislead and re-direct the discussion by (re)-debating the pros and cons of embryonic stem cell research. This is not relevant in the current debate because embryonic stem cell research is legal and funded by the Government.

The ethical issue under debate is about "somatic cell nuclear transfer" and "therapeutic cloning". Somatic cell nuclear transfer is the technique used to clone animals like Dolly the sheep. Therapeutic cloning is the same technique used to make embryonic stem cells, rather than cloned animals, or humans. The Committee should be aware that the only difference between these terms is whether the blastocyst, which is generated in exactly the same way in both techniques, is implanted in the womb (for human cloning) or placed in a culture dish (for therapeutic cloning). In other words, legislative approval for development of therapeutic cloning is at the same time legislative approval for developing the techniques for human cloning. The technical aspects of generating a blastocyst from and adult cell nucleus and a human egg are the same in both cases. The difference is in what is done next, implantation in the womb or production of embryonic stem cells. It is possible to legislate against the implantation of these blastocysts into the womb.

In my view, such development of the techniques of the initial steps for human cloning is a giant ethical step. Human cloning is universally abhorred and is illegal in all countries and jurisdictions. Even advocates of therapeutic cloning agree that this is an ethical boundary over which they do not want to step. However, technical development of human therapeutic cloning provides all the steps necessary for human cloning except the last, implantation into the womb, which is already a standard procedure in IVF. Legislative approval of therapeutic cloning will therefore lead to development of all the steps necessary for human cloning. Such approval should be carefully

considered and the ethical, scientific and social risks weighed against the proposed and demonstrated benefits.

There is no doubt that any new technical developments will lead to unintended or unexpected consequences. Development of the atom bomb led to nuclear energy. Development of pre-implantation genetic diagnosis to identify embryos as risk of genetic mutation has led to profoundly deaf parents selecting embryos with the same genetic mutation. Development of memory enhancing drugs for the elderly has led to their use by the young to help them study. Development of EPO for medical purposes led to its abuse in sport. It follows that development of therapeutic cloning will lead to human cloning. This may be legislated against in Australia but technology is international. The Committee and Parliament must decide whether it is ethical to tacitly support this inevitable outcome.

Is there a scientific and medical case to be made to support therapeutic cloning that may outweigh ethical concerns about developing the techniques for human cloning? The case presented in the Lockhart Review, in the media and elsewhere essentially presents the same case made for embryonic stem cell research in general, that it will lead to treatments and cures for diseases not currently treatable. However, the extra ethical burden of therapeutic and human cloning requires extra evidence in the scientific and medical case. This evidence is lacking. Embryonic stem cell research has not advanced enough. It is well recognized that the use of embryonic stem cells for transplantation therapies is severely hampered by immunological rejection problems and by their very high rate of tumour formation in all animal models tested to date. These barriers to therapeutic use of embryonic stem cells should be overcome in animal experimentation before taking the next ethical step and allowing human therapeutic cloning.

The immunological rejection problem is the main argument for allowing human therapeutic cloning. There are no animal studies to demonstrate that therapeutic cloning will solve this problem. Therapeutically cloned cells are not identical to the parent adult cell because they contain genes passed down from the donor egg (“mitochondrial genes”). There are no animal studies to show that therapeutically cloned cells are not rejected. There are no animal studies to show that therapeutically cloned cells are “therapeutic” in animal models of disease. There are no animal studies to show that tumour formation by therapeutically cloned cells is any different from other embryonic stem cells. Tumour formation is a major outcome of embryonic stem cell transplantation in animals. Some public debate has suggested that these are “benign” because they remain contained and can be surgically removed. Hydatiform moles are teratomas that can form from embryos in the womb. These are potentially lethal if undetected. Teratomas in the brain after embryonic stem cell transplantation would be lethal if undetected and require life-threatening surgery otherwise. The Committee should consider whether the scientific evidence for the benefits of embryonic stem cell research is strong enough yet to make the next ethical step to therapeutic cloning.

Research on “adult” stem cells demonstrates that they provide alternatives to therapeutically cloned embryonic stem cells. The public debate is full of half-truths and lies about adult stem cells. Scientific, media and lay advocates of embryonic stem cell research dismiss adult stem cells suggesting that they have “less developmental potential”, meaning that they are not proven to make all the cells of the body. It is often stated that they can only make cells from the tissues in which they normally reside. Apart from being simplistic arguments, they miss the point and avoid the published evidence. Adult stem cells from numerous sources (e.g. bone marrow, olfactory mucosa, skin, hair follicles, muscle, fat) have been shown in numerous independent laboratories to develop into cells not normally found in the originating tissues and, despite the rhetoric to the contrary, some develop into most cell types of the body. Adult stem cells are currently used in human therapies and there are numerous animal studies demonstrating their efficacy in a variety of animal

models of disease and injury such as spinal cord injury, stroke, Parkinson's disease and cardiac ischemia. The scientific evidence for the therapeutic potential of adult stem cells in currently incurable diseases is as strong for adult stem cells as it is for embryonic stem cells with two major differences. Adult stem cells do not form teratomas and they can avoid immune rejection when derived from and transplanted into the same person.

Research on adult stem cells demonstrates that many of them (e.g. bone marrow, olfactory mucosa, fat) can be propagated in the laboratory to make large numbers required for therapeutic applications and for drug discovery. The public debate has suggested that only embryonic stem cells have this characteristic.

One application of stem cell research is to provide "cellular models" of diseases. The understanding of cancers has advanced enormously by being able to study cells from different forms of cancer. A justification for therapeutic cloning is that is will provide cellular models of incurable diseases such as motor neuron disease. It certainly has this potential but the potential is limited compared to adult stem cells. Adult stem cells are available in all adults and are much easier to propagate than embryonic stem cells. Even if therapeutic cloning were possible the logistics of producing cloned cells would preclude making cells lines from many patients. This will limit the utility of this approach in discovering causes common to all persons with the disease. The ease of adult stem cell production obviates this problem. For example, in our laboratory we have adult stem cells from over 50 people with diseases such as schizophrenia, Parkinson's disease, and motor neuron disease.

In summary, the debate needs to be focused on the real ethical issue, namely, whether there is enough scientific and medical justification for the benefits of therapeutic cloning to overcome the ethical barrier of developing the technology for human cloning. This debate needs to focus on whether this justification can be made on evidence currently in the scientific literature or whether it is simply a promise or hope. This debate should also consider whether the moratorium on human therapeutic cloning should continue until embryonic stem cell research matures sufficiently to determine whether therapeutic cloning is justified from animal studies. This debate should also consider whether adult stem cell research may mature to obviate the need to take this next ethical step.

Yours sincerely,

Alan Mackay-Sim

Professor, School of Biomolecular and Biomedical Science
Director, National Adult Stem Cell Centre
Deputy Director, Eskitis Insitute for Cell and Molecular Therapies