CORRIGENDUM

Additional Comments from Senator Kerry Nettle

Egg Donation

Issues were raised throughout the course of the Senate Inquiry about the donations of eggs by women for embryonic stem cell research.

Witnesses compared the procedures surrounding the donating of eggs for embryonic stem cell research to those surrounding the donating of organs or tissues.

Women's Forum Australia wrote on page 7 of their submission:
'a better model to describe egg donation by women is altruistic organ donation by living donors to strangers (for example a kidney or liver lobe)'

The issue was raised during the inquiry about whether or not women donating eggs and/or their families should have a right to any benefits or treatments that come about as a result of their donation.

Recommendation 45 of the Lockhart Review states:
'donors of tissue that is going to result in immortal stem cell lines should be informed by means of processes monitored by human research ethics committees about the potential use of that stem cell line, including the potential for commercial gain and the fact that they may not have any rights in potential stem cell developments.'

Some IVF clinics are making arrangements with women who donate eggs in relation to this issue.

Sydney IVF indicated in their submission:
'in each instance of embryo donation for research… we require of users of resulting stem cell lines their agreement that they will never object to our retaining early-stage stem cell samples for possible future use to benefit the family that made the donation.'

It is important for Parliament to not just leave it to IVF clinics to make different, individual, commercial arrangements with the women who donate eggs to them about this issue. Rather Parliament should indicate what rights, if any, women and their families have to benefits from research done on the woman's donated eggs. This can be done either through legislation, regulation or through the NHMRC guidelines and other procedures.

A comment in the Sydney hearings from Dr Sidhu of the Diabetes Transplant Unit at Prince of Wales Hospital and University of New South Wales highlighted this:
'That is a big issue at the present moment but, as I said, when the patients sign those papers what the regulations say from an ethics point of view and other points of view, depending on your institution, is that they sign that anything subsequently developed from that donation will not be the property of the patient.'

Recommendation 32 of the Lockhart Review states:
'the NHMRC should develop guidelines for egg donation' but it does not ask or require the NHMRC to go into any more detail about whether or not women who donate eggs should have access to any benefits or treatments that arise from research done using their donated eggs.

Senator Patterson asked Dr Sidhu from the Diabetes Transplant Unit at Prince of Wales Hospital and University of New South Wales about how possible it was to keep track of donors in order to link their donation with any breakthroughs in research.

Dr Sidhu*—There is a difficulty at the present moment, but I think we are improving at tracing back day by day—for example, keeping track with a database and other stuff. Possibly, yes, we can trace back to the donors, but the issue remains of the intellectual property at the present moment and which way we want to go.*

Sydney IVF wrote in their submission:
'The fact is that there is about a 25% chance (actually slightly less) that a human embryonic stem cell line created from an embryo from a couple will be completely immunologically compatible with any of that couple's children. Justice is not served if stem cells derived from such embryos are prevented from being "donated" to a child of the couple.

Please note that use on this basis within families applies only to the children of the couple; such stem cells are not genetically compatible with either parents or, for example, with any grandchildren.'

It is important to ensure that any system to ensure that women donating eggs and their children have access to any benefits or treatments derived from their eggs does not become a de facto method of payment to or inducement of women to donate eggs.

The committee did not hear any support for women being paid to donate eggs. Indeed the committee heard several groups express concern about the possibility of such payments occurring.

Women's Forum Australia describe on page 12 of their submission:
'The North East England Stem Cell Institute now offers women IVF at a reduced cost in return for their surplus eggs for research.'

The process described by Sydney IVF in their submission regarding arrangements with the users of stem cell lines derived from donated embryos to keep stem cell samples for the benefit of donor families may be a useful model for parliament to adopt. This model ensures that there is no direct link between a woman donating eggs and any benefits or treatments she or her family may receive that could become, or be seen as, a de facto method of payment or inducement to donate eggs.

Dr Munsie from Stem Cell Sciences Ltd. described the process that occurs in the UK.

Dr Munsie*—As I understand the UK system, when you obtain a licence in the UK you undertake to deposit a sample of your line in the bank. So that is perhaps something that could be contemplated in Australia.*

Recommendation

That the Parliament amend the Research Involving Human Embryos Act 2002 to require all licence holders to deposit a sample of any stem cell lines that they derive to be deposited in a publicly run national stem cell bank.

Commercialisation

The Senate Committee and the Lockhart Review heard a range of views about the commercialisation and privatisation of embryonic stem cell research and any benefits or treatments to arise from such research.

Victorian Premier Steve Bracks was reported in The Australian October 2 this year to have said that Australia will lose billions of dollars in income and lag behind the world scientific community if the ban on therapeutic cloning is not lifted.

The Lockhart Review states on page 140:
'People are concerned that these benefits and profits remain in the public domain, through public ownership, and that therapies remain available within the public health system.'

Witnesses that appeared before the Senate committee were asked to comment on these issues and responded with a number of suggestions about what needed to be done to ensure that any benefits of this research remained in the public domain.

Professor Bernie Tuch the Director of the Diabetes Transplant Unit at Prince of Wales Hospital and University of New South Wales stated that money was required to keep research in public hands:

***Senator NETTLE**—My particular interest in this area is in ensuring that any therapies that do come from embryonic stem cell research are available in the public domain and, ideally, through the public health system. Of course it is always a very difficult thing to do, and especially at this point in the development of the research. One proposal that has been put to me is about requiring people when they made applications to the licensing committee to address in their application, and then for the licensing committee to look at, what contribution their research would make to reducing the global health burden, or some similar phraseology to allow that public interest and public health component to be in it. I wondered if you have a view about the feasibility of that or how that would work, and if you have any other suggestions for ways to inject that public health component into—*

***Prof. Tuch**—Sure, it is called money. I work in a public hospital, as part of a university. We put our hands up some time ago and said, 'Thank you very much, we'd like to be able to create some embryonic stem cells lines and we'd like a good manufacturing practice facility to be able to produce them for the public good.' Basically government—let us leave out who—said 'That's nice,' but never supported it. In the end we had to do it privately to push the thing along. To create our embryonic stem cell line we took an initiative not from the public but from private foundations who had enough vision to be able to say, 'Let's move it; let's not sit around waiting.' To be able to do that, a relationship was built up with the hospital involved, the private foundation and the IVF foundation so that all parties would gain from it. So there was a benefit. But if you do not put money behind it you expect people to sit. They are not going to do nothing, in which case the only other options, I guess, are private organisations or foundations. You cannot expect, in five or 10 years time when things*

are developed, that things are going to be easy for the public situation unless you are prepared to put funding up-front to support it. In other words, once legislation gets passed—as it was passed four years ago—you have got to have the funding available generally to allow it to be implemented; otherwise you will not reap the benefits so easily.

Professor Tuch comment later:
'It is an issue of: if you want it, you invest the funds in development organisations and you say what is produced is public.'

Witnesses at the public hearings were asked whether the NHMRC could be required to assess whether any treatments would be provided through the public domain and how those treatments would be equitably delivered, through the public health care system or through other mechanisms.

Professor Warwick Anderson, Chief Executive Officer of the NHMRC replied that *'if parliament did wish for such a consideration to be taken into account, the NHMRC could certainly add that to the process.'*

Some witnesses indicated that given the preliminary nature of the current embryonic stem cell research into possible treatments for human disease such an assessment maybe difficult at this stage.

Recommendation
That the Parliament amend the Research Involving Human Embryos Act 2002 to require the NHMRC Licensing Committee in deciding whether to issue a licence to have regard to not only the likelihood of significant advance in knowledge or improvements in technologies for treatment as a result of the use of excess ART embryos proposed in the application and the capacity of such benefits to be delivered through the public health system and/or reduce the global disease burden.

Stem Cell Bank

The Research Involving Human Embryos Act 2002 and the Prohibition of Human Cloning Act 2002 both required the Lockhart Review to look at *'the applicability of establishing a National Stem Cell Bank.'*

Recommendation 47 of the Lockhart Review states:
'A national stem cell bank should be established.'

Neither Senator Patterson's Bill nor the exposure draft of Senator Stott-Despoja and Senator Webber's bill legislate for a national stem cell bank.

Senator Stott-Despoja indicated in her second reading speech that *'this is partly because a national stem cell bank does not necessarily require legislation.'*

Senator Stott-Despoja says in her second reading speech:
'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.'

Senator Patterson's bill requires the Minister to report to Parliament within six months on the establishment of a National Stem Cell Centre.

The committee received submissions that highlighted the important role that a national stem cell bank can play in keeping this research in public hands.

Associate Professor Wendy Rogers from Flinders University stated in her submission:
'Finally, some of the key issues in the Lockhart Report have not been addressed in the proposed legislation. In particular the establishment of a stem cell bank and conditions for benefit sharing are not considered. Some of the reasons for these omissions have been explained, but in my view there is a serious ethical issue of equity that arises when tissues donated by Australians for the benefit of the Australian community (including both researchers and patients) are then used to develop commercial products for private enterprise. The products and profits from the research involving SCNT and the development of stem cell lines including a stem cell bank (should they proceed in Australia) should remain in public control, and equally available within the public healthcare system. The current climate of competition between the states for commercial biotechnology investment raises concerns that there will not be public ownership of many resources donated by Australian women for stem cell research. It is appropriate that any legislation recognises the interest of those groups who provide the basic resources for the development of potential therapeutic treatments in having access to those treatments.'

Professor Robert Williamson from the Australian Academy of
Science stated at the Canberra hearing why he supported a stem cell bank:
'I personally think—and I think it would be the academy's view on this—that everyone, whatever their view on the more general issues, should support this particular recommendation. In the first place, if we have a national stem cell bank, that bank reduces the number of experiments that will be done on embryos. In the second place, it guarantees a level of transparency because people will be noted as using it. And, in the third place, it will operate in practice to facilitate public rather than private research. For all of those reasons, I think everyone should support bringing this in as quickly as possible.'

Recommendations 48 of the Lockhart states:
'Consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem bell bank.'

In its submission to the Senate Committee the Australian Stem Cell Centre was supportive of this notion, suggesting it was:
'the logical organisation to oversee a national stem cell bank as it has an existing cell storage facility and trained staff.'

In the Prime Minister's press release of 23 June 2006 he indicated:
'The Government also supports further exploring the establishment of a national register of donated excess embryos created originally for ART purposes and a national stem cell bank. This infrastructure would offer a way of assisting research by making donated excess embryos and stem cell lines more widely available to the research community.'
Currently both Senator Patterson's Bill and the exposure draft of Senator Stott-Despoja and Senator Webber's bill require reports to be made to parliament about establishing a stem cell bank.

The establishment of a national stem cell bank is an important mechanism for ensuring that embryonic stem cell research occurs in the public domain and that any benefits from this research remain in the public domain.

The Australian Greens moved amendments to the Research Involving Human Embryos Act in 2002 that required the government to establish a national stem cell bank. These amendments were not passed by the Lockhart Review looked at the issue and recommended that a national stem cell bank should be established.

The Parliament must ensure that this occurs.

Professor Livesey, CEO of the Australian Stem Cell Centre described an overseas example where developing a stem cell bank had taken between 18months and 2 years.

Prof. Livesey*—It took us six months to develop our repository. As for developing that further into a bank after a feasibility study, the Scotland stem cell network has been involved in the development of a GMP bank there and they took somewhere between 18 months and two years to fully establish it.*

Recommendation
That the Parliament amend the Research Involving Human Embryos Act 2002 to require the government to establish a publicly run national stem cell bank within 2 years.

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