SOMATIC CELL NUCLEAR TRANSFER (SCNT) AND RELATED RESEARCH AMENDMENT BILL 2006
No. , 2006
Senator Natasha Stott Despoja

Introduction:

Today, I introduce an exposure draft of a bill to permit the ongoing development of medical and scientific research using stem cells, including the strictly regulated use of techniques such as Somatic Cell Nuclear Transfer (SCNT) in research.

This legislation also seeks to allow development of techniques for the efficient training, research and improvements in clinical practice in Assisted Reproductive Technology (ART).

This bill is for informative and committee use. It can be updated and improved.

The aim is to put the recommendations of the Lockhart Legislation Review (which reported to the Parliament in December 2005) in a detailed and legislative form so that the Senate Community Affairs Committee can benefit from and build on my work on this issue.

This bill enshrines the scientific recommendations of the Lockhart Review that require legislative change to the original Acts.

The inclusion of all the Lockhart recommendations gives the Parliament the opportunity to accept, reject or amend them, but, at least, debate them. I am not cherry-picking recommendations – it should be for the Parliament to decide which ones become law.

This is an exposure draft. It will raise technical issues for debate. It offers ideas for the Committee to examine.

I have been asked to table this bill at this time by Senators – those who in favour of and opposed to the proposals it contains – as they consider it important that the Senate has a bill now that the Senate is proceeding with a committee inquiry.

In the Explanatory Memorandum (which is not required for an exposure draft), I have highlighted the technical, legal and scientific basis behind this bill.

Background:

I have long-argued for a debate on the Lockhart Review's recommendations.

On March 24, I indicated that if the Government failed to provide an opportunity for a parliamentary debate on the recommendations, I would draft a Private Member's Bill to ensure there was a legislative and policy framework for debate.

I presented a draft of this bill to a meeting of stakeholders on this issue in Sydney on August 24. The feedback from that meeting was to include all the scientific recommendations from the Lockhart review that require legislation.

Conscience vote:

I welcome the Prime Minister's decision to grant a conscience vote on this issue, no doubt, in recognition of the burgeoning support for this technology and reflecting the changing attitudes of our community since the 2002 parliamentary debates.

This support was illustrated by a recent Australian poll which found 80% of respondents approved of so-called therapeutic cloning or Somatic Cell Nuclear Transfer (SCNT).[1]

Options for legislative change:

This exposure draft gives a legislative basis to the Lockhart Review recommendations that require amendments to the current Acts: The *Prohibition of Human Cloning Act 2002* (PHC Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act).

Apart from the inevitable differing views on the research and the technology, there will be debates about the best way to achieve change.

Arguably, the cleanest way to update our laws would be if we were amending one principal Act, not two, as is the case in other countries including Singapore and the UK.

However, in Australia, the decision was taken in 2002 to split the legislation in two parts, so I have taken the approach of amending those Acts (as opposed to writing a new Act).

There are other options that the Parliament might consider and I am sure these will be discussed during the Committee process. I look forward to contributing to that process.

The 2002 laws included a provision that the laws be reviewed by an independent committee following 3 years of operation.

The Lockhart Review:

The Lockhart Legislation Review, chaired by the late former Federal Court Judge, the Hon. John Lockhart AO QC, conducted an exhaustive, independent review of the laws.

Hearings took place in all State and Territory capitals, and 1035 submissions were received from the community representing a diversity of viewpoints. In addition, the Committee met with a range of scientists and other stakeholders. Its recommendations

[1] Roy Morgan Research "Large Majority of Australians Approve Extraction of Stem Cells from Human Embryos for Medical Research." 21/6/06 http://www.roymorgan.com/news/polls/2006/4036/

were referred for tabling in both Houses of Parliament out of session on December 19 last year.

I pay tribute to the work of the Lockhart panel and, in particular, Justice Lockhart, who was held in high esteem by those in the legal and scientific communities and who made a critical contribution to the debate on stem cell research.

The Lockhart Legislation Review Reports made 54 recommendations including that Human Somatic Cell Nuclear Transfer "*be permitted… to create and use human embryos clones for research, training and clinical application, including the production of human embryonic stem cells as long as…these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days."*[2]

Other recommendations endorse the status quo thus, requiring no change to the law, and some require regulatory change.

This bill enshrines the Lockhart Legislation Review's critical recommendations: permitting SCNT; amending the definition of human embryo; and, allowing fresh embryos that have been determined unsuitable for implantation due to the existence of disease to be used in research.

This bill also provides for further review of the operation of the amended Acts after three years.

Human Reproductive Cloning Prohibition:

Importantly, this bill does not alter provisions prohibiting human reproductive cloning, a practice I continue to oppose wholeheartedly.

Science Interest:

Scientific endeavour is an area of enduring interest to me. I have been particularly concerned with balancing the importance of facilitating wide-ranging and pioneering research with the need to protect the community through effective regulation of research.

I have campaigned for nearly a decade to highlight increasingly urgent issues in science and advocated for a balance to be struck between scientific discoveries that can benefit the community and the imperative of preserving human rights, including the right to genetic privacy.

To this end, I have long advocated for regulation of research involving human embryos and human embryonic stem cell lines. I have also highlighted the intellectual property and patent issues for genes and gene sequences as well as stem cells and stem cell products.

The ongoing lag between scientific discovery and its regulation has concerned me for many years and is one motivating factor for introducing this legislation today.

[2] Lockhart Legislation Review Reports Recommendation 23 - December 2005

The Parliament has a critical role to play in regulating research to protect the community. It must foster the dazzling promise of new technologies such as SCNT while ensuring it is tempered by sound regulation that protects the community.

Some opponents of SCNT have warned that legalisation of this technique may lead to the commodification of human eggs. It is important to note that this bill maintains the current prohibition of the sale of human eggs, sperm and embryos and clarifies "reasonable expenses" in relation to permitting reimbursement of expenses for the supply of human eggs, sperm and embryos.

It is important to emphasise that SCNT does not involve sperm or fertilisation or making genetically identical fetuses or making a baby. Implantation of an embryo created through SCNT is illegal and will continue to be prohibited under this bill.

In fact, this bill actually strengthens prohibitions on a number of practices, by creating a new Division 1 which lists practices prohibited outright under this Bill, some with increased penalties.

Developments in medical and scientific research:

The Lockhart Legislation Review was charged with investigating the scope and operation of the 2002 Acts, taking into account a number of terms of reference including: "developments in medical research and scientific research and the potential therapeutic applications of such research."[3]

Some opponents of this technology claim developments in embryonic stem cell research since the 2002 legislation are insufficient to warrant legalising SCNT. This is misleading.

Currently, research using embryonic stem cells and SCNT is in its infancy. From the outset, scientists have stated this technology may take up to 15 years or longer to realise therapeutic applications.

There *have* been breakthroughs in this technology since 2002 which hint at promise, and, while they may not have yielded immediate cures or treatment, we have an obligation to facilitate this research, albeit in a regulated manner.

The Lockhart Legislation Review Literature Review provided examples of developments in research using embryonic stem cells, albeit mostly at the preclinical stage.[4]

It revealed that: embryonic stem (ES) cells have shown promise in creating treatments for diabetes - animal ES cells have differentiated into insulin producing beta cells.[5]

Mouse embryonic stem cells injected into rats with spinal damage differentiated into neural cell types which improved function.[6]

[3] Lockhart Legislation Review Reports December 2005
[4] Lockhart Legislation Review - Literature Review December 2005
[5] Ibid

Meanwhile, research into Parkinson's disease, in which dopaminergic neurons in the brain are destroyed– a very active area of research – has shown that mouse embryonic stem cells have the ability to differentiate into these neurons, potentially providing a source of new cells.[7]

Time magazine recently reported the progress of scientist, Lorenz Studer who has differentiated embryonic stem cells into "just about every cell type affected by Parkinson's disease and has transplanted them into rats and improved their mobility."[8]

United States Biotech company, Geron, apparently is close to seeking permission to conduct the first human trials using embryonic stem cells to create cells that produce neurons.[9]

Research is also being conducted on embryonic stem cells to explore diseases such as macular degeneration, brain injury, and Huntington's disease.[10]

Some have lauded the seemingly less controversial adult stem cell research, claiming that advances in this area have made redundant the need to continue embryonic stem cell research.

However, we should be wary of advocating one type of research over the other. Each has its strengths and weaknesses – such as the pluripotency (ability to differentiate into any body cell) of embryonic stem cells versus the more limited multipotency (restricted to certain cell types) of adult stem cells – although new research is challenging this idea. Embryonic stem cells also have the unlimited capacity to keep dividing.

Most scientists agree that both forms of research must be pursued in the quest for knowledge of diseases and conditions and potentially treatments; that neither area of research can single-handedly provide all treatments.

Embryonic stem cells created through techniques, such as SCNT, can facilitate the creation of disease-specific stem cells which will assist in investigating cause and cures. There is also the prospect that SCNT will facilitate the creation of ES cells that match a patient's DNA thus, eliminating the problem of immune rejection in potential transplantation therapies.

Research using SCNT is also in its infancy. There have been some advances: ES cells gleaned from a SCNT created mouse embryo with a genetic immunity defect have been differentiated into haematopoietic progenitors in vitro and transplanted, resulting in the immune deficiency being cured permanently without any immune rejection.

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[6] Op cit
[7] Op cit
[8] Nancy Gibbs "Stem Cells- the hope and the hype" *Time Magazine* 7/8/06
[9] Ibid
[10] Lockhart Legislation Review - Literature Review December 2005

Last year, UK researchers started research using SCNT to create embryonic stem cells from the cells of patients afflicted by motor neurone disease, thus, allowing investigation of this disease.

To claim that we have not seen enough development to justify legalising regulated SCNT, as some have done, is disingenuous. This is not a field of rapidly realised cures or quick fixes – this takes time, investment and importantly, a supportive legislative framework.

In the 2002 debate on the *Research Involving Embryos Bill 2002*, I highlighted that the likely pace of any discoveries or "transplantation therapies" using embryonic stem cells "may be 5, 10, or 15 years away, if they are possible at all.'[11] However, given the potential shown then and the constant steps being made since, it is still inappropriate to constrain or even deny research including that involving SCNT.

As Professor Peter Rathjen, Dean of the University of Melbourne's Faculty of Science and internationally recognised stem cell researcher, stated recently "You need to understand how science progresses. It doesn't progress with a single step that means you suddenly have cures. It moves incrementally towards a goal, and you gradually put in place bits of the jigsaw and solve various technical problems that are required."[12]

This bill seeks to assist this progress by: allowing regulated use of SCNT for research purposes; clarifying and improving consent provisions for donating excess ART Embryos; permitting donation to research of ART embryos already identified through Pre-Implantation Diagnosis to have a genetic disease; clarifying the definition of a human embryo**;** and, reviewing the amended Acts after three years of operation.

Countries such as the UK, Singapore, Sweden, Belgium, Japan, Spain, Israel, China and some US States already permit SCNT. Australia risks the loss of more of our best and brightest scientists if they are thwarted from pursuing cutting edge technology - already we have seen the loss of some very high profile scientists and peak bodies fear attracting foreign researchers to such a restrictive and uncertain research environment will prove impossible.

Other notable scientists such as Australian of the Year, Professor Ian Frazer and Professor John Burn, Medical Director and Head of Institute *of the Institute of Human Genetics* in Newcastle upon Tyne, UK have criticised the lack of action on the Lockhart recommendations. Professor Burn warned that Australia not permitting the recommendations "is a cost to the international research effort because Australia's a very important component of it…" [13]

Stem cell bank:

The Lockhart Committee's terms of reference included an examination of the "applicability of the establishment of a stem cell bank" as a result of a successful amendment moved by Senator Jan McLucas and me in the 2002 debate.

[11] *Research Involving Embryos Bill 2002* – Second reading speech – Senator Stott Despoja
[12] Alexandra Kirk "*Stem cell debate still raging in federal politics*" AM ABC Radio 4/9/06
[13] BioNews 370 "No 'conscious vote' on embryo cloning in Australia" 7/8/06

In this draft bill, I have not legislated for a national stem cell bank. This is partly because a stem cell bank does not necessarily require legislation. In fact, the UK has a national stem cell bank which does not have a legislative basis. There are options for such a framework including the possibility of establishing a stem cell bank along similar lines to that of blood bank.

This bill requires the Attorney-General's Department and the Department of Health and Ageing to examine in some detail the issues surrounding a stem cell bank. The terms of reference are more detailed than those under which the Lockhart Review was operating.

Conclusion:

This legislation gives us the opportunity to foster scientific innovation and discovery in addition to potentially providing treatments and cures for many Australians, who are currently afflicted by disease or may be in the future, in a manner we are able to strictly regulate.

As the Australian Democrats' Science and Biotechnology portfolio holder, I have come into contact with many people to whom stem cell technology offers hope. My office has received large amounts of correspondence from sufferers of disease and their family members pleading for SCNT to be legalised.

It is critical that the potential of such therapies is not overestimated nor unrealistic timeframes for therapeutic application made.

It is also critical that we allow for this potential to be explored, to deny this would be unethical.

In the absence of Federal Government action on the Lockhart recommendations, the Victorian and Queensland Governments indicated they may legislate to permit SCNT.

While these States – both leaders in biotechnology – are understandably concerned by the Federal Government’s initial inaction on the recommendations, I believe a nationally consistent legislative framework that permits research using SCNT is necessary and preferable. If we fail to broker such legislation now, we run the risk of, yet again, relying on inconsistent and widely varying State laws as we did prior to the 2002 Acts.

I have long-campaigned for regulation of research involving human embryos and for laws to prohibit human reproductive cloning. I am proud to continue this work with this bill which seeks to further hone our laws regarding research and allow them to catch up with scientific innovation.

I commend this exposure draft to the Senate.