# CHAPTER 4

# THE CASE AGAINST

# Arguments opposed

**Summary**

4.1 The arguments presented in submissions and in oral evidence to the Committee against the Lockhart Review's recommendations, and the Bills that seek to implement them, are summarised below:

- The lack of scientific evidence, including lack of `proof of concept' and lack of any clinical trials, regarding the potential benefits of human embryonic stem cell research.
- The dangers (such as cancer formation) inherent in the research and clinical application of human embryonic stem cells.
- The work of Korean researchers (Professor Hwang) that promoted cloning, relied upon by the Lockhart Review, exposed as fraudulent.
- The significant number of clinical trials already underway around the world in relation to adult stem cells.
- The small number of licences (9) granted by the Licensing Committee since the establishment of the current regulatory regime, and the even smaller number of licences granted for research into human disease. The majority of licences issued (5) relate to artificial reproductive technology research. If human embryonic stem cells are so efficacious and safe, why so few licences, and why even fewer specifically for research into disease? The NHMRC has confirmed that only 1 licence, issued to IVF Australia, has been issued that aims at treating a specific condition.
- The ethical boundary, long-recognised in medical research codes, that would be crossed in legislating to allow **the creation of cloned human life exclusively for the purpose of it being destroyed** in the pursuit of knowledge.
- The health risks to women in egg harvesting, as well as the risk of exploitation of women to gain access to more human eggs.
- The conclusion of the independent *mpconsulting report*, prepared for the Department of Prime Minister and Cabinet and released by the Prime Minister on 31st August 2006, which found: 'On each of these issues [the definition of human embryo; the creation and use of embryos for ART research; and the creation of embryos for stem cell research] … there has not been any significant change in the state of play since 2002'.

- The risk that, just as those in the current debate have changed their mind from opposing therapeutic cloning in 2002 to promoting it in 2006, the current ban against reproductive cloning could, equally in a few short years, be lifted because sections of the scientific community, using the same arguments advanced today, argue that it would facilitate the pursuit and accumulation of knowledge.
- The complexity of issues, the speed of examination, and the highly contested case (medically and ethically) that promotes change, is not an adequate foundation to alter the current legislative framework.

## Insufficient scientific merit of SCNT

4.2 Many participants in this inquiry said there needed to be overwhelming evidence of the benefits of creating cloned embryos for embryonic stem cell research to justify changing the current legislative regime. They argued that the onus was on its proponents to prove the case for allowing SCNT to a standard that acknowledges the moral and ethical questions the practice raises. It was asserted that this had not been achieved for the following reasons:

- New breakthroughs had not been demonstrated to warrant a change to the position adopted by legislators in 2002;
- There were inherent limitations of and dangers in the potential application of embryonic stem cell technology;
- Adult stem cells continue to provide ethical and scientific advances; and
- The number of human eggs required for SCNT would, in the absence of unethical practices, and in the risks to women, make the technology impractical.

### *Embryonic stem cell research has not justified allowing SCNT*

4.3 It was argued that the scientific benefits advocated by supporters of SCNT were unproved and unlikely, and do not justify crossing the ethical boundary previously established by the parliament when the PHC Act was passed in 2002.

4.4 Professor John Martin of Melbourne University submitted that:

> Any move towards the deliberate manufacture of human embryos for research purposes constitutes a major elevation in the ethical barrier, and the standard of proof required for a positive outcome of that research becomes all the higher.[1]

1 Professor Martin, *Submission 35*, p. 1.

Professor Martin quoted the Lockhart Report itself, which states that '…at this stage, ES cell research has not reached the stage needed to start clinical trials (ie proof of principle of a safe and efficacious treatment in animal models)'.[2]

4.5 The Southern Cross Bioethics Institute also queried the imperatives for change:

> At the time of the 2002 debate about stem cells and cloning, the opposition to any form of cloning was unanimous and held on ethical grounds. The reasons for any change would need to be extremely compelling. Yet neither scientific advance nor change in community standards have been anywhere near compelling.[3]

4.6 For Professor Alan Mackay-Sim, the ethical barrier crossed by allowing therapeutic cloning is tacit support for its inevitable successor, human reproductive cloning. He contended that legislative approval for developing the techniques for reproductive cloning needed to be justified by 'extra evidence' of their benefits. In his view, this had not been demonstrated.[4]

4.7 In this respect, the Lockhart Review was criticised for proposing to allow SCNT when animal studies have not yet established proof of concept for deriving human embryonic stem cells lines by this method. Professor Martin said in a Parliamentary Library Lecture that, in order to demonstrate proof of concept for this activity, proponents had to 'establish prolonged efficacy and safety in appropriate animal models of disease'.[5] Indeed, the Lockhart Review itself observed that 'ES cell research has not reached the stage needed to start clinical trials (ie proof of principle of a safe and efficacious treatment in animal models)'.[6]

4.8 Evidence to the Committee highlighted medical ethical guidelines such as the Nuremburg Code and Declaration of Helsinki's requirements with regards to

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2 *Legislation Review*, p.42. See also Dr Monique Baldwin, *Submission 57*, p.2; Gene Ethics, *Submission 106*, p.2; Professor Mackay-Sim, *Submission 178*; Dr Silburn, *Submission 180*; Associate Professor Sherley, *Submission 181*.

3 Southern Cross Bioethics Institute, Submission 16, p. 2. See also evidence of Dr van Gend (Do No Harm) Senate Committee *Hansard* 24 October 2006, pp.97-98.

4 Professor Alan Mackay-Sim, *Submission 178*, pp. 1-3. See also Submission 105 & evidence of Dr van Gend (Do No Harm) *Committee Hansard*, 24 October 2006, pp.97-98 citing publications of Professor Savulescu "Should we clone human beings? Cloning as a source of tissue for transplantation," (1999) 25 *Journal of Medical Ethics* 87, and D. Elsner, "Just another reproductive right? The Ethics of human reproductive cloning as an experimental medical procedure," (2006) 32 *Journal of Medical Ethics* 596. Elsner is from the University of Melbourne.

5 Professor John Martin, *Parliamentary Library Lecture*, 10 October 2006.

6 *Legislation Review*, p.42.

experimentation involving human subjects.[7] The Declaration of Helsinki, issued by the World Medical Association, stipulates that:

> 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 medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.[8]

4.9 Other evidence referred to and cited sections of the United States President's Council on Bioethics 2002 Report, *Human Cloning and Human Dignity*. That Report stated:

> The technical description of the cloning method (that is SCNT) omits reference not only to cloning but also to the immediate product of the activity. This obscurity enables some to argue that the immediate product of SCNT is not an 'embryo' but rather 'an egg' or 'an unfertilised egg' or 'an activated egg', and that the subsequent stages of development should not be called embryos but 'clumps of cells' or 'activated cells.' …we insist on making the effort to describe the product of SCNT as accurately and as fairly as we can.[9]

4.10 Members of the Lockhart Review gave evidence to the Committee and were asked about the inclusion of the Indian Council of Medical Research (2004) draft guidelines for stem cell research/regulation, and the omission of reference to any of the three reports (2002, 2004 & 2005) of the United States President's Council on Bioethics relating to cloning, stem cell research and alternative sources of human Pluripotent stem cells. Professor Loane Skene said:

> We had six months for our deliberations. …We did not have time to do a very extensive investigation of what was happening in other parts of the world.[10]

4.11 It was argued that these requirements, especially for proven clinical results in animal trials, had not been satisfied.[11] Professor Martin commented that the only

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7 See for example Professor John Martin, *Submission 35*, p. 2; Dr Monique Baldwin, *Submission 57*, p. 2; Catholic Archdiocese of Sydney, *Submission 100*, p. 6; Evidence of Mr Campbell (Queensland Bioethics Centre) Senate Committee *Hansard* 24 October 2006, p.98.

8 World Medical Association Declaration of Helsinki, http://www.wma.net/e/policy/b3.htm, (accessed 11 October 2006). The Nuremberg Code provides that "the experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random or unnecessary in nature."

9 Catholic Health Australia, *Submission 26*, p.4. The citation from the President's Council on Bioethics 2002 report, *Human Cloning and Human Dignity*, is from p.49.

10 *Committee Hansard*, 20 October 2006, p.6.

11 See for example Professor Alan Mackay-Sim, *Submission 178*, p. 2 & Catholic Archdiocese of Adelaide, *Submission 78*, p. 9.

scientific evidence the Lockhart Review was impressed by was that of South Korea's Dr Hwang Woo Suk.[12] Dr Hwang's claims that he succeeded in deriving stem cell lines from SCNT were later revealed to be fraudulent, including the number of eggs used in his cloning experiments. It was also later revealed that junior researchers from his laboratory were 'encouraged' to donate their eggs.

4.12 Dr Nicholas Tonti-Filippini argued that the case for SCNT had actually deteriorated since 2002:

> Nothing has changed scientifically to support some kind of new argument of necessity to use SCNT embryonic stem cells. If anything, the possibility of developing therapies involving cultured embryonic stem cell transplant has become more remote as more has become known about the difficulties.[13]

4.13 He suggested that the status quo be maintained at least until more is understood about embryonic stem cells:

> In the future, there may be some greater benefit to be obtained from using embryos, but as a matter of science it is not clear that they will be of benefit. There seems to be little reason to overturn the existing compromise supported last time by the NHMRC and by a large majority in the Parliaments. A balanced approach may be to maintain the status quo allowing access to excess IVF embryos only and then address the question of deliberately creating them for research purposes at some time if the future if and when animal models show some evidence that benefit is to be obtained from them.[14]

### *The limitations of embryonic stem cells*

4.14 The problems experienced by researchers investigating ES cells were raised, though many of these were acknowledged by proponents as issues that needed to be resolved before tangible benefits would be seen. However, while their view was that these problems would be overcome, others saw them as being more intractable.

4.15 Many opposing the bills argued that there were scientific impediments limiting the effectiveness of embryonic stem cells generally, and those derived from SCNT more specifically.

*Embryonic stem cells cause cancer*

4.16 The problem of tumour formations caused by transplanted embryonic stem cells was frequently referred to in submissions from opponents of the Lockhart

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12 Professor John Martin, *Parliamentary Library Lecture*, 10 October 2006. See also Australian Family Association, *Submission 97*, p. 20.

13 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 7.

14 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 8.

Review's recommendations.[15] Embryonic stem cells' capacity to differentiate easily - pluripotency - is seen to be one of their promising characteristics by advocates of ES cell research. However, it was highlighted as a significant problem.

4.17 Professor John Martin discussed the extent of this difficulty:

> Whatever the origin of ES cells, animal or human, whenever they are transplanted into an animal, they have up to a 25% incidence of growth of a particular type of cancer, a teratoma. No substantial progress has been made towards resolving this problem of cancer development with ES cells. This problem is sufficient by itself to exclude any possibility of using ES cells in therapy for human disease, even if there were strong indications of likely efficacy on other grounds.[16]

*Stem cell lines from SCNT are genetically unstable*

4.18 Genetic abnormalities have been a major impediment to bringing cloned animals to birth and enjoying a full life span. Dr Nicholas Tonti-Filippini described this difficulty:

> A disadvantage of SCNT embryos is that they are epigenetically compromised. That is to say, because they have been formed using the nucleus of a somatic cell, many of the gene functions that would normally be available in an embryo are not available. The latter explains the problems of immune system diseases in cloned animals such as Dolly the sheep. (Dolly was euthanased.) It may also explain why it has proved to be so difficult to clone some animals, including humans.[17]

4.19 Clinical neurologist, Dr Silburn, stated in evidence to the Committee:

> …[embryonic stem] cells are genetically and epigenetically unstable and the resources are not there in either human or other.[18]

4.20 Professor Martin indicated that the abnormalities in gene expression that have plagued efforts to clone animals to birth would affect ES cell lines also derived from SCNT.[19]

*Embryonic stem cells are difficult to control*

4.21 Because of their pluripotent character, ES cells present the difficulty of being difficult to maintain in any given differentiated state. Professor Martin described this

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15 See for example, Catholic Archdiocese of Sydney, *Submission 100*, p. 7.

16 Professor John Martin, *Submission 35*, p. 2.

17 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 6.

18 *Committee Hansard*, 20 October 2006, p.25.

19 Professor John Martin, *Submission 35*, p. 3.

phenomenon succinctly: 'they want to become other cells'.[20] Dr Joe Santamaria submitted:

> It is known that cell lines established from such embryonic stem cells tend to undergo genetic drift or changes as successive populations are generated from the original cloned cell.[21]

### *Adult stem cells provide greater hope*

4.22 Another common argument against allowing SCNT is best expressed as a rhetorical question: why would we cross this ethical line when adult stem cells promise so much hope for curing a number of diseases? This view held that there is no need to pursue 'unethical' avenues of research when adult stem cells are already used in clinical treatments and are continuing to offer a number of breakthroughs.

4.23 Those in favour of pursuing adult stem cell research *instead* of, rather than in conjunction with, embryonic stem cells highlighted that adult stem cells were not as erratic and unpredictable and therefore did not pose the same difficulties as those discussed above.

4.24 Professor Alan Mackay-Sim, a molecular biologist from Griffith University, rejected claims that adult stem cells lacked sufficient plasticity. He described their benefits as follows:

> Adult stem cells from numerous sources (e.g. bone marrow, olfactory mucosa, skin, hair follicles, muscle, fat) have been shown in numerous independent laboratories to develop into cells not normally found in the originating tissues and, despite the rhetoric to the contrary, some develop into most cell types of the body. Adult stem cells are currently used in human therapies and there are numerous animal studies demonstrating their efficacy in a variety of animal models of disease and injury such as spinal cord injury, stroke, Parkinson's disease and cardiac ischemia. The scientific evidence for the therapeutic potential of adult stem cells in currently incurable diseases is as strong for adult stem cells as it is for embryonic stem cells with two major differences. Adult stem cells do not form teratomas and they can avoid immune rejection when derived from and transplanted into the same person.[22]

4.25 He added that adult stem cells were also much easier to access for research:

> A justification for therapeutic cloning is that is will provide cellular models of incurable diseases such as motor neuron disease. It certainly has this potential but the potential is limited compared to adult stem cells. Adult stem cells are available in all adults and are much easier to propagate than embryonic stem cells. Even if therapeutic cloning were possible the

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20 Professor John Martin, *Parliamentary Library Lecture*, 10 October 2006.

21 Dr Joe Santamaria, *Submission 25*, p. 4.

22 Professor Alan Mackay-Sim, *Submission 178*, pp. 2-3.

> logistics of producing cloned cells would preclude making cells lines from many patients. This will limit the utility of this approach in discovering causes common to all persons with the disease. The ease of adult stem cell production obviates this problem.[23]

Dr Silburn stated:

> One of the specific areas to mention is that people seem to have the notion that adult stem cells are not capable of generating many different cell types and that it is necessary to clone to generate different cell types. This is incorrect.
>
> …If you have a galloping horse like adult stem cells, why not pursue that? I cannot see the big argument with the necessity for cloning. Why I am here is to say that cloning is not necessary …[24]

4.26 Associate Professor of Biological Engineering at the Massachusetts Institute of Technology, Professor James Sherley, described the different roles of the two cell types and how this affects their capacity to be used to develop cellular therapies. He wrote:

> Mature functional cells are short-lived. Within days to weeks, they die and are lost from the tissue. Therefore, they must be continuously replenished or "renewed" without the tissue losing the instructions for their elaboration. Adult stem cells accomplish this function by a process called asymmetric self renewal. When an adult stem cell divides to make two cells, one cell is a "worker" cell that multiplies to become the short-lived mature functional cells. The other cell is a new adult stem cell that retains the gene instructions for how to elaborate more worker cells.
>
> For success, any proposed approach to disease therapies for tissues in children and adults must be able to sustain the essential renewal process of adult tissues. Only adult stem cells can accomplish this feat. Embryonic stem cells cannot, because they lack the property of asymmetric self-renewal.[25]

4.27 Some evidence framed the argument in terms of allocating resources in the most efficient manner:

> In a society where research funding is limited, it makes more public policy sense to allocate scarce resources to those areas of research that hold the best promise and have evidence to justify funding. Adult stem cell research is by far the most appropriate field to support.[26]

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23 Professor Alan Mackay-Sim, *Submission 178*, p. 3.

24 *Committee Hansard*, 20 October 2006, pp.24- 25.

25 Professor James Sherley, *Submission 181*, p. 4.

26 Catholic Health Australia, *Submission 26*, p. 9. See also Professor James Sherley, *Submission 181*, p. 4, and the testimony of Dr Silburn, Senate Committee *Hansard*, 20 October 2006, pp.25 & 26.

4.28 Reference was made to a Japanese clinical trial in which induced adult mouse cells can be reprogrammed into pluripotent stem cells by introducing four specific genes.[27] A number of submitters highlighted this as a breakthrough that could circumvent the need for SCNT.[28] Professor Martin described it as 'an exciting proof of concept that a pluripotent cell could be generated from an adult cell without cloning'. If able to be refined to the point where the results could be replicated in human cells, he suggested this reprogramming technique could potentially obviate the problems, ethical and logistical, associated with SCNT-derived stem cells.[29] In discussing the Japanese study, Dr Silburn commented: 'We are talking about cloning. Do we need to clone to get adult cells to try and treat disease? No, we do not'.[30]

***The egg supply problem***

4.29 Finally, objections to SCNT were raised because the supply of human eggs would simply not be sufficient to undertake research on ES derived in this way. They articulated concerns that the subsequent new demand for human eggs, without accompanying health benefits to the donor, would lead to the unethical sourcing of eggs from vulnerable women including the possible commodification of human eggs.

4.30 The Lockhart Review's approach to this supply problem, which they acknowledged, was to permit the use of animal eggs as a replacement. This was criticised by some respondents, who questioned either the morality or usefulness of allowing such a procedure. Evidence to the Committee confirmed that researchers could not quantify how many eggs would be required for research. For example, in answer to a question '…do you think there are enough eggs to do all the potential research that you want to do?' Professor Jenkin from Monash Immunology and Stem Cell Laboratories said 'No'. Associate Professor Elefanty, from the same laboratory, said:

> That is not a question which is easy to answer, simply because there has not been the opportunity to actually determine what the requirements would be for this sort of research.[31]

4.31 Ms George, from Women's Forum Australia, stated in evidence:

> What we can see from overseas is that it is impossible to obtain near sufficient supplies of ova without offering women some sort of commercial incentive. …If cloning is opened up in this country, it then creates demand

27 Takahashi and Yamanaka, Induction of Pluripotent Stem Cells from Mouse Embryonic and adult Fibroblast Cultures by Defined Factors, *Cell*, 126, pp. 663-676, 25 August 2006.

28 See for example Dr Monique Baldwin, *Submission 57*, p. 1; Caroline Chisholm Centre for Health Ethics, *Submission 68*, p. 4.

29 Professor John Martin, *Submission 35*, p. 3.

30 *Committee Hansard*, 20 October 2006, p.27.

31 *Committee Hansard* 24 October 2006, p.72.

> for ova and, as I said, overseas experience would suggest that that can only be satisfied by paying women to undertake these risks.[32]

*Egg donation risks*

4.32 The Women's Forum of Australia (WFA) said that SCNT should not be allowed while its proponents had failed to ensure the safety of egg donors:

> Since research cloning is impossible without access to thousands of women's ova, advocates of this research bear the onus of demonstrating that sufficient ova can be sourced without harm to women. They have failed to discharge this onus.[33]

4.33 The WFA submission described the unpleasant experience of donating eggs:

> Extracting sufficient ova can only be achieved with high doses of ovulation stimulating agents.
>
> Women describe the extraction process as invasive and uncomfortable, requiring several clinic visits and multiple injections of hormones. Often a dozen or more eggs are produced at a time, instead of the usual one or two per cycle.[34]

4.34 The Feminist International Network of Resistance to Reproductive and Genetic Engineering (FINRRAGE) submitted that it was unethical to harvest eggs from women with no associated health benefit.[35]

4.35 According to WFA, the process of stimulating the ovaries to produce large numbers of eggs at a time was in fact no longer best practice for IVF clinics:

> The proposal is...contrary to recent developments in fertility technology that are moving towards minimal stimulation IVF where only one ovum at a time is extracted. In this patient-friendly procedure only low doses of hormones are administered for only a few days causing few side effects. Retrieval of the egg is comparatively quick and easy and can be performed without analgesia…
>
> Hyper-stimulating IVF patients to produce extra eggs for research might benefit the researchers but it is against the best interests of the women patients when less intrusive techniques are now available.[36]

4.36 It was argued that the process was not only unbeneficial and unpleasant, but unsafe. WFA described short term symptoms ranging from pain, hot flushes, nausea and vomiting to more serious symptoms associated with ovarian hyper stimulation

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32 *Committee Hansard*, 24 October 2006, p.60.

33 Women's Forum of Australia, *Submission 80*, p. 2.

34 Women's Forum of Australia, *Submission 80*, p. 3.

35 FINRRAGE, Submission 32, p. 2.

36 WFA, *Submission 80*, p. 10.

syndrome that can require hospitalisation.[37] It was also claimed that the long-term risks of the drugs used to stimulate ovulation were unknown, and that some had been implicated in the development of cancer.[38]

*Ensuring informed consent*

4.37 Given the absence of health or fertility imperatives for donating eggs for SCNT research, the prospect that women may be improperly pressured to do so was raised. IVF patients, who already supply eggs for their own fertility treatment, were identified as being particularly susceptible.

4.38 Dr Sheryl de Lacey, from the Research Centre for Reproductive Health at the University of Adelaide, suggested that women in the general community were unlikely to volunteer to donate eggs. As such, women undergoing IVF treatment were vulnerable to 'recruitment strategies' for egg donation that may not serve their best interests. Dr de Lacey submitted:

> Research has so far relied on the donation of embryos that are excess or surplus to a patient's treatment. But there is no such thing as a 'surplus' egg. Every egg collected represents a potential embryo and a potential pregnancy for an infertile woman. Donating eggs to research during treatment is likely to reduce the woman donor's chance of success thereby increasing her risk of ongoing childlessness, her use of ART and elevating the costs involved, and thereby risking harm to her.[39]

4.39 Although supportive of permitting SCNT, Professor Wendy Rogers stressed the importance of the consent process ensuring donors were fully informed:

> Because of the potential risks to women, women donating oocytes or other tissues for research should be offered all relevant information about the likely use of their donation, including details about likelihood of production of patentable products and profits, and whether profits will accrue to the public or private sector. Women seeking fertility treatments may be unusually vulnerable in terms of feeling dependant upon staff and technology and therefore fell obliged to consider donating eggs if requested.[40]

4.40 FINRRAGE questioned whether informed consent was possible in the context of existing power imbalances and expressed concern that 'reimbursement' could in fact equate to 'payment' for poorer women:

> Although women may not be physically forced to 'donate' eggs, women's decisions take place in particular social contexts, in which there are often significant imbalances in power between women and a) the researchers who

37 WFA, *Submission 80*, pp. 3-4.

38 See for example Dr Con Pelanki, *Submission 49*, p. 2; WFA, *Submission 80*, pp. 4-5.

39 Dr Sheryl de Lacey, *Submission 27*, p. 3.

40 Professor Wendy Rogers, *Submission 67*, p. 2.

> want embryos to pursue their research; and, b) the companies looking to cash in on a biotechnology investment that may be worth millions, especially when they can 'patent' the products from women's eggs...
>
> Reimbursement of women's 'expenses' or 'inconvenience' for 'donating' ova may not seem profitable to the people considering this legislation, but it can represent a substantial sum of money to poorer women, particularly students and unskilled or unemployed women. These are women who may not otherwise be able to earn extra money in any other way.[41]

4.41 WFA commented that:

> Already, with cloning research only in its infancy, all indications are that this research is not practicable without the commercial sale of ova. In the UK extensive publicity campaigns have failed to recruit sperm and egg donors without commercial payment (Mc Laughlin 1998).[42]

4.42 The Sydney Diocese of the Anglican Church expressed the view that sidestepping the usual 14 day cooling off period to allow fresh embryos to be obtained for research could generate undue pressure to donate. The Diocese submitted:

> ...if consent for research were to be given immediately, it would be difficult to ensure that there was no coercion involved, given the time-pressure for decision-making. One would also want to be convinced that the persons responsible, at such an early stage of treatment when they will be extremely vulnerable and expecting treatment to be successful, were completely sure they have no further use for the embryos, especially considering the research mentioned above regarding the non-correlation of appearance and viability of embryos. Would the less-perfect embryos still be considered 'excess' if the implantation of apparently more suitable embryos proved unsuccessful? If prospective parents' choice was between a less perfect embryo and none at all, it is highly likely that some would deeply regret the relegation of these embryos to research. The decision is therefore too complex to make quickly and in advance of knowing the results of treatment.[43]

4.43 The proposed change to the consent regime to enable 'unsuitable' fresh ART embryos to be used for research is discussed later in the chapter.

*Alternative egg sources*

4.44 Recognising the difficulties of obtaining a sufficient supply of human eggs, the Lockhart Review recommended allowing SCNT using animal eggs. However, aside from the moral objections expressed by some submitters, others expressed doubt over the effectiveness of the practice, particularly when embryonic stem cells derived

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41 FINRRAGE, *Submission 32*, p. 7.

42 WFA, *Submission 80*, p. 12.

43 Anglican Church, Sydney Diocese, *Submission 41*, p. 5.

from an animal egg would contain animal DNA. This would, according to the objections raised, produce results that could be misleading and would certainly be unsuitable for any clinical treatment.

4.45 The Southern Cross Bioethics Institute wrote:

> So far the only alternative to the many thousands of human eggs required for even the most rudimentary cloning experiments is using animal eggs. Creating hybrid embryos is not only an ethical Pandora's box in its own right, but rests on a naïve assumption that inserting the human nuclear genome into an extraordinarily complex structure with very different cytoplasmic machinery to that in the human egg, will produce a comparable result. The level of scientific knowledge about the interaction between genes and their cytoplasmic environment is very preliminary. We can only guess at the possible result of transferring human nuclei and animal oocytes.[44]

4.46 Dr Peter McCullagh concurred: 'studies within one (non-human) species would be much more likely to provide interpretable data than those obtained in highly contrived inter-species hybrid experiments'.[45]

4.47 Dr Klein, from FINRRAGE, and Mr Phelps, from Gene Ethics Network, both expressed concerns about egg harvesting. Mr Phelps put it in slightly wider context, saying that 'We do bridle at the term 'therapeutic cloning'. There is no evidence that this is therapeutic. It seems designed to divert our attention from the broader activities and implications: egg harvesting, destructive experimentation and drug testing and development'.[46] The Catholic Archdiocese of Adelaide highlighted the egg supply dilemma faced by researchers in this field:

> While possessing the DNA from the somatic cell donor, the entity would also possess the animal DNA found in the mitochondria.
>
> This mixture of DNA would render any ESCs harvested as probably useless for therapeutic outcomes. Even though the majority DNA would be histocompatible, the introduction of non-human DNA could result in unforeseen consequences.
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> It would seem, therefore, that any legislative outcome from Lockhart will find itself with a dilemma: For the sake of women's health, the harvesting of great numbers of human oocytes should be avoided; yet the alternative is problematic and probably unacceptable to the great majority of Australians.[47]

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44 Southern Cross Bioethics Institute, *Submission 16*, p. 3.

45 Dr Peter McCullagh, *Submission 85*, p. 5.

46 *Committee Hansard*, 24 October 2006, p.101 (Mr Phelps); pp.99-100 (Dr Klein).

47 Catholic Archdiocese of Adelaide, *Submission 78*, p. 10. See also Do No Harm, *Submission 105*, p. 13.

4.48 Despite being generally supportive of the Lockhart Review's recommendations, the Australian Stem Cell Centre offered only mixed support for the practice:

> The ASCC prefers the use of human eggs to animal eggs in SCNT experiments that involve a human nuclei (somatic cell). The Centre believes there is limited merit in inserting human nuclei into an animal egg. In addition, due to the scarcity of human eggs, the Centre believes that, ideally, preparatory training for scientists in the technique of SCNT should occur using animal eggs with animal nuclei until such time that a very high standard of technical capability has been achieved.[48]

4.49 Professor Bob Williamson, Chair of the National Committee for Medicine at the Australian Academy of Science, also suggested that the practice of using animal eggs would only be beneficial for training purposes, in order to ensure that human eggs are not wasted.[49]

## The slippery slope

4.50 Opponents of these bills regularly argued that allowing SCNT would, after a period of time, lead to calls for more drastic research activities to be legalised. They were sceptical that a line would be drawn at SCNT, particularly after it was rejected by the Parliament in 2002.[50]

4.51 The Southern Cross Bioethics Institute claimed that the utilitarian nature of the arguments for change rendered further calls for destructive research on embryos likely:

> ...there is little reason why attempts will not be made to argue for more and more extreme practices to be justified on the grounds of possible benefit. That is precisely what is happening here, even though the potential benefit is as yet unproven.
>
> Second, what grounds does the community have for believing those who previously firmly stated their opposition to both therapeutic and reproductive cloning on ethical grounds, but who now state that one form, that is, therapeutic cloning, has become acceptable to them? If those same proponents now claim to be opposed to reproductive cloning on ethical grounds, the community could be forgiven for being sceptical. That is the nature of utilitarian ethics.[51]

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48 Australian Stem Cell Centre, *Submission 63*, p. 6.

49 Professor Bob Williamson, *Parliamentary Library Lecture*, 11 October 2006.

50 Medical law text books question how long legislative bans on reproductive cloning can be maintained. For example, see *Law and Medical Ethics*, Seventh Edition, (J.K. Mason; G.T. Laurie) (Oxford: Oxford University Press, 2006) p.252: "We suspect that the days of the outright prohibition on reproductive cloning are numbered."

51 Southern Cross Bioethics Institute, *Submission 16*, p. 2.

4.52 The Australian Family Association predicted that biotechnologists would seek to be allowed to develop cloned embryos beyond 14 days, or have them implanted into a woman.[52] Many feared that allowing SCNT would inevitably lead to reproductive cloning.[53] The Southern Cross Bioethics Institute was concerned that SCNT would give valuable practice to those wishing to create a living clone:

> Research on cloning human embryos is inextricably connected to bringing clones to birth. Regardless of the legislative restrictions on 'reproductive cloning', the groundwork will be laid for those in other settings who will implant cloned embryos for development to birth. If this legislation is passed, government funded research that results in the refinement of procedures for producing cloned human embryos will be taken up by others who are intent on producing born human clones. This needs to be acknowledged as a real consequence of such legislative permission.[54]

4.53 Some respondents predicted that another future review would create pressure for further concessions.[55] Among them was Festival of Light Australia:

> 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.[56]

4.54 WFA focussed on what they saw as an emerging commercial market for human gametes. They asserted that the commodification of human eggs would occur due to an absence of willing, altruistic, donors.

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52 Australian Family Association, *Submission 97*, p. 22.

53 See for example Do No Harm, *Submission 105*, pp. 14-15. Evidence of Dr van Gend citing D. Elsner, "Just another reproductive technology? The ethics of human reproductive cloning as an experimental medical procedure," (24 October 2006) 32 *Journal of Medical Ethics* 596-600.

54 Southern Cross Bioethics Institute, Submission 16, p. 3. See also Anglican Church, Sydney Diocese, *Submission 41*, p. 8; Catholic Archdiocese of Melbourne, *Submission 108*, p. 4. Dr. McCullagh, *Submission* 85 quotes prominent philosopher and IVF advocate, Baroness Warnock, in relation to the "14 day marker" as indicating that it was at that time "that I became me." In 2002 she asked rhetorically "Would the cloning of humans be intrinsically wrong?" See Mary Warnock, *Making Babies: Is there a right to have children?* (Oxford: Oxford University Press, 2002) pp.102-108. Australian researchers have very recently pursued the same argument in favour of reproductive cloning. See D. Elsner, "Just another reproductive technology? The ethics of human reproductive cloning as an experimental medical procedure," (24 October 2006) 32 *Journal of Medical Ethics* 596-600. Elsner is from the University of Melbourne.

55 See for example Gene Ethics Network, *Submission 106*, p. 5.

56 Festival of Light Australia, *Submission 34*, p. 16.

## Other changes opposed

4.55 Other proposed changes to the regulation of this area of research also received critical comment. They related to:

- The inappropriateness of the proposed new definition of a human embryo and its potentially adverse effect on regulating research on embryos; and
- The problems associated with attempting to define 'unsuitable' fresh embryos that could be donated for research.

### *Legislative definition of an embryo*

4.56 The earlier discussion on the proposed new definition of an embryo related to claims that arbitrary legislative distinctions were being sought to confuse peoples' understanding of the nature of the activities, currently unlawful, proposed to be allowed. These arguments were based on the premise that the proposed definition bore no relationship to the reality of when an embryo starts; merely representing a legislative strategy to access certain research techniques.

4.57 There was significant conflict in evidence before the Committee, and among Committee members, regarding the definition of 'embryo' and 'cloning'. Some, such as the Coalition for the Advancement of Medical Research in Australia (CAMRA) (Submission 21) and SpinalCure Australia (Submission 29), both contend that 'SCNT is not cloning'. This is contrary to standard medical dictionaries, such as Stedmans and Dorlands. Some members of the Committee, such as Senator Ferris, suggested to witnesses that there was a fundamental difference between an embryo created by the fusion of sperm and ovum, on the one hand, and an embryo created by SCNT or therapeutic cloning. Such a distinction was denied as relevant by many witnesses.[57]

4.58 Professor Skene, Deputy Chair of the Lockhart, also did not accept this distinction, saying: 'We did not shy away from calling it an embryo because it is conceiveable, as happened with Dolly the sheep, that if that entity were put into a woman, after a lot of care, it could in fact develop into a foetus'.[58]

4.59 In addition to those complaints, it was argued that the scientific basis of the definition is flawed, that it was prematurely lifted from a working document and that it could have unintended consequences for the regulation of this research field.

*The source of the definition*

4.60 Firstly, the argument was made that it was inappropriate to use a definition that was still a work in progress as the definition of a human embryo in the legislation regulating this area of research. In its submission to this inquiry the NHMRC indicated that their 'discussion paper' definition had not been formally endorsed:

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57 Evidence of Dr van Gend, *Committee Hansard*, 24 October 2006, p.104; Dr Klein, p.105.

58 *Committee Hansard*, 20 October 2006, p.9.

> ...in December 2005 the National Health and Medical Research Council released the final report of the Biological Definition of Human Embryo Working Party as a discussion paper. The definition of "human embryo" provided in that discussion paper (Attachment B) was not endorsed by the NHMRC.[59]

4.61 Dr Nicholas Tonti-Filippini contended that it was premature for the Lockhart Review to rely on a definition that was mooted in a NHMRC discussion paper:

> ...the proposed biological definition has not been promulgated by the NHMRC but has only been made available as a discussion paper prepared by an NHMRC Working Party. As far as I am aware, the NHMRC has not altered the position taken on this matter in the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* developed by the Australian Health Ethics Committee. The guidelines were issued at the 154th Session of the NHMRC in 2004. The Australian Health Ethics Committee has statutory responsibility for developing ethical guidelines for medical research. The new proposed biological definition of the embryo has not been developed in a way that is consistent with the ethical guidelines. Its use in this way is thus premature and problematic for the existing guidelines.[60]

4.62 Dr Peter McCullagh commented on the lack of consultation that the discussion paper definition was intended to elicit. He said:

> The selected definition is derived from a discussion paper, 'Human Embryo' – A Biological Definition, released by the NHMRC in December, 2005. This paper presents considerable background information on the subject of embryological nomenclature with the intention, expressed in its Preface, of eliciting comment from a 'wider audience'. The incorporation of its definition in legislation in the apparent absence of any widespread debate to inform the Parliament of community attitudes on its specific features could be regarded as inappropriate.[61]

*Part (a) of the definition*

4.63 Another source of opposition to the proposed definition was disagreement over the starting point of an embryo created by fertilisation of a human egg by a human sperm. In the opinion of many, the embryo exists once the sperm and the egg are united, not at an arbitrarily defined point that occurs afterwards.[62] The Southern Cross Bioethics Institute's submission stated:

> Regardless of the terminology used, the new entity created by union of sperm and egg or by any other means is developmentally continuous in time

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59 NHMRC, *Submission 168*, p. 4.

60 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 2.

61 Dr Peter McCullagh, *Submission 85*, p. 1.

62 See for example Catholic Archdiocese of Melbourne, *Submission 108*, p. 2.

> and should not be treated differently because of an arbitrary selection of a time at which greater moral significance is said to arise.[63]

4.64 Dr Nicholas Tonti-Filippini agreed:

> The mitotic division is not the beginning of the new entity, but something that occurs in an entity which already has a completed human genome and which is already organised for further development.[64]

4.65 Dr Joe Santamaria submitted that the definition lacked scientific credibility:

> It bears no resemblance to any definition of the human embryo found in the standard textbooks on Human Embryology.[65]

4.66 The Sydney Diocese of Anglican Church queried the Lockhart Review's justification for choosing one identifiable marker over another, more logical one:

> We do not see evidence of why the completion of fertilisation, rather than its beginning, is used to define the starting point of fertilised embryonic life. The text of the Lockhart Report suggests that the primary purpose of this change is to allow recommencement of research during the early stage of fertilisation, rather than being based upon any biological criteria (see p.xv). However, precisely these restrictions on research were identified in the debate prior to the passing of the 2002 legislation, so it is unclear how they can now be seen as having 'apparently unintended consequence(s) of impeding valuable research and clinical practice in ART clinics'(p. xv).[66]

4.67 The Diocese further submitted that if research on fertilised eggs was to be permitted, then these activities should remain under the scrutiny of the Licensing Committee of the NHMRC.[67] Similarly, the Caroline Chisholm Centre for Health Ethics and the Catholic Archdioceses of Sydney and Melbourne expressed concern that fertilised eggs could be experimented on until the two-cell stage without regulatory oversight.[68]

4.68 Dr Peter McCullagh suggested that defining the embryo from the first observable marker after fertilisation has occurred would be overtaken by technological advancement, explaining that:

> ...the placement in time of any developmental point is entirely at the mercy of the technology which is available at the time to recognise when that

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63 Southern Cross Bioethics Institute, *Submission 16*, p. 3.

64 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 3.

65 Dr Joe Santamaria, *Submission 25*, p. 6.

66 Anglican Church, Sydney Diocese, *Submission 41*, p. 3.

67 Anglican Church, Sydney Diocese, *Submission 41*, p. 3.

68 Caroline Chisholm Centre for Health Ethics, *Submission 68*, p. 6; Catholic Archdiocese of Sydney, *Submission 100*, p. 8; Catholic Archdiocese of Melbourne, *Submission 108*, p. 2.

> point has been attained. Inevitably, the time of recognition will move closer to the actual time of occurrence of the event as science advances.

He thought that a more appropriate 'marker event' to demonstrate the existence of a new entity would be the release of Early Pregnancy Factor (EPF):

> This entails amplification of the message (I'm here) by a 'cascade' mechanism with resemblance to that responsible for blood coagulation. EPF is produced at the single cell stage of development and Morton has demonstrated its appearance within 6-24 hours of a fertile mating. I suggest that it is a much more sensitive indication of the appearance of a new entity (historically referred to as an embryo) than any other. It certainly represents a recognition signal which is observable much closer to the event it signifies than any other.[69]

*Part (b) of the definition*

4.69 Concerns were also raised about the possible consequences of the second part of the proposed new definition. The use of the phrase 'has the potential to develop up to, or beyond, the stage at which the primitive streak appears', has led some to believe that embryos created through SCNT could be placed outside the regulatory framework altogether.[70]

4.70 Dr Tonti-Filippini explained the significance of the word 'potential' in the context of creating embryos for destructive research:

> The definition is open to the interpretation that an embryo that is never to be transferred to the uterus of a woman lacks the potential to form a primitive streak. The formation of a primitive streak depends on implantation. Thus the second part of the definition would allow an interpretation that a cloned embryo was only an embryo if it is to be implanted. Thus it would be permissible, using this definition, to form embryos by cloning, as long as they were not to be transferred into an environment where it would be possible for implantation to occur and development to the stage of the formation of a primitive streak. Those unimplanted, cloned embryos would then be completely outside the regulatory framework established by the guidelines and by the proposed legislation.[71]

4.71 He, as well as the Catholic Archdiocese of Sydney, suggested the following:

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69 Dr Peter McCullagh, *Submission 85*, pp. 2-3.

70 See for example Queensland Bioethics Centre, *Submission 31*, p. 4; Catholic Archdiocese of Adelaide, *Submission 78*, p. 13.

71 Dr Nicholas Tonti-Filippini, *Submission 15*, pp. 3-4.

> The second part of the definition at least needs a qualifier such as adding the words "if placed in a suitable environment" after the words "potential to develop".[72]

4.72 In his submission, Dr Tonti-Filippini also speculated that researchers may intentionally disable the embryo such that it could not reach the primitive streak stage currently proposed in the bills. Accordingly, he suggested the point of distinction be moved to the blastocyst stage.

### *Fresh 'unsuitable' ART embryos*

4.73 Argument in support of researchers accessing currently discarded fresh embryos is included earlier in the chapter. However, a number of submissions expressed doubt over the appropriateness of objectively defining embryos as 'unsuitable' for implantation, which could then be made freshly available for research.[73] In particular, concerns were raised over the practical difficulty of making such an assessment, as well as the potential for viable embryos to be donated contrary to the best interests of the patient's fertility treatment.

4.74 The Sydney Diocese of the Anglican Church commented:

> We are surprised that this category of embryo has been recommended for inclusion as according to research it does not exist. While there have been suggestions that there is some correlation between the external appearance of an embryo and its likelihood of implantation and successful development, research has previously shown that appearances can be misleading. Some unhealthy-looking embryos implant and develop successfully while some healthy-looking embryos fail to implant or have developmental problems. We are not aware of any method of embryo assessment that has been proven effective or valid in terms of predicting the viability of ART problems. If there are viable cells present, some clinicians would consider going ahead with uterine transfer, despite unfavourable morphology, considering this the only way to determine true viability.[74]

4.75 As a consequence of the difficulty of making such a judgment, the Southern Cross Bioethics Institute doubted the likely objectivity of such a process:

> In one of the Bills, the permission granted to use ART embryos deemed unfit for implantation amounts to the selective destruction of embryos on grounds that it is difficult to imagine would be entirely objective. If that is

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72 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 4; Catholic Archdiocese of Sydney, *Submission 100*, p. 8. See also Pro-Life Victoria, *Submission 43*, p. 4.

73 Subject to proposed changes to the consent process, ie removing the 14 day cooling off period in some circumstances. See the committee's discussion of Lockhart Review recommendations 20-22.

74 Anglican Church, Sydney Diocese, *Submission 41*, p. 4.

> the case, then an element of subjectivity could be used to enhance the supply of embryos for programmes when the supply is failing.[75]

4.76 Dr Peter McCullagh offered an alternative suggestion:

> I disagree with this recommendation on the basis that to tamper with the general recommendation for an adequate 'cooling off' period in order to overcome one specific difficulty is a bad approach (the 'What never – well, hardly ever' solution). If the Senate believes that these 'unsuitable for implantation' embryos could advance research, it is preferable to arrange its legislation so that they may legitimately be declared as 'excess' so permitting their cryopreservation followed by incorporation of the regular incorporation of an appropriate 'cooling off' period before use.[76]

4.77 The NHMRC noted a lack of clarity over its potential responsibility in this regard. It submitted that while the Lockhart Review had recommended that they 'develop ethical guidelines for the use of embryos that are unsuitable for implantation',[77] the recommendations did not propose any NHMRC requirement to develop objective criteria upon which such an assessment of unsuitability would take place.[78] Recommendation 22 in the Lockhart Review suggests this be left to 'an expert body'. However, Senator Patterson's Bill stipulates that the criteria should be 'specified in guidelines issued by the CEO of the NHMRC'.[79]

4.78 Finally, fertility advocates expressed concerns that the implementation of this proposal could have implications for IVF treatment procedures. The Fertility Society of Australia suggested:

> The determination of objective criteria for "unsuitable for implantation" could have significance upon ART. The concern being that anything deemed not "unsuitable for implantation" by the objective criteria is suitable for implantation. What implications will this have to the person undertaking treatment?[80]

### *Number of excess IVF embryos and embryos from cadavers and aborted foetuses*

4.79 The Lockhart Report addressed the problem of sourcing sufficient donated eggs for SCNT and related technologies. Reference was made to the harvesting of eggs from cadavers and aborted foetuses,[81] though these were not formal recommendations.

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75 Southern Cross Bioethics Institute, *Submission 16*, p. 4.

76 Dr Peter McCullagh, *Submission 85*, p. 6.

77 See Lockhart Review Recommendation 30.

78 NHMRC, Submission 168, p. 4.

79 Schedule 2, Item 4.

80 Fertility Society of Australia, *Submission 40*, p. 2. Also ACCESS, *Submission 176*, p. 2.

81 For example, *Legislation Review*, p.176.

4.80 A number of witnesses questioned both the ethics and medical safety of using eggs harvested from cadavers or aborted foetuses, as well as such suggestions being completely contrary to the Parliamentary debate and agreement in 2002. It appears no gauging of community reaction to such concepts was attempted by the Lockhart Review.

4.81 These practices are, however, permitted under the Patterson Bill.[82]

## The Lockhart Review Committee's preconceived approach

4.82 Two main contentions emerged with regard to the composition and conduct of the Lockhart Review Committee. The first was that it was initially 'stacked' with members predisposed to supporting the legalisation of the activities their recommendations ultimately suggested be permitted. The second was that this inherent bias was confirmed by the way the Lockhart Committee approached its terms of reference, particularly with regards to changing community attitudes in this area and the scientific evidence that had emerged since the original Acts were passed.

### *Lockhart Committee 'stacked'*

4.83 The Lockhart Review Committee was appointed in June 2005 by the then Minister for Ageing the Hon. Julie Bishop MP. The Lockhart Review stated that, in accordance with the Acts, these appointments were agreed to by each State and Territory. However, a number of submissions expressed the view that at least some of the Lockhart Review Committee held known, pre-conceived, views on the issues central to this debate. Many provided examples of quotes from Lockhart Review Committee members, articulated prior to the human cloning debate in 2002, and advocating the potential benefits of therapeutic cloning, or SCNT.[83]

3.162 The Queensland Bioethics Centre blamed the COAG selection process for a lack of diverse views on the Lockhart Review,[84] while the Australian Family Association viewed the Review's attitude to opponents of change as 'dismissive':

> ...the statement by the Chairman of the Review, Justice John Lockhart, that the Committee's task was "...to strike a balance between emotional reaction and rational progress" further compromised the neutrality of the Review. In reading the Review's Issues Paper and its Report, it becomes very apparent that the use of the words "emotional reaction" was indicative of a dismissive attitude at the outset to those in favour of the current legislative restrictions.[85]

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82 See the exchange between Senator Moore and Dr van Gend, *Committee Hansard*, 24 October 2006, pp.110-111.

83 See for example Family Council of Queensland Inc, *Submission 89*, p. 2; Do No Harm, *Submission 105*, p. 23; Coalition for the Defence of Human Life, *Submission 23*, p. 2.

84 Queensland Bioethics Centre, *Submission 31*, pp. 2-3.

85 Australian Family Association, *Submission 97*, p. 8.

4.84 Associate Professor of Biological Engineering at the Massachusetts Institute of Technology, James Sherley, queried the technical expertise of the Lockhart Committee:

> There was no one with stem cell science expertise on the Lockhart Committee. To external reviewers, it seems unthinkable that the Australian Parliament would have charged such a poorly outfitted group with the responsibility of rendering such a crucial document for the debate on human embryo cloning research. Although the Committee reports that it interviewed stem cell scientists, the absence of such official expertise on the Committee proper is such an unbelievable oversight that it calls into question the integrity of the selection process and the quality of the Report. Thus, the absence of stem cell expertise on the Lockhart Committee is viewed to be sufficient cause to disallow the recommendations of the Report in the current debate.[86]

### *Demonstrated bias*

4.85 A number of submitters complained that the Lockhart Review cherry-picked the surveys they used to convey community attitudes on therapeutic cloning. Many also criticised the Lockhart Review for failing to highlight that a majority of submissions to their review expressed opposition to SCNT, or therapeutic cloning.

4.86 Opponents of the Lockhart recommendations claimed that two surveys in particular were ignored in the Lockhart report, while one that produced a favourable result for SCNT advocates, a Morgan telephone poll was quoted.[87] For instance, the Queensland Bioethics Centre submitted that:

> The Lockhart Committee's approach to community standards was novel and not scientifically based. A Swinburne University study published in 2004 clearly indicated that the majority of Australians were not comfortable with scientists cloning human embryos for research purposes. Although this research was available to the Lockhart Committee, no reference is made to it. A more recent study by the Sexton Marketing Group for the Southern Cross Bioethics Institute gave a similar result.
>
> There would appear to be no grounds for asserting that community standards have changed since 2002.[88]

4.87 Professor Martin stated that the premise of the Morgan Poll, that stem cells had in fact already been derived from SCNT, was false and misleading.[89] The Catholic Archdiocese of Melbourne criticised it for omitting particular key phrases:

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86 *Submission 181*, p. 2.

87 See for example Australian Family Association, *Submission 97*, p. 8.; Do No Harm, *Submission 105*, p. 27. The details of this survey can be found at http://www.roymorgan.com/news/polls/2006/4036/, (accessed 16 October 2006).

88 Queensland Bioethics Centre, *Submission 31*, p. 3.

89 Professor John Martin, *Submission 35*, p. 4.

> A recent Morgan Poll claimed 80% public support for the extracting of embryonic cells from human embryos. However such claims are unreliable, and misleading given that the public is told that embryonic stem cells are made by "merging an unfertilised egg with a skin cell, in which case no fertilisation and no merger of the egg and sperm takes places." No mention here of cloning or that a new human life has been manufactured. Certainly no mention of the word 'embryo'.[90]

4.88 The Caroline Chisholm Centre for Health Ethics contrasted this survey with the result of the Swinburne University study,[91] which was the outcome of a process that provided information to its participants prior to measuring their opinions:

> It is worth noting that this was a survey of people across Australia who had become informed by participating in focus discussion groups. Participants knew that therapeutic cloning involves the destruction of embryos, and, as I have mentioned above, not all surveys make that known. It is clear, properly informed Australians understand what 'therapeutic cloning' of embryos for research means, and they do not like it.[92]

4.89 The Australian Family Association claimed that 'curiously, not a single reference to promising developments in search of pluripotent stem cells without embryos appears in Lockhart's literature review'.[93]

4.90 Others noted the Lockhart Review's reference to the fraudulent claims by South Korean researcher Dr Hwang, the only evidence at the time of successfully deriving embryonic stem cells from cloned embryos. In evidence to the Committee, Professor Schofield of the Lockhart Review noted that '…there was no single linchpin study and in fact there were some rumours and machinations going on in the scientific community regarding the Korean work'.[94] Do No Harm criticised the Lockhart Review Committee for not amending their recommendations and report after the results of Dr Hwang were revealed to be fraudulent:

> The one allegedly significant scientific advance that Lockhart used to justify overturning our ban turned out, within days of tabling the Lockhart report (tabled Dec 19th 2005), to be a monumental fraud.
>
> The serious question is why, realising that their recommendations were almost exclusively based on what was now shown to be fraudulent science, the Review did not recall and amend their recommendations?

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90 Catholic Archdiocese of Melbourne, *Submission 108*, p. 3.

91 Critchley and Turney, 'Understanding Australians' Perceptions Of Controversial Scientific Research', Australian Journal of Emerging Technologies and Society, Vol. 2, No. 2, 2004, pp. 82-87, http://www.swin.edu.au/sbs/ajets/journal/V2N2/pdf/V2N2-2-Critchley.pdf, (accessed 16 October 2006).

92 Caroline Chisholm Centre for Health Ethics, *Submission 68*, p. 3.

93 Australian Family Association, *Submission 97*, p. 18.

94 *Committee Hansard*, 20 October 2006, p.6.

Senator Gary Humphries
Chair

October 2006

Senator Concetta Fierravanti-Wells
LP, New South Wales

Senator Helen Polley
ALP, Tasmania

Senator John Hogg
ALP, Queensland

Senator Steve Fielding
FFP, Victoria

Senator Guy Barnett
LP, Tasmania

Senator the Hon Ronald Boswell
NATS, Queensland

Senator Ursula Stephens
ALP, New South Wales