

29 September 2006

Elton Humphery Secretary Community Affairs Committee Australian Senate

SUBMISSION FROM THE MEMBERS OF THE LOCKHART COMMITTEE

The members of the Legislation Review Committee (the Lockhart Committee), make the following submission:

- 1. It is nearly 12 months since the Committee submitted its report to the federal government and to COAG. Since that time our views and recommendations remain the same as those in our report.
- 2. We have closely followed the developments in research involving embryos since the report was tabled. These include the discrediting of Dr Hwang's research in South Korea on the ground of academic misconduct and the subsequent retraction of those scientific papers. They also include the recent publication by American researchers that they have obtained embryonic stem cells from one cell removed from an eight-cell embryo (Klimanskaya et al, 2006 see below). We have also read the press reports of the debates on issues related to embryo research and we have all participated in public discussions ourselves. None of these experiences has led us to change our minds about any of our recommendations.
- 3. We have read the Mathews Pegg Consulting Report commissioned by the Government that concluded that the 'state of play' has not changed sufficiently since 2002 to warrant amending the legislation. However, the review undertaken for that Report had much narrower Terms of Reference than those of the Lockhart Committee. We were required to report not only on *developments* in technology, medical research and scientific research, but also on the 'potential therapeutic applications of such research' and 'community standards' (emphasis added). In addition, our Committee was required to undertake extensive consultation with the states and territories, stakeholders and the broader community. We held public meetings in the capitals of all states and territories and received more than 1,000 submissions. In a number of areas in which the Mathews Pegg Consulting Report concluded that there had been no change in the 'state of play', the Lockhart

Committee concluded that there had been substantial changes in both the potential of such research (see Appendix); and community standards (see next paragraph).

- 4. One of the key terms of reference for the Lockhart Committee was to assess 'community standards'. The Committee argued early in the Report that community standards were dynamic, complex and varied between communities, and that the views of any one individual may be influenced by the range of communities to which they belong, eg religious, cultural, scientific, illness and so forth. For this reason the Committee based its recommendations not only on reflective consideration of the moral issues raised by these Acts, but on the range of community views expressed in the public hearings it conducted and the submissions it received, and also on extensive research described in the report that was undertaken and described to the Committee by Biotechnology Australia. [This survey found that of 1067 people surveyed, nearly two-thirds approved or strongly approved in response to the question: 'In relation to human stem cell issues, for each of the following situations, do you see them as being morally acceptable to society or not? Human stem cells being derived from embryos' (Lockhart Committee Reviews p 83 (Table 1).] These broad community views in support of human embryonic stem cell research have continued to be observed following the current debate on the potential implementation of the Lockhart Committee recommendations. An ACNielson/Age opinion poll of 1415 respondents, reported in The Age on 12 September 2006, asked the question 'Do you support or oppose legislation which allows the cloning of stem cells for medical research?' It found 62% support, 12% oppose and 12% had no opinion [sic].
- 5. The Committee found from its community consultations, conducted as part of the Review, that the views on this type of research are widely polarized and that they cannot always be reconciled. Our report and its recommendations proposed that a middle ground which reflected the values and priorities of the community would be supported by the majority of Australians, while recognising that some would consider that the recommendations went too far, and others would argue that they did not go far enough.
- 6. The Committee recommended that many of the current statutory prohibitions should continue and that the creation of a 'sperm-egg embryo' for research should continue to be prohibited by law. This was based on community views that we heard during the consultation process, especially from couples undertaking treatment in fertility programs. They considered the embryos formed from their genetic material to be different from embryos formed by somatic cell nuclear transfer (SCNT), which have closer resemblance to the donor's bodily material than to a potential child. Similarly, key prohibitions on the development of any embryo beyond 14 days and on the implantation into a woman's body of any embryo used in research should also be maintained.
- 7. The Committee did recommend that somatic cell nuclear transfer (therapeutic cloning) and a number of other related practices should no longer be a criminal offence but should be permitted under strict regulation, subject to a licence and close monitoring, with a transparent process of reporting to both the NHMRC and to federal Parliament.

8. Critics of the Lockhart Committee's Report have said that human embryos have a special moral status and it is morally abhorrent to create and destroy them for research. Arguments have also been made that allowing SCNT will inevitably lead to reproductive cloning (the creation of a duplicate person) and that embryonic stem cell research is unnecessary or ill-founded as it has produced no new insights or therapies and can be done using adult stem cells.

However, the Lockhart Committee concluded after careful deliberation that none of these arguments justified *prohibiting* embryo research and SCNT. The Committee was acutely aware of the special moral status attached to embryos and the concerns that many groups, particularly Christian churches, had regarding their destruction. But the Committee also recognised that not all communities in Australia attach the same significance to the embryo, and that other concerns, such as the need to care for the sick and vulnerable and respect the wishes of individuals, are also morally important. The Committee also noted that the community, legal system and government already allow donated embryos to be used in research and that legislation mandates that stored IVF embryos must eventually be destroyed.

- 9. While we strongly believe that different viewpoints must be respected, in the face of moral diversity, it is unjustifiable to ban embryo research or SCNT.
- 10. Allowing SCNT under licence will not inevitably lead to reproductive cloning. The Australian community almost unanimously opposes it and it should remain prohibited. However, the best safeguard against reproductive cloning is restricting the degree to which embryos can be matured and prohibiting them being implanted into women. It is reassuring that there have been no instances of non-compliance with legislative and regulatory requirements in Australia (where embryo research is allowed under licence) or in the UK (where SCNT is allowed).
- 11. History shows that medical advances like small pox vaccination, oral medicines and analgesics for the relief of pain, once stirred religious and moral objections that were overcome as the benefits became obvious and they created their own moral force. We suggest that the same may be true for embryonic stem cell research. But in saying this we recognise that embryonic stem cell research has not yet led to new therapies or cures (as we make clear in our report). Major practical outcomes from embryonic stem cell research will take time and considerable pre-clinical and clinical research. Adult somatic stem cell research (like transplantation for leukaemia and lymphoma) is promising but should be regarded as complementary. SCNT has the potential to create new disease models for research and mechanisms for drug and toxin screening (in the short term) and novel therapies or regenerative process (in the long term). If these provide benefits for patients with spinal injury or Parkinson's disease, it is inconceivable that moral objections to SCNT would not be overridden.
- 12. Committee members have assisted both Senator Patterson and Senator Stott Despoja in the preparation of their respective draft Bill and Exposure Draft. We consider that both of these fairly represent the efforts of the sponsors to implement all of the Lockhart Committee's recommendations.

13. The Lockhart Committee members would be pleased to appear before the Senate Community Affairs Committee to elaborate on this submission, the Lockhart Report or to answer any questions that the Senators may have. We consider that the most appropriate time would be at the beginning of your deliberations in Canberra on 20 October when several of the committee members would be willing to appear.

Yours sincerely

Professor Loane Skene

Deputy Chair, Lockhart Committee

On behalf of the Lockhart Committee members Associate Professor Ian Kerridge Professor Barry Marshall Associate Professor Pamela McCombe Professor Peter Schofield Professor Loane Skene

Appendix

Scientific Developments since 2002

Many recent scientific papers published in leading journals demonstrate that progress has been and is being made, although none are yet routine procedures. The following are examples of this research:

1. Research reported in the United Kingdom in 2005 that showed that nuclear transfer can be achieved in human oocytes using heterologous donor nuclei and surplus and donated oocytes. This work was referenced in the Lockhart Committee's Report. Following the discrediting of the Korean work this is the first publication of the production of licensed human SCNT embryo clones:

'Derivation of a human blastocyst after heterologous nuclear transfer to donated oocytes', by Miodrag Stojkovic, Petra Stojkovic, Christine Leary et al, *Reproductive Biomedicine Online*, vol. 11, no. 2, pp. 226-231.

2. Research reported from the US used the fusion of existing human ES cell lines that had been enucleated with adult cells to create cytoplasmic hybrid (cybrid) individual specific human ES cell lines. This research was also referenced in the Committee's Report but was published after the review:

'Reprogramming of human somatic cells by embryonic stem cell cytoplast', by Nick Strelchenko, Valeri Kukharenko, Artem Shkumatov et al, *Reproductive Biomedicine Online*, vol. 12, no. 1, pp. 107-111.

3. Research reported from the United States obtained human embryonic stem cell lines from single cells extracted from blastomeres. This suggests that embryonic stem cells might be derived from one cell removed from an eight-cell embryo:

'Human embryonic stem cell lines derived from single blastomeres', Irina Klimanskaya, Young Chung, Sandy Becker et al, *Nature*, letters published online 23 August 2006,

4. Research reported from Japan demonstrated that protein factors could be used to reprogram mouse fibroblast (skin) cell lines to become induced pluripotent stem cells that were demonstrated to contribute to embryonic development in mice.

'Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors', by Kazutoshi Takahashi and Shinya Yamanaka, *Cell*, vol. 126, pp. 1-14 and supplemental data.

5. Research aimed at elucidating the genetic consequences of cloning is currently being conducted in a number of centres, and the results of this research are likely to be enormously significant to the entire field.

These peer reviewed scientific publications were included in the list of documents tabled in the Senate on 14 September 2006 by Senator Kay Patterson.