Submission

on the

Inquiry into the Legislative responses to Recommendations of the Lockhart Review

to the

Senate Community Affairs Committee

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1. Introduction

1.1 Legislative responses to the recommendations of the Lockhart Review

There are two legislative responses to the recommendations of the Lockhart Review. One is the exposure draft of the Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006 tabled in the Senate on 14 September 2006 by Senator Natasha Stott-Despoja. The other is the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 tabled out of session on 26 September 2006 by Senator Kay Patterson (hereafter called the Patterson Cloning Bill).

Both legislative responses seek to give full effect to all the recommendations of the Lockhart Review which require legislative change if they are to be implemented.

Senator Stott-Despoja has described the exposure draft of the Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006 as being "for information and committee use". The Bill is poorly drafted and exceeds the recommendations of the Lockhart Review. For example, proposed new section 23 of the Prohibition of Human Cloning Act 2002 would allow the creation and development to 14 days of a chimeric embryo although Recommendation 6 of the Lockhart Review explicitly supported maintaining the prohibition on the creation of a chimeric embryo. This submission will make no further reference to Senator Stott-Despoja's Bill.

The Patterson Cloning Bill more closely follows the recommendations of the Lockhart Review. There is likely to be a debate on this Bill in the Senate in the sitting week of 6 November-9 November 2006. This submission will comment on the provisions of this Bill and on the recommendations of the Lockhart Review which the Bill seeks to implement.

1.2 The human embryo and the right to life and integrity

The human embryo, whether created by fertilisation (in vivo or in vitro), by somatic cell nuclear transfer or by any other means is an individual human being. If the right to life is inherent to our humanity rather than arbitrarily bestowed on some human beings by those human beings who happen to hold power in a particular society then it must inhere in the human individual as soon as that individual comes into being. It cannot be dependent on the existence of some specific manifestation of human nature such as consciousness or the ability to plan for tomorrow or having a white skin.

The Research Involving Human Embryos Act 2002 allows for the violation of the right to life and integrity of those human embryos determined to be "excess" to the requirements of those for whose reproductive purposes they were created. Many of those who voted for this Act in 2002 stated that they could not see a moral distinction between killing a human embryo for research and letting it die if it was not required for the reproductive project for which it had been created. However it was noteworthy that all of those who voted in 2002 for the passage of the Research Involving Human Embryos Act 2002 also voted, along with those who upheld the inherent right to life of the human embryo, for the Prohibition of Human Cloning Act 2002.

This Act comprehensively prohibited the creation of a human embryo by any means, including fertilisation or cloning, for the purpose of research. The principle that underlay the unanimous vote in both houses of the Federal Parliament was succinctly and forcefully expressed by Senator Kay Patterson:

"I believe strongly that it is wrong to create human embryos solely for research. It is not morally permissible to develop an embryo with the intent of truncating it at an early stage for the benefit of another human being."[1]

The Patterson Cloning Bill tabled by Senator Patterson in September 2006 directly violates the principle she enunciated in 2002 - a principle unanimously supported by the Senate and by parliaments throughout Australia.

The fundamental issue before this inquiry is whether or not the principled position taken unanimously by the Senate in 2002 should be maintained.

2. Ethical issues

2.1 Rationale of the Lockhart Review

An Explanatory Memorandum on the Patterson Cloning Bill has been circulated by authority of Senator Patterson. This Memorandum therefore presumably reflects the Senator's rationale for her new position. The Memorandum states[2]:

"The Committee made 54 recommendations and outlined its rationale for the recommendations as follows:

"Australian society is made up of diverse 'communities' with different perspectives, interests and values. Furthermore, an individual may be the member of multiple communities, each with divergent perspectives, or 'standards', and these standards vary between and within communities and over time. Because of these divergent values and interests represented within Australian society, the Committee has accepted that some disagreement will remain, whether or not any changes are made to the two Acts.

"However, certain moral values are held in common by all communities, such as commitment to social justice and equity and to the care of vulnerable people. This is reflected in broad community support for medical research aimed at understanding, preventing or treating disease, and for research and clinical practice aimed at assisting people to have children (including a general acceptance that this process may involve the 'wastage' of some embryos). Therefore, in considering whether certain activities should be made illegal, the social and moral value that some communities attach to the human embryo needs to be balanced against the social and moral value that other communities attach to the treatment of disease and to helping people to have a family." (page xiii)

In framing its recommendations, the Committee "considered that the higher the potential benefits of an activity, the greater the need for ethical objections to be of a high level and widely accepted in order to prevent that activity. Conversely, where benefits are not yet established, or where there is widespread and deeply held community objection, then total prohibition through the legal system may be justified. In addition, even though some people think that an activity is unethical, it does not necessarily follow that the activity should be made illegal. Furthermore, the wider the range of ethical views on a particular activity, the weaker becomes the case for declaring that activity to be illegal, with all the attendant consequences of criminal conduct." (page xiv)

This rationale is superficial, simplistic and incoherent.

It abandons any attempt to consider whether an activity is right or wrong in itself and considers only what distinct and diverse "communities" might think about the rightness or wrongness of the activity.

This approach is completely irreconcilable with the kind of statement Senator Patterson, along with many others, made in 2002 in their speeches in favour of the Prohibition of Human Cloning Act 2002. Senator Patterson said then: "It is not morally permissible to develop an embryo with the intent of truncating it at an early stage for the benefit of another human being."[3]

Under the view of ethics and public policy proposed by the Lockhart Review, and now adopted by Senator Patterson, it is not possible to make such a clear and unambiguous statement of principle. Rather they are saying something like, "Some communities in Australia want to be allowed to create human embryos for research so we must allow it."

This approach is incoherent because if followed consistently it would lead to the abandonment of any legal prohibition as soon as an identifiable community demanded the lifting of the prohibition.

The Lockhart Review's rationale goes on to modify this approach somewhat by including a benefits test: "The higher the potential benefits of an activity, the greater the need for ethical objections to be of a high level and widely accepted in order to prevent that activity" and, conversely, "where benefits are not yet established, or where there is widespread and deeply held community objection, then total prohibition through the legal system may be justified."

This rationale can be rebutted on two levels.

Firstly, it is wrong in itself to develop an embryo with the intent of truncating it at an early stage for the benefit of another human being.

Secondly, even applying their own rationale, the Lockhart Review failed to assess properly either the potential benefits of cloning and other activities for which they recommended a lifting of the existing prohibitions, or the widespread and deeply held community objection to cloning and related activities.

2.2 Creating a human embryo in order to destroy it is wrong

It was not just Senator Patterson but many of her colleagues who said in 2002 that creating a human embryo in order to destroy it is wrong.

The Senate Committee Affairs Committee would do well to read and reflect on the comments made then. They remain just as true today as they were four years ago.

Sharman Stone (Liberal – Murray)

… I have little doubt that most Australians feel repugnance at the thought of human cloning or the creation of a hybrid human… There is no place in the world, much less Australia, for commercial exploitation of embryos for research or their deliberate creation for research.[4]

Brendan Nelson (Liberal – Bradfield)

If you look at Australia's competitors in the US, public sector research has continued to make advances with the National Institutes of Health permitted cell lines. At the same time, in the US private sector there has been something of a free-for-all. One company, ACT, recently claimed that it had succeeded in creating an early stage embryo via human therapeutic cloning, to which of course I would be most opposed.[5]

Hon Julie Bishop (Liberal – Curtin)

Put simply, I support a prohibition on human cloning and other such unacceptable practices as outlined in the bill and I support the regulated use for research of excess human embryos created by assisted reproductive technology. I have arrived at this position after a great deal of consideration over a

number of years… The most controversial aspect of the bill is not the issue of human cloning. There seems to be unanimity for the proposed prohibition on research that would yield a human clone…[6]

Bronwyn Bishop (Liberal – Mackellar)

All are in agreement that cloning should be outlawed, and that is what this bill does… I conclude my contribution to this debate by saying that it is a very difficult area, that the idea that any legislation should permit the production of embryos for the purpose of harvesting those stem cells to me would be an anathema. I believe this bill is sufficient to prevent and to outlaw that occurring, just as it outlaws cloning.[7]

Peter Costello – Deputy Leader of the Liberal Party

The first is to prohibit cloning and to make certain offences in relation to cloning and crossing animal and human genetic matter. As far as I am aware, there is general agreement that those practices ought to be banned. I have not heard anybody in the debate suggest that that aspect of the bill is wrong or that they would be voting against those parts of the bill that put in place, in my view, very important prohibitions… Some of my colleagues who have lobbied me on this issue have said, `If you let this go you'll compromise your ability to call a halt to such experimentation in future circumstances; you'll be in a worse position and more compromised down the track.' I do not feel that is the case. I feel—and I had some involvement in bringing this about—that this bill does draw a line.[8]

Teresa Gambaro (Liberal – Petrie)

I agree, however, that we should not support human cloning, whether reproductive or therapeutic cloning.[9]

Warren Entsch (Liberal – Leichhardt)

With regard to the first section of this bill, human cloning, let me state that I totally and fully support the ban on human cloning. I am totally opposed to human cloning in any shape or form. I think it is absolutely abhorrent and I would never support it.[10]

Michael Johnson (Liberal – Ryan)

In the first place, let me state my complete support for the relevant provisions of the bill that seek to legislate a ban on human cloning. Like the Prime Minister, I advocate the position that any attempt to introduce human cloning should be vigorously resisted by every member and senator who sits in this parliament. The bill provides for any form of human cloning to be an offence and provides a 15-year maximum prison sentence. The prison sentence is indicative of the gravity in which the parliament holds the offence of human cloning.[11]

Kay Hull (Liberal – Riverina)

While this bill will prohibit human cloning—an issue I strongly believe has no place in our society—it will ensure that work can continue on embryonic research, and in turn this may discover cures for many terminal and disabling diseases… Each of us are individuals with our own genetic make-up derived from our parents. I believe that creating copies of ourselves sets a dangerous precedent. That is why I certainly do not support any research into human cloning. It is a frightening thought and something that this bill completely outlaws. As a society, we could never allow fellow human beings to be used as living experiments.[12]

Senator John Watson (Liberal - Tasmania)

I believe it is therefore important to keep both routes to therapy open. Unlike some in this chamber, I have no innate or unreasoned fear of terrible crimes against humanity waiting for medical scientists to

be let off the leash. At the same time, I want to put on the record and make abundantly clear that I am firmly against all forms of cloning.[13]

Alexander Downer (Liberal – Mayo)

I do not think many would argue with one of the two central propositions of this legislation, and that is to ban human cloning. I think all of us would agree that the implications of allowing human cloning are uncertain and, to some of us, even somewhat frightening. It raises concepts of eugenics and those who have argued for these things over the generations in some totalitarian regimes; one particularly reflects here on the Nazis during the 1930s and the 1940s. Anyway, the whole notion of breeding out certain genetically inherited characteristics and trying to breed particular types of humanity is one for me which is instinctively anathema, regardless of what the moral arguments may be.

The moral arguments are put forward by all of the major religions of the world. They argue that a person's unique identity would be challenged, would be undermined by some system of cloning and that human beings would be treated as a means to an end rather than as ends in themselves, the ultimate of unattractive utilitarian arguments. In any case, to the best of my knowledge there is unanimous support in the parliament in opposition to human cloning. This legislation provides for that.[14]

Dr Andrew Southcott (Liberal – Boothby)

I will first address the issue of human embryo cloning. The bill provides for the prohibition of human embryo cloning. This technology is relatively new. In 1997 it was announced that Dolly the sheep was successfully cloned. However, only about 10 per cent of cloned embryos result in live births, and amongst the live births there is a high percentage of malformations and deformities. In fact, when you look at the process that was required to create Dolly the sheep, you see that it took about 430 eggs, 40 donor sheep and 277 reconstructed eggs to develop 29 embryos. After using 13 surrogate mothers, one clone was born: Dolly. Clearly this technology is dangerous, and it is unacceptable to experiment in this way with humans. Apart from these obvious technical problems, Dolly appears to have cells that are just as old as the adult cell from which she is cloned. She already has arthritis.

Some scientists in Italy, South Korea and the United States may have already cloned humans to a four-cell stage. I join with the vast majority of my parliamentary colleagues to condemn human embryo cloning and to support the measures in this bill which will prohibit this. This technology is dangerous: it raises the spectre of designer babies and could lead to the commodification of children. If pursued, it will distort families and relationships within them. Division 1 of part 2 of this bill, which codifies prohibited practices, prohibits the creation, implantation and import and export of a human embryo clone. I support this section of the bill.[15]

Kim Beazley (Labor - Leader of the Opposition)

We have made moral judgments against human cloning. There is no doubt the scientists can take us down that road, should they be permitted by the law of the land. There is no doubt too that, were they to take us down that road, there might be some interesting things found out as that process was undertaken by them. Nevertheless, we say no.[16]

Simon Crean (Labor – Hotham; then Leader of the Opposition)

Our policy does not support human cloning. It will only support research on embryos created for IVF purposes that would otherwise be destroyed.[17]

Jenny Macklin (Labor – Jagajaga)

In speaking to this bill tonight, I will be joining many others in supporting a ban on human cloning. I am sure everybody in the parliament will support that ban, and I imagine everybody will support the ban on the creation of embryos specifically for research. It is important that the parliament is not silent on these issues.[18]

Jennie George (Labor – Throsby)

I am happy that it provides restrictions and regulation to ensure that embryos will not be commodified now or in the future, either by those who might create excess embryos for the sole purpose of providing material for research for commercial gain or by those who might trade on human misery by promising to provide childless couples with an opportunity to be parents through cloning technologies. This bill rightly bans cloning embryos for research purposes and also rightly prevents what I find to be totally repugnant, the cloning of human beings.[19]

Anthony Albanese (Labor - Grayndler)

The Labor Party are allowing a conscience vote on this bill, but we do have a party position—and it is a position I support. We do not support human cloning; we only support research on embryos created for IVF purposes that would otherwise be destroyed.[20]

Stephen Smith (Labor – Perth)

A ban on human cloning is sensible, is necessary and, on the basis of the debate both here and in the Senate, has the universal and unanimous support of the parliament.[21]

Martin Ferguson (Labor – Batman)

I am not in any way advocating human cloning. This bill is not about allowing our nation's scientists to create the so-called perfect human being. Indeed, that is a totally unacceptable consideration. The farming of embryos will also be banned. Embryos will not be created for the specific purpose of scientific research…

The United Kingdom, for example, allows the creation of new embryos for the explicit purpose of harvesting their stem cells. In my view, that policy stretches the boundaries of what this parliament is being asked to consider. My support of this bill is conditional on the outlawing of embryo creation for the purpose of stem cell farming…[22]

Senator Chris Evans (Labor – Western Australia)

Human cloning experimentation also has implications for public safety… Indeed, the potential for therapeutic applications to arise from human cloning - this potential providing the only justification to my mind for even considering allowing cloning - cannot even be explored until the full negative effects of cloning in animals are known and techniques for reversing them are developed.

One of the offences this bill proposes is the intentional creation of an embryo that is a genetic copy of another human being, dead or alive, by whatever means. This blanket prohibition on cloning is very important because it rejects exceptionalism. The bill prohibits the copying of another human's genes, whether or not the maker's intention is to destroy the resultant embryo or to allow it to grow full term into a human baby. Prohibition of human cloning per se, rather than allowing a clone to be developed to a certain cellular stage, is important because of how we regard ourselves. To the extent that our sense of identity is predicated on individual uniqueness, this sense would be threatened whether a 32-cell clone of ourselves or a fully developed child clone existed.

Ever since the European Enlightenment, and arguably since the collapse of feudalism where a serf's identity was officially subsumed within the corporate status of a land-holding other, individualism has been accorded the highest value in western society. Australians would need to think very hard about the implications for their sense of self or their identity in ceding scientists the liberty to make even an embryo with two pronuclei that shares the genes of another human being.[23]

Wayne Swan (Labor – Lilley)

Firstly, I wish to state that I fully support the prohibition in the bill of human cloning. I consider the notion of such a pseudo-scientific development abhorrent.[24]

Julia Gillard (Labor – Lalor)

Finally, the other aspect of this bill is the prohibition on human cloning, which I support. I understand it to be universally supported in this parliament. It is very important that we, as a parliament, make a statement about that through the passage of this bill—and I thank you, Mr Deputy Speaker, for the opportunity.[25]

Senator Jan McLucas (Labor – Queensland)

Clause 13 of the bill makes it an offence to create or develop a human embryo other than by fertilisation. This clause specifically prohibits embryo splitting, parthenogenesis and, importantly, somatic cell transfer… BresaGen, a company involved in the therapeutic application of embryonic stem cell technology, advised the committee: 'There are a large number of scientific hurdles to be overcome before this can be considered a feasible theory, and using human eggs as the recipient cells is technically infeasible since about 50-100 eggs would be required for each successful reprogramming event' …

I agree with BresaGen's conclusion that the creation of such a large number of eggs is 'ethically unacceptable as well as impractical'… Hyperstimulation is a dangerous and unacceptable practice and, whilst not explicitly banned in the bill, the incentives to hyperstimulate are prohibited. The bill expressly prohibits somatic cell nuclear transfer. It bans commercial trade in human eggs, sperm and embryos, and it bans the creation of embryonic stem cell lines from somatic cell donors…

In conclusion, the Prohibition of Human Cloning Bill 2002 provides conservative and nationally consistent legislation that delivers on the COAG agreement of earlier this year and it should be supported.[26]

Joel Fitzgibbon (Labor – Hunter)

I set aside the question of human cloning because I am not aware that there is a member of this House who supports that proposition. We all agree, as I understand it, that that is an unacceptable proposition. More importantly, this is a bill which seeks to regulate the use of existing embryos—not to create embryos but to regulate their use—and to put in place a national uniform framework for dealing with these very important issues, a framework that would regulate those uses…[27]

Steven Gibbons (Labor – Bendigo)

I am pleased that the bill outlaws any form of human cloning, both reproductive and therapeutic, and prohibits such practices from occurring in Australia. The bill makes it an offence, with a maximum prison term of 15 years, for a person to create a human embryo, clone or import a human embryo clone into Australia. I believe that this is an appropriate penalty…[28]

Nicola Roxon (Labor – Gellibrand)

If it is passed, and then passed in other states, these prohibitions will be introduced across the entire nation to prevent human cloning. There is no such legislative provision in place at the moment. We need a clear statement and we need clear penalties. This bill makes it an offence, in a way that has not been made clear previously, to conduct any research or to manipulate an embryo in any way that would result in human cloning…

There are sections in the bill which prohibit the sorts of things that we read about in sci-fi books, including some of the more extreme things, such as the creation of animal-human clones or placing part of a human embryo into an animal womb. We are prohibiting those sorts of things in this legislation…[29]

Maria Vamvakinou (Labor – Calwell)

More importantly, it also imposes a ban on human cloning. Today we have reached a point in our scientific and medical evolution where the cloning of human beings is possible. The cloning of animals, and in particular the recent story of Dolly the sheep, has fuelled the debate about the future cloning of human beings. The notion is abhorrent to many—including me—because it stretches the human capacity to push the boundaries of experimentation and scientific advancement into uncharted waters.

I believe we must always keep in perspective what we take from scientific advancement in order to benefit humanity and what we reject because we determine it to be harmful to human progress. There is no evidence that cloning of human beings is medically or scientifically necessary. I am therefore pleased and reassured that this bill seeks to ban human cloning.[30]

Anna Burke (Labor – Chisholm)

There is no support in this parliament—or, indeed, in the wider community—for human cloning. I abhor the idea that the cloning of humans may be carried out anywhere. The cloning of any human for any purpose is morally repugnant to me. Therefore, I support the provision within this bill that prohibits human cloning.[31]

Senator Linda Kirk (Labor)

The Labor Party's position against human cloning is one which I wholeheartedly support. I do not believe that there is any significant level of public support for human cloning, and little is to be gained from it.[32]

2.3 Widespread and deeply held community objection to cloning

The Lockhart Review failed to disclose that over 80% of the 1035 submissions received opposed any change to the prohibition on human cloning for research.

While recording the total number of submissions received as 1035[33] and giving a breakdown of these as 921 from individuals, 98 from organisations, 8 from government agencies and 8 from members of parliament, nowhere in the Report are we given any indication of the weight of the submissions for or against relaxing the prohibition on human cloning for research. Anyone who takes the trouble to read the 1035 which are available on the Lockhart Review website can establish that in fact over 80% of the submissions were opposed to relaxing the prohibition on human cloning for research. The Report repeatedly refers to “some”, “several” or “a number” of submissions arguing for or against human cloning, but carefully avoids communicating any impression of the balance of opinion.

As well as suppressing information on the weight of submissions opposed to lifting the prohibition on cloning the Review also failed even to mention, let alone give due consideration to, the most in-depth research on Australian attitudes to human cloning. This was conducted by researchers from Swinburne University of Technology and published in 2004. It concluded that "The results suggest that the majority [63%] of Australians were comfortable with the research using adult cells, but were not comfortable with scientists using cells created by cloning."[34]

The avoidance of the usual practice, certainly of Senate committees, of recording the relative balance of opinion in submissions received, along with its ignoring of key evidence on community attitudes to cloning published in the academic literature, undermines the credibility of the Review's claim – foundational to its rationale for its recommendations – that there is not widespread and deeply held community objection to cloning.

2.4 The benefit test

Thus there is real evidence – ignored by the Lockhart Review – of widespread and deeply held community objection to cloning. Those who wish to follow the Lockhart Review's rationale for its recommendations - and Senator Patterson's rationale for the Patterson Cloning Bill – must then consider if claims of potential benefits from cloning are sustainable.

3. The potential benefits of human cloning and related activities

3.1 The Lockhart Review on the science of human cloning

The Lockhart Review coincided with a six month period from June to December 2005 when the whole world was deceived into believing that Korean scientist Hwang Woo Suk had succeeded in deriving 11 patient specific embryonic stem cell lines from human embryo clones created by somatic cell nuclear transfer.

The Australian Stem Cell Centre's submission[35] put it this way to the Lockhart Review:

"Some notable advances would include both the initial proof-of-concept of human SCNT and a subsequent greatly enhanced efficiency of SCNT by Professor Woo Suk Hwang from Korea. At the time of the previous legislative debate, human SCNT had not been achieved and there was some controversy in the field as to whether it was in fact possible. Within the last three years, Professor Hwang has shown that it is indeed possible and, in his recent paper in the journal *Science* [coincidentally published 17 June 2005 the very day the Lockhart Review was established], he has shown that it can be performed with a level of efficiency that greatly increases its potential therapeutic application. Thus, this technique is no longer theoretical; it has been proven, optimised, and is being performed in laboratories throughout the world."

The Lockhart Report's assessment of the potential benefits of human cloning, and the extent to which these had been established, was inevitably distorted by these apparently authoritative submissions.

It was on 23 December 2005, just four days after the Lockhart Review was completed and its Reports handed down. that an academic panel at Seoul University found that the 11 patient specific embryonic stem cell lines reported as created by Hwang did not exist. They were pure fabrication.

On 10 January 2006 Seoul National University found that Hwang's earlier 2004 research in which he reported the creation of 30 human embryo clones was also fraudulent.

The following editorial retraction was published in *Science* on 20 January 2006:[36]

"The final report from the investigation committee of Seoul National University (SNU) has concluded that the authors of two papers published in *Science* have engaged in research misconduct and that the papers contain fabricated data. With regard to Hwang et al., 2004, the Investigation Committee reported that the data showing that DNA from human embryonic stem cell line NT-1 is identical to that of the donor are invalid because they are the result of fabrication, as is the evidence that NT-1 is a bona fide stem cell line. Further, the committee found that the claim in Hwang et al., 2005 that 11 patient-specific embryonic stem cells line were derived from cloned blastocystsis based on fabricated data. According to the report of the Investigation Committee, the laboratory 'does not possess patient-specific stem cell lines or any scientific basis for claiming to have created one.' Because the final report of the SNU investigation indicated that a significant amount of the data presented in both papers is fabricated, the editors of *Science* feel that an immediate and unconditional retraction of both papers is needed. We therefore retract these two papers and advise the scientific community that the results reported in them are deemed to be invalid.

"As we post this retraction, seven of the 15 authors of Hwang et al., 2004 have agreed to retract their paper. All of the authors of Hwang et al., 2005 have agreed to retract their paper.

"*Science* regrets the time that the peer reviewers and others spent evaluating these papers as well as the time and resources that the scientific community may have spent trying to replicate these results."

This retraction of the Hwang papers meant that there is now no evidence published in a peer-reviewed journal of any researcher successfully creating a human embryo clone let alone deriving embryonic stem cells from a clone.

This makes the Lockhart Review Reports completely useless. Its recommendations were premised on the "notable advances" in cloning achieved by Hwang. After the Hwang fraud was exposed the Lockhart Review Reports should have been shredded, or at least comprehensively ignored.

Applying the Lockhart Review's own rationale, there is now no case for its recommendations to lift the existing prohibitions on cloning and related activities - because there is widespread community and deeply held community objection to cloning and no benefits of human cloning or related activities have been established.

3.2 The Patterson papers

The Community Affairs Committee lists as documentation relating to this inquiry eight documents tabled in the Senate on 14 September 2006 by Senator Kay Patterson.

Senator Patterson's tabling statement was brief:[37]

"I seek leave to table a number of articles from published refereed journals."

Presumably these articles are supposed to give some scientific foundation for the benefits to be gained from lifting the prohibition on human cloning.

The following comments on these papers, prepared by *Do No Harm – Australians for Ethical Stem Cell Research*[38] indicate that these articles taken either separately or together give no such foundation.

1. Chang, J et al, "Correction of the sickle cell mutation in embryonic stem cells", *PNAS*, vol 103(4), pp 1036-1040, 24 January 2006

This paper does not deal with therapeutic cloning but rather with the application of gene therapy. It reports the use of genetic engineering to correct an abnormality that had been introduced into a mouse

gene leading to sickle cell anaemia. ES cells were derived from the mice by SCNT, the gene defect was corrected and it was shown that the blood-forming cells could now form normal haemoglobin. This approach to gene therapy could theoretically be used for many single-gene defects. The starting point would not need to be ES cells but could use adult haemopoietic stem cells.

2. Stojkovic, M et al, "Derivation of a human blastocyst after heterologous nuclear transfer to donated oocytes", *Reproductive Biomedicine Online*, 2005 Aug 11(2), pp 226-31

This paper describes a failed attempt at therapeutic cloning. This paper from the UK Newcastle group was published rapidly in this online journal at the time of the claim (later shown to be entirely fraudulent) by the Korean group led by Hwang Woo Suk to have developed 11 patient-specific cell lines by SCNT. What this paper shows is that the Newcastle team were able to conduct nuclear transfer of a human ES cell nucleus (not a somatic cell nucleus) to an enucleated ovum, and develop a blastocyst, but take it no further. They had one success in 36 attempts, and concluded that they needed ova within one hour of collection. None of this has been reported in any adequately peer-reviewed journal, nor has this team been able to advance this work to the point of deriving human ES cell lines by SCNT (therapeutic cloning).

3. Klimanskaya, I et al, "Human embryonic stem cell lines derived from single blastomeres", *Nature online*, 23 August 2006

This paper describes the establishment of ES cell cultures from single cells obtained by completely disaggregating an 8-cell embryo. The paper claims that this procedure could be used in conjunction with "Preimplantation Genetic Diagnosis" (PGD), where a single cell is taken at the 8-cell stage to make a genetic diagnosis in high risk cases. This methodology has no relevance to therapeutic cloning. There is no current legislative restriction on the derivation of embryonic stem cells from a single cell that has been removed from an 8-cell ART embryo for the purpose of PGD.

4. Takahashi, K and Yamanaka, S, "Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors", *Cell*, Vol 126, 1-14, 25 Aug 2006

Rather than supporting the case for therapeutic cloning, this paper illustrates why such it is unnecessary. The paper reports 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. This is work carried out in mouse cells. It obviously needs to be confirmed, and there will be much more to be done to refine the method and establish whether the reprogramming is complete, and fully reproduces the ES cell. What can be said though, is that it is an exciting "proof of concept" that a pluripotent cell could be generated from an adult cell without cloning. It remains to be translated to human cells, and the approaches used for the mouse work will be invaluable in informing that work.

5. Barberi, T et al, "Neural subtype specification of fertilisation and nuclear transfer embryonic stem cells and application in parkinsonian mice", *Nature Biotechnology*, vol 21(10), October 2003

In this paper either standard mouse ES cells or cloned ES cells were used to treat chemically-induced Parkinson's disease in mice. There was no advantage gained with the cloned cells, although there were only 6 mice per group, possibly because the brain is a relatively "immune privileged" site. This experiment was only of 8 weeks duration, thus insufficient to provide for development of tumours, which have occurred so commonly in recipient mice in other published experiments. Any experiment to establish therapeutic potential such as this must be continued long enough to allow an assessment of safety. Unless both safety and efficacy are clearly established in animal models, it is both reckless and futile to propose therapeutic cloning in humans.

6. Blelloch, R et al, "Nuclear cloning of embryonal carcinoma cells", *PNAS*, 28 Sept 2004, vol 101(39), pp 13985-13990

This work involved transferring the nucleus of a primitive mouse cancer to an enucleated ovum, and both therapeutic and reproductive cloning were carried out. The tumour cells retained their malignancy, and embryos died or were abnormal. Previously these same scientists carried out similar experiments, using nuclear transfer from mouse melanoma tumours to create embryos. The melanoma malignancy first appeared to regress, but then all embryos and mice developed tumours. These approaches could be very informative about the genetic changes in cancer, but they have no relevance to the need for therapeutic cloning in Australia. It would be absolutely essential that all such work be confined to mouse models because any meaningful research along these lines can only be carried out if the generated embryos are allowed to develop much further, including development after implantation into the uterus.

7. Strelchenko, N et al, "Reprogramming of human somatic cells by embryonic stem cell cytoplast", *Reproductive Biomedicine Online*, 2006 Jan, 12(1), 107-11

This online paper describes an attempt to bypass the need for therapeutic cloning. It is a preliminary technical report, in which the authors are seeking to find factors in ES cells that can be used to "reprogram" adult cells to behave like ES cells. They fused ES cells with adult cells and found some evidence that they could transfer some "stem" behaviour to the adult cells, but they finished with a mixture of cells, fused and non-fused, that were clearly difficult to work with. The reprogramming work by Takahashi and Yamanaka (above) is at a more advanced stage of achievement, although still in mouse cells.

8. Cooper, D, "The Lockhart Review: Where now for Australia?" 2006, 14 *JLM* 27

The PhD student author in this superficial analysis embraces warmly the full recommendations of the Lockhart Committee Report, quoting selectively from it, without including any comment on its many shortcomings, and concluding that "the potential benefit to countless Australians of stem cell therapies should be accorded more weight than the objections of some sections of the Australian community…"

3.3 The adult stem cell challenge

Proponents of lifting the prohibition on human cloning need to demonstrate that there is an important benefit to be obtained that cannot be obtained in any other way.

There have been two major claims made for the benefits of human cloning.

The first claim is that cloning could be used to produce patient-specific stem cells for use in therapies. The second claim is that cloning could be used to produce diseased stem cells lines for basic research and drug testing.

Emeritus Professor John Martin has said:[39]

"There are no cell-based therapies for any disease that would warrant the preparation of human embryonic stem cells by somatic cell nuclear transfer.

"Proof of this as an approach has never been obtained from any experimental model of disease in animals. When claims of the benefits of embryonic stem cells are made, the list of diseases usually consists of Parkinson's disease, Alzheimer's, diabetes, muscular dystrophies, the replacement of dead heart muscle following heart attacks, of brain tissue following strokes, and the like.

"For several of these conditions there are experimental models that can be studied in animals, but embryonic stem cells have never yet been shown in animal research to provide a cure sufficiently

prolonged and free of complications to warrant human studies. To accept the urgency of work on human embryonic stem cells in the face of the ethical barrier, then at least one experimental example of safe, prolonged and substantially effective treatment better than any existing treatments should be provided.

"It is argued that very valuable research into certain diseases could be carried out by preparing embryonic stem cells with somatic cell nuclear transfer, using nuclei from patients with those diseases. Again, proof of this has not been provided by appropriate animal experimentation, yet this could be done to establish the possibility."

Professor Mackay-Sim and his team at the Eskitis Institute for Cell and Molecular Therapies at Griffith University have shown that adult stem cells from the olfactory muscosa, the organ of smell in the nose, can be grown in the laboratory into many different types of cells, including heart, muscle, liver, kidney and blood cells.

These adult stem cells have potential clinical application in stem cell transplantation therapies and will be used to understand and ultimately develop treatments for brain diseases such as Parkinson's disease, motor neurone Disease and schizophrenia.[40]

In his submission to the Lockhart Review Professor Mackay-Sim stated:[41]

"It is often stated that therapeutic cloning will be required to investigate the biology of certain diseases and to find cures for them by studying embryonic stem cells and their progeny derived from the patients… Therapeutic cloning is a long and laborious procedure that will require donor oocytes and will produce an inexact 'copy' of the donor because of the handful of mitochondrial genes passed on through the donor egg. An alternative source of stem cells for these important investigations is provided by adult stem cells. In our lab we already have over 40 adult cell lines derived from persons with schizophrenia, Parkinson's disease, motor neuron disease, and mitochondrial disease. These are relatively easily obtained, easy to grow in the lab in large numbers and amenable to cell culture studies, gene expression profiling and proteomics analyses. It is probable that such cell lines as these will render therapeutic cloning irrelevant and impractical."

There has been no adequate answer from the proponents of human cloning to these challenges from Emeritus Professor John Martin and Professor Mackay-Sim. The scientific case for cloning has not been made out.

4. Other abhorrent practices

4.1 Hybrid embryos

Recommendation 24 of the Lockhart Review is that:

"In order to reduce the need for human oocytes, transfer of human somatic cell nuclei into animal oocytes should be allowed, under licence, for the creation and use of human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days."

The Patterson Cloning Bill seeks to implement this recommendation. If passed into law it would be permissible to create and develop for 14 days a hybrid embryo formed by introducing the nucleus of a human cell into an animal egg.

There is no scientific justification for this procedure.

The Chief Scientist, Dr Jim Peacock has said:[42]

"In the Lockhart Review it was suggested that animal eggs could be used for some of the research so that fewer human eggs would be required. Many scientists think that using a nucleus and egg cell from different species complicates the research. Most scientists regard this particular recommendation to be of little importance."

This dismissal of this key recommendation of the Lockhart Review by Australia's Chief Scientist is a further illustration of its lack of rigour.

Section 6 of the Patterson Cloning Bill seeks to exclude a hybrid embryo from being considered to be a human embryo.

This position is inconsistent. Any scientific rationale for using animal eggs for cloning with human somatic cell nuclei depends on a claim that no, or at least only minimal, mitochondrial DNA from the animal egg will be replicated in the embryonic stem cells harvested from the hybrid embryo. If this were the case it is hard to see why a hybrid embryo should not be considered to be a human embryo.

If, however, as the Chief Scientist Dr Jim Peacock maintains, the presence of animal mitochondrial DNA in the embryonic stem cells derived from a hybrid embryo will "complicate the research", then there is no justification for the provisions in the Bill which permit the creation of hybrid embryos.

The Bill does prohibit developing a hybrid embryo past 14 days. It also prohibits placing a hybrid embryo in the body of a woman. However, the Bill does not prohibit placing a hybrid embryo in the body of an animal. Once an embryo is placed in the body of an animal, those who created it and who placed it in the body of the animal are no longer "developing" the embryo. The Bill, therefore, could allow an experiment in which a hybrid embryo made by somatic cell nuclear transfer of a human cell nucleus into an animal egg is placed in the body of the animal and gestated there to foetal stage or even live birth.

4.2 Foetuses as parents

Recommendation 27 of the Lockhart Review is that:

"Creation of embryos using precursor cells from a human embryo or a human foetus should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days."

Precursor cells are cells in the embryo or foetus which can develop into sperm or eggs.

Embryos could be created by fertilization using either precursor sperm cells or precursor egg cells or both. Embryos could also be created by using precursor eggs as the recipients for somatic cell nuclear transfer.

The most ready source of precursor cells would be from aborted foetuses.

The effect of this provision is that an aborted baby girl or an aborted baby boy could become the mother or father of a human embryo who would in turn to be killed for research.

It is astounding that there is not a single word of justification for this recommendation in the Lockhart Review Reports. There is no discussion of the scientific rationale for this procedure, no indication of any potential benefits and no mention of community attitudes to this practice.

There is likely to be widespread and deeply held community objection to such a recommendation.

The adoption of this recommendation, without any discussion or justification being offered, demonstrates the utter inadequacy of the Lockhart Review. The tabling in the Senate of two Bills which seek to give effect to this recommendation shows that ethical considerations have been completely ignored.

5. Where will all the eggs come from?

Diane Beeson, a medical sociologist and Professor Emerita of Sociology at California State University, East Bay explained to a US Congressional hearing:[43]

"Initial reports indicated Hwang's team used 242 human eggs to create one embryo in 2004. Then in 2005 he claimed to have generated '11 patient-specific stem-cell lines with a success rate of 1 line for approximately every 20 oocytes.' This created the illusion that significant progress had been made in bringing down the number of eggs SCNT would require. It has now been revealed that Dr Hwang used over 2000 eggs in his discredited research. His failure to produce even one cloned embryo reminds us that we still do not know how many thousands, or possibly even millions of eggs it may require to perfect SCNT. Furthermore, it has become clear that payment, coercion, and lying were used to acquire the eggs that we were told many women were eager to donate."

The only claim still standing – after the six-month hoax perpetrated by Korean scientist Hwang Woo Suk was exposed - to actually have produced a human embryo clone is from the Newcastle team.[44] This team didn't use somatic cell nuclear transfer. Using 36 ova procured from women undergoing IVF they managed only to produce a single blastocyst by enucleating an ovum within one hour of collecting it from the woman and fusing it with an embryonic stem cell. This method seems to have been chosen because the nucleus of an undifferentiated embryonic stem cell would need less reprogramming by the ovum then a somatic or body cell. However, there doesn't seem to be any possible practical application of this technique. Even if the blastocyst made this way had survived long enough for stem cells to be extracted, all that would have been achieved would be cloning an embryo you had already killed for its stem cells in order to get more stem cells with the same DNA somewhat scrambled by the cloning process.

The Newcastle team has never had this research published in an adequately peer-reviewed journal. Since then they have lost their lead researcher Dr Miodrag Stojkovic to the Prince Felipe Research Centre in Valencia. He is now working for Sintocell in Serbia.

As Gretchen Vogel noted in her review article, "Cell biology: picking up the pieces after Hwang"[45] would-be human cloners "face two substantial hurdles: a limited supply of human oocytes and a lack of data on how to use them most efficiently."

The Patterson Cloning Bill seeks to maintain the prohibition on giving valuable consideration in exchange for ova. "Valuable consideration" is defined in the relation to the supply of a human egg to include "any inducement, discount or priority in the provision of a service to the person".

The Newcastle team was getting eggs[46] by asking women undergoing IVF to hand over two of their eggs if they produce 12 or more in one treatment cycle. By this means they only netted only 66 eggs for research in 7 months. This is apparently insufficient to make any further advances in human cloning. The team succeeded in an application to the Human Fertilitisation and Embryology Authority for a licence permitting them to offer discounted IVF to women in order to increase the egg procurement rate. The Human Fertility and Embryo Authority[47] is now considering a general change to the rules to allow payment for eggs.

Californian would-be cloner Renee Reijo Pera[48] is also calling for a change to the rules to allow payment to women for their eggs. In the United States it is common practice to pay women to have their eggs harvested for use in creating IVF embryos for infertile women. The rate of payment is as high as $50,000. However, under Proposition 71, by which Californians voted $3 billion for stem cell research including cloning, payment to women for eggs for cloning is prohibited.

Some commentators have suggested that eggs which fail to fertilise during IVF procedures could be used. However, these have proved ineffective[49] in cloning research. Good, fresh eggs are needed!

It seems that women everywhere in the world are sensibly reluctant to undergo the risks of ovarian hyperstimulation, including death, simply to accommodate the demands of the would-be cloners.

6. The next step to the brave new world

In 2002 Senator Kay Patterson joined the whole Senate in rejecting the creation of a human embryo by cloning to be used and destroyed in research.

She said then:

"I believe strongly that it is wrong to create human embryos solely for research. It is not morally permissible to develop an embryo with the intent of truncating it at an early stage for the benefit of another human being. I believe it is disingenuous to suggest that approving this research will open the door to further killing of living human beings when the Prohibition of Human Cloning Bill 2002 bans the creation of a human embryo for a purpose other than achieving a pregnancy."[50]

By tabling the Patterson Cloning Bill, Senator Patterson has not only abandoned the moral principle she stated so forcefully in 2002 but she has proved that the passage of the Research Involving human Embryos Act 2002, which permitted destructive research on so-called excess ART embryos, did indeed "open the door to further killing of living human beings".

The mechanism by which that door is opening was the Review provided for under both that Act and the Prohibition of Human Cloning Act 2002. The result of that Review – the Lockhart Review – is the Patterson Cloning Bill which is currently under consideration.

This Bill permits the creation and killing of living human beings for research.

Sections 8 and 35 of the Bill lay the foundation for a further erosion of any remaining legal limits on scientific research by providing for a review which must consider "any research or clinical practice which has been prevented as a result of legislative restrictions". We are likely to be told then by some scientists that to get the full benefits from human cloning we need to allow clones to develop to the foetal stage in order to harvest their organs. We could be told that in order to get sufficient ova to bring about the potential benefits of human cloning we need to offer reimbursement to women for their time and compensation for the risks they must undergo.

Having crossed the moral line which Senator Patterson, along with the whole Senate, told us solemnly in 2002 we should never cross - creating human embryos in order to destroy them - what ethical principles will then hold us back from caving in to this next demand from the proponents of science's brave new world?

7. Conclusion and recommendation

Creating a human embryo, by cloning or any other means, with the intention of destroying it is wrong and should remain prohibited by law.

The Patterson Cloning Bill has been introduced by Senator Patterson to give effect to the recommendations of the Lockhart Review. It has been demonstrated that even based on the rationale adopted by the Lockhart Review, there is no case for implementing its recommendations.

There is a widespread and deeply held community objection to cloning, and the benefits of cloning have not been established.

It is therefore recommended that the Community Affairs Committee advise the Senate to reject the Patterson Cloning Bill and to make no further legislative response to the Lockhart Review.

8. Endnotes

[1] Senate Official Hansard No. 13, 2002 Tuesday, 12 November 2002 p. 6136

[2] Explanatory Memorandum on the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006, p2-3

[3] Senate Official Hansard No. 13, 2002 Tuesday, 12 November 2002 p. 6136

[4] House of Representatives Official Hansard No. 11, 2002 Wednesday, 28 August 2002

[5] House of Representatives Official Hansard No. 11, 2002 Tuesday, 27 August 2002

[6] House of Representatives Official Hansard No. 10, 2002 Thursday, 22 August 2002

[7] House of Representatives Official Hansard No. 11, 2002 Tuesday, 27 August 2002

[8] House of Representatives Official Hansard No. 11, 2002 Wednesday, 28 August 2002

[9] House of Representatives Official Hansard No. 10, 2002 Wednesday, 21 August 2002

[10] House of Representatives Official Hansard No. 10, 2002 Tuesday, 20 August 2002

[11] House of Representatives Official Hansard No. 11, 2002 Wednesday, 28 August 2002

[12] House of Representatives Official Hansard No. 10, 2002 Wednesday, 21 August 2002

[13] Senate Official Hansard No. 13, 2002 Wednesday, 11 November 2002

[14] House of Representatives Official Hansard No. 11, 2002 Wednesday, 28 August 2002

[15] House of Representatives Official Hansard No. 11, 2002 Tuesday, 27 August 2002

[16] House of Representatives Official Hansard No. 11, 2002 Wednesday, 28 August 2002

[17] House of Representatives Official Hansard No. 10, 2002 Tuesday, 20 August 2002

[18] House of Representatives Official Hansard No. 10, 2002 Tuesday, 20 August 2002

[19] House of Representatives Official Hansard No. 10, 2002 Thursday, 22 August 2002

[20] House of Representatives Official Hansard No. 10, 2002 Wednesday, 21 August 2002

[21] House of Representatives Official Hansard No. 18, 2002 Wednesday, 11 December 2002

[22] House of Representatives Official Hansard No. 10, 2002 Wednesday, 21 August 2002

[23] Senate Official Hansard No. 13, 2002 Wednesday, 11 November 2002

[24] House of Representatives Official Hansard No. 11, 2002 Wednesday, 28 August 2002

[25] House of Representatives Official Hansard No. 11, 2002 Wednesday, 28 August 2002

[26] Senate Official Hansard No. 13, 2002 Wednesday, 11 November 2002

[27] House of Representatives Official Hansard No. 11, 2002 Tuesday, 27 August 2002

[28] House of Representatives Official Hansard No. 11, 2002 Tuesday, 27 August 2002

[29] House of Representatives Official Hansard No. 10, 2002 Tuesday, 20 August 2002

[30] House of Representatives Official Hansard No. 10, 2002 Wednesday, 21 August 2002

[31] House of Representatives Official Hansard No. 11, 2002 Tuesday, 27 August 2002

[32] Senate Official Hansard No. 13, 2002 Wednesday, 11 November 2002

[33] Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002, Reports, December 2005, p18

[34] Christine Critchley and Lyn Turney, Understanding Australians' Perceptions Of Controversial Scientific Research, Australian Journal of Emerging Technologies and Society, Vol. 2, No. 2, 2004, pp: 82-107

[35] Available at: http://www.lockhartreview.com.au/_pdf/501-600/LRC535.pdf

[36] Science 20 January 2006: Vol. 311. no. 5759, p. 335

[37] Senate Hansard (Proof) Thursday, 14 September 2006 p.80

[38] www.cloning.org.au/Documents/Analysis%20of%20papers%20tabled%20by%20Senator%20Patterson.pdf

[39] John Martin, Hold fire on therapeutic cloning until there's proof it works, Sydney Morning Herald, 26 July 2006

[40] http://www.griffith.edu.au/centre/eskitis/

[41] http://www.lockhartreview.com.au/_pdf/201-300/LRC217.pdf

[42] Dr Jim Peacock, Stem Cell Research, speech delivered at Parliament House, Canberra, 13 September 2006, p3

[43] Testimony of Professor Emerita Diane Beeson, Congressional Hearings, March 7, 2006, House Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources -- Hearing on Stem Cell Research

[44] Stojkovic, M et al, Derivation of a human blastocyst after heterologous nuclear transfer to donated oocytes. Reproductive Biomedicine Online, 2005 Aug 11(2) pp 226-31

[45] Science 28 April 2006: Vol. 312. no. 5773, pp. 516 - 517

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[49] M-C Lavoir, et al, Poor development of human nuclear transfer embryos using failed fertilized oocytes, Reproductive BioMedicine Online, Volume 11, No 6 December 2005

[50] Senate Official Hansard No. 13, 2002 Tuesday, 12 November 2002 p. 6136