

25 October 2006

## Dear Mr Humphery

## Lockhart Review's comments on Mathews Pegg Consulting Report

Professor Schofield, Professor Kerridge and I make the following comments in response to your questions.

- 1. We have read the Mathews Pegg Consulting Report that was commissioned by the Government.
- 2. That report was asked to investigate the 'state of play' which appears to have been interpreted as meaning development of actual therapies. The Mathews Pegg Consulting Report concluded that the 'state of play' has not changed sufficiently since 2002 to warrant amending the legislation. This is not surprising since the Terms of Reference for the review undertaken for that Report were very much narrower than those of the Lockhart Review.
- 3. The Lockhart Review was required to report not only on developments in technology, medical research and scientific research, but also on 'potential therapeutic applications of such research' and 'community standards' (emphasis added).
- 4. In the key area of somatic cell nuclear transfer, the executive summary of the Mathews Pegg Consulting Report is misleading and has been inappropriately reported (see below). Also, in contrast to the Lockhart Review, the methodology of the Mathews Pegg Consulting Report is unclear and the rigour of the approach is not sufficiently transparent to allow critique.
- 5. Because the Mathews Pegg Consulting Report was not required by the Terms of Reference for its review to investigate community attitudes, it did not undertake any community consultation.
- 6. In contrast, the Lockhart Review was required by its Terms of Reference to consider community standards and it undertook extensive consultation with the states and territories, stakeholders and the broader community. There were

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public meetings in the capitals of all states and territories and more than 1,000 submissions were received. Members of the Review Committee were also briefed on a very extensive study of community attitudes over several years, undertaken by Biotechnology Australia. That study 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': Report p 83 (Table 1).

- 7. The Lockhart Review reported on the findings of this extensive community consultation in its report. It found, inter alia, that:
  - community understanding of embryo research, including somatic cell nuclear transfer (SCNT), has increased substantially since 2002;
  - the majority of people support human embryo research, including the creation and use of embryos formed from SCNT;
  - many couples in fertility programs want to donate their embryos for research.
- 8. The Lockhart Review concluded from submissions made to it by members of the scientific community, and a literature survey conducted for the Review, that there have been many advances in science since 2002. These were mainly in the field of animal research. The Review noted Dr Hwang's then published research in South Korea on human somatic cell nuclear transfer, which was later retracted as a result of being shown to be fraudulent. However, we stress that this information was not the single or sole evidence on which the Lockhart Committee made its recommendations. The Lockhart Report also referred to other scientific work which had not been published at the time the report was delivered but has since been published. The Review considered this research was important, not because it has led to cures, but because of the potential it has for future scientific developments.
- 9. In the past 3 years, the following bodies have been sufficiently convinced of the merits of the science behind ESC research and its therapeutic potential to advocate for its support: the House of Lords; the UK Legislative Review team; the majority of US Senators (almost 2/3); 80 Nobel Laureates in the US; most, if not all, of the living medical Nobel Laureates in Australia; the Australian scientist of the year, Professor Ian Frazer; the American Medical Association; and the Canadian Medical Association. It is possible, though highly improbable that these groups and individuals are all wrong about the potential of human embryonic stem cell research.
- 10. The Mathews Pegg Consulting Report did acknowledge that scientific developments have occurred since 2002. That report stated:

In the [Lockhart] Committee's Report, the Committee noted that this is a very active field of research and that there have been a number of developments since 2002. Specific reference is made in the Committee's Report to:

• the first report of human cloning in 2002 when South Korean scientists claimed that they had cloned human embryos until the blastocyst stage to create ES cells.

It was noted that in 2005, the same group of researchers applied the nuclear transfer methods to clone human embryos using somatic cell nuclei from patients who have various disease or injuries to derive 'tailor-made' stem cell lines;

- 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;
- other researchers attempting to produce patient-matched ES cells by fusing the somatic cell nuclei from patients with ES cells. It was noted that one United States—based group has claimed to have achieved this (and called the resulting cells 'stembrids') but that the research has not yet been published in the peer reviewed literature; and
- 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.

The Literature Review also describes various studies aimed at understanding the developmental processes and improving methods of cloning. The section in the Literature Review specifically on cloning human embryos, is relatively short and reflects the developments detailed above (and included in the body of the Committee's Report).

Since the Committee published its Report there have been some further developments which have discredited the work of the South Korean researchers. On the basis of advice from the NHMRC it would not appear that there have been any other scientific developments relevant to the question of whether the ban on the creation of embryos by SCNT should be lifted. Despite this, it is clear that there have been developments since the legislation was introduced in 2002.

However, it does not appear that these developments particularly influenced the Committee's recommendations regarding the creation and use of embryos using SCNT. Rather the Committee's considerations appeared to be based around the potential of SCNT for the treatment of illness and the Committee's own resolution of the ethical issues rather than an assessment of the state of the science as at a certain point in time.

- 11. We note that the Mathews Pegg Consulting Report refers to advice from the NHMRC which has not been provided to us.
- 12. We note that the Mathews Pegg Consulting Report concluded that 'it is clear that there have been developments since the legislation was introduced in 2002' supporting the Lockhart committee recommendations. We also note that the Mathews Pegg Consulting Report goes on to state that 'it does not appear that these developments particularly influenced the Committee's recommendations regarding the creation and use of embryos using SCNT. Rather the Committee's considerations appeared to be based around the potential of SCNT for the treatment of illness and the Committee's own resolution of the ethical issues rather than an assessment of the state of the science as at a certain point in time'. This is a selective interpretation by the authors of the Mathews Pegg Consulting Report. It does not reflect the Terms of Reference or the conduct of the Lockhart Review. We therefore disagree with this aspect of the Mathews Pegg Consulting Report.
- 13. The Mathews Pegg Consulting Report made numerous criticisms of the Lockhart Review because it stated that the Committee had not provided a direct link justifying its recommendations to a specific research advance, etc. We reject this view, as the Lockhart Terms of Reference were substantially

broader that those of the Mathews Pegg Consulting Report, and our recommendations were based on a synthesis of all evidence presented and the Committee's deliberations.

14. We note that no other group or individual has suggested that the Lockhart Review failed to meet the requirements of its Terms of Reference. The most important difference between the two reports is that the Mathews Pegg Consulting Report, by interpreting the 'state of play' as meaning therapies concluded that there had been few developments in the state of play and that there is no need to change the legislation. The Lockhart Review, on the other hand, found that there have been developments in science which have considerable potential for therapeutic applications and the majority of scientists and the broader community support embryo research.

Yours sincerely

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Associate Professor Ian Kerridge

Professor Peter Schofield.