Submission to the Senate Community Affairs Committee

Inquiry into the Legislative responses to Recommendations of the Lockhart Review

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The average person is baffled by the stem cell debate. Blastocysts, mitochondria, cytoplasm, somatic cell nuclear transfer and dozens of other words are terms most people never even learned properly in high school science. But you don't need to be a research scientist to understand the importance of the ethical controversy which has put stem cells on the front pages of newspapers around the world.

Stem cell research is an exciting field with enormous potential for repairing damaged organs and body parts with human stem cells. A lot of progress has been made using adult stem cells.¹ However, most media attention is on embryonic stem cells and the urgent pressure to use them in treatments and perhaps cure chronic diseases that are currently untreatable. Under existing Australian legislation experimentation can be allowed on human embryos in excess from IVF programs. However, preparation of the human embryo for research remains a significant ethical obstacle for a substantial portion of the community.² Since the licensing system was introduced in 2002 there have been no discoveries through this work to support arguments of an urgent need for somatic cell nuclear transfer, often called "therapeutic cloning".³

In addition, cloning needs human eggs and extracting eggs from women involves an operation with its own risks.⁴

There are no specific, credible reasons why Australia needs to approve therapeutic cloning. Last month in "Cell" it was reported that it is possible to "reprogram" an adult cell by providing it with a set of specific genes - 4 in number - and finish with cells that can behave virtually as ES cells in the tests that were applied.⁵ In a Commentary on the paper in the same issue of Cell by independent scientists from the Harvard Stem Cell group concluded that this work "*represents a significant step toward a rational approach for generating patient-specific ES cell lines that could be used either as a source of autologous tissue for transplantation or for modelling different diseases. This method is encumbered by neither the logistical constraints nor the societal concerns presented by somatic cell nuclear transfer".⁶*

Science and ethics have unfairly been portrayed in this debate as being opposed to one another. But good science is ethical science. This recent publication illustrates how rapidly good science is progressing within the legislative boundaries already existing in Australia.

The recommendations of the Legislation Review Committee on the Research Involving Human Embryos Act 2002 (the Lockhart review) surrounding cloning are included in the draft bills by Senators Patterson and Stott Despoja. The implementation of these recommendations would enable scientists to create more embryos via cloning, the same way they cloned Dolly the sheep. A number of other animals have been cloned during the past decade, but no humans. South Korean scientist Hwang Woo-Suk claimed to have produced the first human embryo clone two years ago but was exposed as a fraud. In fact, the whole South Korean research program failed, despite using more than 2000 human eggs from 130 women in a three-year period. Even Dolly was the result of 277 attempts.

 ¹ W Murrell, F Fe'ron, A Wetzig, N Cameron, K Splatt, B Bellette, J Bianco, C Perry, G Lee, A Mackay-Sim Developmental Dynamics 233:496–515, 2005
² Eureka Strategic Research (2005). Public Awareness Research 2005 Reports: Overview, Cloning, Stem

² Eureka Strategic Research (2005). Public Awareness Research 2005 Reports: Overview, Cloning, Stem Cells, Biotechnology Australia. <u>http://www.biotechnology.gov.au/reports</u>

³ N Cobbe Journal of Medical Ethics 32:298-302 July 2006

⁴ Editorial, *Nature Biotechnology* 23(7) July 2005; The Lancet 365 (2005), 9477

⁵ K Takahashi & S Yamanaka *Cell* 126:663-6767, 2006

⁶ KT Rodolf & K Eggan *Cell* 126:652-655, 2006

In addition to the scientific issues, there are serious ethical concerns. The lack of research on animals is at odds with international medical ethics guidelines such as the Declaration of Helsinki. This states that "research involving human subjects includes research on identifiable human material" and "medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information and on adequate laboratory and, where appropriate, animal experimentation".

In contrast to the lack of proof of the benefits of cloning, there is ample evidence that alternatives such as adult stem cell research, which does not involve the same ethical problems, holds more promise. The federal Government recognised the potential of adult stem cell technology by giving a \$22 million grant to Griffith University researchers who are using stem cells from the nose to study diseases.

Griffith's Professor Alan Mackay-Sim says: "It is probable that such stem cell lines as these will render therapeutic cloning irrelevant and impractical."

Paradoxically, it is the restrictions on federal funds for embryonic stem cell research in the US that are fuelling important advances in cancer research using adult stem cells, as reported in Time magazine in April.

As a scientist, I know that, as in many other fields, my profession is a minefield of value judgments about what should or should not be done, and that is the debate our community needs to have with respect to cloning human embryos for experiments. Arguing that research may improve the lives of some people and that this outweighs the cost of destroying human embryos is not a scientific claim but an ethical one.

It is misleading and unfair to suggest that those opposed to cloning human embryos are insensitive to the suffering of those with chronic disabilities. To find innovative ways of helping people with debilitating or incurable conditions was my motivation for becoming a scientist.

James L. Sherley, associate professor of biological engineering at the Massachusetts Institute of Technology, said in a recent interview that the only strategy by which embryonic stem cells might be used to develop therapies was if they could be used to produce adult stem cells.

"However," he argues, "since natural adult stem cells are available from informed consenting adult donors, this possible embryonic stem cell-dependent strategy is not absolute, as has been suggested by proponents of human embryo cloning."

This debate is about good science v bad science. Good science is ethical science. The ethical science here also has all the successes.

In conclusion, the recommendations of the Lockhart Review should be rejected. The federal parliament's ban on human embryo cloning, put in place just four years ago, should remain.

Dr Monique Baldwin has a PhD in neuroscience and works as a drug regulatory affairs associate for a pharmaceutical company, facilitating approval for patients to access new therapies in Australia.