AUSTRALIAN FEDERATION OF
RIGHT TO LIFE ASSOCIATIONS

Submission to the

Senate Community Affairs Committee

on the

Legislative responses to Recommendations of the Lockhart Review

by the

Australian Federation of Right to Life Associations

October 2006

www.righttolife.asn.au

PO Box 333 Civic Square ACT 2608
Tel 02 6251 5786 Fax 02 6253 0362

Right to Life Association (NSW) Inc • Queensland Right to Life Association
ACT Right to Life Association • Right to Life Association (WA)
Human Life Protection Society, Tasmania • Pro-Life South Australia

EXECUTIVE SUMMARY

The Federation is a significant grouping of informed community organisations which advocate respect for human life from its first beginnings to natural death. The Federation's principles are founded on the rational ethical position that protection of, and respect for human life is a peremptory norm or *ius cogens* as reflected in international and domestic law and in the customary law of nations.

The changes proposed in the Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006 and in the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 rely on recommendations of the Lockhart Review Committee. These include permission to produce human embryos through fertilisation solely for research; and also to manufacture human embryo clones and hybridised embryonic entities solely for research purposes, ie so-called therapeutic cloning. However, cloning either for reproduction or research produces a new human being. To destroy the cloned embryo in research is ethically repugnant.

Both Bills present a fundamental and radically permissive change in the definition of a ***human embryo*** by denying that status:

(1) to embryos created by fertilisation (egg and sperm) before the first mitotic cell division; however, this criterion is wrong because an embryo created by the combination of egg and sperm is a distinct genetic living entity (zygote) well before cell division can be detected; and
(2) to embryos created other than by fertilisation if they are deemed not capable of surviving for at least 14 days (appearance of primitive streak). Capacity to survive does not change the nature of a human embryo produced by these technologies.

The new definition enables destructive research on whole classes of embryos either presently protected, or whose generation is prohibited by the 2002 legislation.

The source of this radical redefinition of **human embryo** is a *Discussion Paper* (*Human Embryo – A Biological Definition.* NHMRC January 2006) produced by a Working Party of the NHMRC Licensing Committee. The Working Party had a majority of members from the IVF industry, a strong advocate of the changes proposed by the *Discussion Paper*.

The Lockhart Review Committee adopted the redefinition in consultation with the Working Party several months **before** the *Paper* was published. *No attempt was made by the Committee to seek community comment on the redefinition.* Several members of the Lockhart Committee had been well known for their pro-cloning views before their appointment; and the majority of the Working Party were employed in the IVF industry.

The review of the Lockhart recommendations for the Department of Prime Minister and Cabinet, June 2006 stated:

> on the basis of a consideration of relevant materials, it would not appear that there have been significant changes, since 2002, in relation to the definition of a human embryo ...[1]

Conclusion .
Legislators bear the responsibility of legislating for the whole community in a manner which protects human life. The Federation wishes the ban on the deliberate creation of human embryos for research purposes and other practices prohibited by the *Research Involving Human Embryos Act* 2002 and the *Prohibition of Human Cloning Act* 2002 be maintained. The Committee, therefore, should not recommend the Bills to the Senate.

---

[1] *Analysis of Advice on Developments in Assisted Reproductive Technology and Related Medical and Scientific Research*. Prepared by mpconsulting for Department of Prime Minister and Cabinet, June 2006

Table of Contents

A. Introduction

The Federation continues its unequivocal support of the prohibition imposed by the *Prohibition of Human Cloning Act 2002* (*POHC Act*) on the following practices:

- creating a human embryo clone [s 9];
- placing a human embryo clone in the human body or the body of an animal [s 10];
- importing or exporting a human embryo clone [s 11];
- creating a human embryo other than by fertilisation, or developing such an embryo [s 13];
- creating a human embryo for a purpose other than achieving pregnancy in a woman [s 14];
- creating or developing a human embryo containing genetic material provided by more than two persons [s 15];
- developing a human embryo outside the body of a woman for more than 14 days (excluding any time in which its development has been suspended) [s 16];
- using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo [s 17];
- intentionally altering the genome of a human cell in such a way that the alteration is heritable by descendants of the human whose cell was altered [s 18];
- collecting a viable human embryo from the body of a woman [s 19];
- creating a chimeric or hybrid embryo [s 20];
- placing a human embryo into an animal [s 21(1)];
- placing a human embryo into the body of a human, other than in a woman's reproductive tract [s 21(2)];
- placing an animal embryo into the body of a human for any period of gestation [s 21(3)];
- importing or exporting a prohibited embryo [ss 22(1) and 22(2)];
- placing a prohibited embryo in the body of a woman [s 22(3)]; and
- commercial trading in human eggs, human sperm or human embryos [s 23].

Together with provisions of the *Research Involving Human Embryos Act 2002* (*RIHE Act*) the *POHC Act* prohibits the creation of human embryos by any means outside the practice of an assisted reproductive attempt through the practice of IVF.

B. Resolution on cloning of the United Nations General Assembly

In relation to the prohibition on creating a human clone as provided by **s.11** of the *POHC* Act, the Federation asks the Committee to note the recent United Nations ban on all forms of human cloning. On 8 March 2005 the United Nations General Assembly approved a declaration calling on UN Member States to ban all forms of human cloning, including cloning for medical treatment, as incompatible with human dignity and the protection of human life. The Assembly adopted the text to be known as the *United Nations Declaration on Human Cloning*. The Declaration calls on member States to take a number of steps, including:

- adopting all measures necessary to adequately protect human life in the application of life sciences;
- prohibiting all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life;

- adopting the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity;
- taking measures to prevent the exploitation of women in the application of life sciences;
- adopting and implementing without delay national legislation to protect adequately human life and to prevent the exploitation of women.

It is to be noted that the Lockhart *Issues Paper* commented that 35 countries did not support the UN resolution.[2] It is surprising that the *Paper* highlighted dissent rather than providing the full voting record: 84 in favour, 34 against, 37 abstaining, with 36 absent (it is a well-known tenet of international law that States who abstain from voting on a resolution are taken not to have vigorous objection to a resolution).

C. Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006.

Senator Stott Despoja in presenting her Bill stated:

> This bill seeks to assist this scientific progress by allowing: regulated use of SCNT for research purposes; clarifying and improving consent provisions for donating excess ART Embryos; permitting donation to research of ART embryos already identified through Pre-Implantation Diagnosis to have a genetic disease; clarifying the definition of a human embryo; and, reviewing the amended Acts after three years of operation.[3]

This description of the Bill's effect on permissible research involving human embryos is simplistic and seriously misleading, particularly in that it does not explain that the means adopted in the Bill of "clarifying the definition of a human embryo" would remove significant areas of destructive research on human embryos from all legal restrictions.

The Senator has set out in the two Schedules of the Bill (dealing respectively with her proposed changes to the *RIHE Act* and the *POHC Act*) those research activities which remain prohibited and others which will now be permitted but subject to regulation.

The currently prohibited practices which the Senator's amendments would allow are contained in her Bill's **Schedule 1 Division 2 – Practices prohibited unless authorised by licence**:

- creating a human embryo clone;
- importing or exporting a human embryo clone;
- creating a human embryo other than by fertilisation, or developing such an embryo;
- creating a human embryo for a purpose other than achieving pregnancy in a woman;
- using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo;
- creating a chimeric or hybrid embryo;

---

[2] Issues Paper: Outline of existing legislation and issues for public consultation. August 2005 Lockhart Review of Australia's *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002* (hereafter referred to as the *Issues Paper*), page 25.

[3] Senator Stott Despoja's introductory speech relating to the exposure draft of the Bill at page 6.

These amendments are presented in a manner which obscures the radical nature of the changes proposed by designating each of these practices as an offence and then allowing that very practice by licence, for example:

17 Offence—creating a human embryo clone

A person commits an offence if:

(a) the person intentionally creates a human embryo clone; and

(b) the creation of the human embryo clone by the person is not **authorised by a licence**, and the person knows or is reckless as to that fact.

Senator Stott Despoja has long been an advocate of regulation of the practices currently prohibited by the *RIHE* and *POHC* Acts. What is inconsistent with her stated intent is that her Bill would establish a situation where the licensing regime contained in the RIHE Act would in fact be powerless to control foreseeable and increasingly significant areas of human embryo research.

This outcome follows inevitably from the radical alteration proposed by the Bill to the definition of a 'human embryo.

Section 8 of the *RIHE Act* defines a ***human embryo*** as follows**:**

> ***human embryo*** means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.
>
> ***human embryo clone*** means a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by human sperm.

In marked contrast **Schedule 1, Item 1** of the Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006 **redefines a human embryo as follows**:

> ***human embryo*** means a discrete entity that has arisen from either:
>
> (a) the first mitotic division when fertilisation of a human egg by a human sperm is complete; or
>
> (b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;
>
> and has not yet reached 8 weeks of development since the first mitotic division.

Senator Stott Despoja states that inclusion of the primitive streak in the proposed definition "*allows medical science more options in research involving embryos*".[4] This is indeed the case; changing a definition because it suits particular research interests, however, is hardly sufficient justification for abandoning current legislative restrictions.

Moreover, the Senator states that she derives her proposed definition from that produced by a Working Party formed by the National Health and Medical Research Council (NHMRC) Licensing Committee to develop a "biological definition" of the human embryo.[5] The source of this "biological definition" and its adoption by the Lockhart Review Committee and by both Senator Stott Despoja and Senator Patterson in their respective amendment Bills will be examined later in the submission.

---

[4] Draft *Explanatory Memorandum* to the Bill, Schedule 1, Item 1.

[5] Discussion Paper: *Human Embryo – A Biological Definition*. NHMRC January 2006. (hereafter NHMRC *Discussion Paper*)

D. Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006

Senator Patterson's Bill permits under licence the same previously prohibited practices in relation to research on human embryos (whether created by fertilisation or by other means) as does Senator Stott Despoja's Bill. Likewise this Bill *provides a definition of 'human embryo' which departs radically from the current legislative definitions.* **Item 3** of **Schedule 1** and **Item 2** of **Schedule 2** each define the human embryo as follows:

> ***human embryo*** means a discrete entity that has arisen from either:
>
> (a) the first mitotic division when fertilisation of a human egg by a human sperm is complete; or
>
> (b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;
>
> and has not yet reached 8 weeks of development since the first mitotic division.

As with the identical definition in Senator Stott Despoja's Bill, this definition obviously is tailored to meet the research interests of those scientists and institutions which wish to have human embryos available for research which will destroy them.

It should be noted that Senator Patterson makes claims for the status of this definition which are not correct. She wrongly states that this definition was the "recommended definition" that was "developed by the NHMRC ……. by forming the Biological Definition of Embryo Working Party, comprising three NHMRC Embryo Research Licensing Committee members and three other Australian experts".[6]

At its 159th Session on 8-9 December 2005 the Council endorsed distribution of the information paper prepared by the Working Party as a discussion paper and asked that the Council be advised of any feedback. In March 2006 the NHMRC's Licensing Committee sponsored a Workshop to further develop the *Discussion Paper*[7] and planned to publish the definition in the peer reviewed literature. Pending the results of peer review the NHMRC has not finalised any recommendation for changing the definition of the ***human embryo*** as the Senator claims.

In view of these facts, and noting that members of the NHMRC said at its 154th Session that "it was not the job of the NHMRC to define when life begins", the reliance on what is merely a Discussion Paper of an NHMRC Working Party by both Senators for the origins of the new definition of ***human embryo*** is unjustified.

Senator Patterson's Bill contains provisions which go further in the debasing of human life than does Senator Stott Despoja's Bill in that its provisions deny human status altogether to human embryos cloned through SCNT and involving enucleated non-human eggs.

It should be noted that **s 8** of the *POHC Act* contains the following definition:

> ***human embryo clone*** means a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by human sperm.
>
> ***hybrid embryo*** means:

---

[6] Explanatory memorandum to the Bill, Schedule 1, item 3.

[7] NHMRC *Discussion Paper*, see footnote 5.

(a) an embryo created by the fertilisation of a human egg by animal sperm; or

(b) an embryo created by the fertilisation of an animal egg by human sperm; or

(c) a human egg into which the nucleus of an animal cell has been introduced; or

(d) an animal egg into which the nucleus of a human cell has been introduced [bolding added]; or

(e) a thing declared by the regulations to be a hybrid embryo.

Paragraph (d) describes an entity which contains a human nuclear genome which is a copy of that of the donor of the somatic body cell. Although this embryo will have also a mitochondrial contribution from the species which provides the enucleated egg, this entity meets the definition of ***human embryo clone*** given in **s 8 of the POHC Act.** As the production of a ***human embryo*** clone is not permitted in the POHC Act that Act necessarily made no further provision for the creation of, and use of these human clones for any purpose at all.

Although Senator Patterson's Bill provides**:**

- in both **Schedules** a definition of ***human embryo*** to include **"**any embryo with a human nuclear genome", and
- in **Schedule 2, Item 3 para (d)** a definition of ***hybrid embryo*** to include an animal egg into which the nucleus of a human cell has been introduced (the same definition provided by **s 8** of the POHC Act cited above) thus creating an entity with "a human nuclear genome"

other provisions stand in complete contradiction to these.

Item 6 in **Schedule 1** and **Item 6** in **Schedule 2** state:

> **A reference in this Act to a human embryo does not include a reference to:**
>
> **(a) a hybrid embryo; or**
>
> **……**

Thus Senator Patterson' Bill strips all humanity from the ***hybrid embryo*** which the current legislation (both the *RIHE* and the *POHC* Acts) considers a ***human embryo clone*** and *which her own Bill admits has a "human nuclear genome*".

If the ***hybrid embryo*** created through transfer of the nucleus of a human somatic cell into an enucleated non-human egg is <u>not</u> a ***human embryo***, then it is not clear why there should be any prohibition or regulation of its creation or use under legislation that deals with the human embryo and human cloning. It is surely then ridiculous for Senator Patterson' Bill to include provisions like:

> **23B Offence—creating a hybrid embryo**
>
> (1) A person commits an offence if the person intentionally creates a hybrid embryo.
>
> (2) A person commits an offence if the person intentionally develops a hybrid embryo.
>
> (3) A person does not commit an offence against subsection (1) or (2) if the creation or development of the hybrid embryo by the person is authorised by a licence.
>
> Maximum penalty: Imprisonment for 10 years.

> Note: A licence to create or develop a hybrid embryo can only be issued under section 21 of the Research Involving Human Embryos Act 2002:

*If Senator Patterson is asserting that the embryo produced by transfer of the nucleus of a human somatic body cell into an enucleated non-human **is not human**, then it is nonsensical to include provisions for its creation and use into the RIHE and POHC Acts.* If her Bill were to be enacted its attempt to regulate these non-human [by her definition] embryos would be challenged with the likely result that there would be no regulation of their creations and use.

E. Lockhart Committee re-definition of human embryo sourced from NHMRC

The NHMRC did not advance such a radically different definition of the human embryo to the Lockhart Committee in its submission[8] lodged late in September 2005. Yet the Committee obviously continued to consult, and take guidance from one or more members of the Working Party after the closing of submissions; it then adopted the Working Party's approach in the *Lockhart Reports* submitted to Federal and State Governments in December 2005, one month *before* publication of the NHMRC *Discussion Paper*.

The Issues Paper issued by the Lockhart Review Committee August 2005

The Lockhart Committee initiated the public part of its Inquiry by providing an Issues Paper in August 2005 for those wishing to make submissions. In relation to the terms ***human embryo*** and ***human embryo clone*** the Issues Paper particularly emphasised the importance of everyone having "the same understanding of these terms and the way that they are currently used in the legislation".[9]

The Lockhart *Issues Paper* provided the accepted definitions of a human embryo and a human embryo clone respectively as in the legislation.

> "Human embryo
>
> A live embryo that has a human genome or an altered human genome and has been developing for less than eight weeks since the development of two pronuclei or the initiation of its development by any other means not including any period when its development was suspended for any reason. [*PHOC Act* s 8(1); *RIHE Act* s 7(1)]
>
> "Human embryo clone
>
> Advances in cell biology have allowed embryonic development to be started by injecting a cell nucleus extracted from any cell in the body into an egg cell from which the nucleus has been removed (nuclear transfer). **This is the basis of cloning technologies …..**. This part of the definition therefore means that **once a cell is created (by nuclear transfer or any other means) that has the same potential to continue development as a cell formed by fertilisation of a human egg and a human sperm, it is included in the definition of a human embryo**."[10] (emphasis added)

Despite this acknowledgement the Lockhart Committee was clearly soliciting submissions which would displace those very definitions. Its Issues Paper, to which submissions were to be addressed, was so phrased that it positively invited dissatisfaction with any restraints currently imposed by these two Acts. For example, it queried:

- whether the definitions of 'human embryo and 'human embryo clone' [in the legislation] were clear and unambiguous; and whether these definitions appropriately reflected community standards; [page12]

---

8 LRC Submission 790.
9 *Issues Paper* p 5.
10 Issues Paper pp 5-10.

- whether legislative restrictions have hampered stem cell researchers [page 15]
- implying that, because other countries allow embryos to be created specifically for destructive research, Australia should do likewise.[25]

To guide the thinking of those submitting to the Review, the ***human embryo*** was wrongly described as "capable of *becoming* a human being",[11] although it is universally accepted that the human embryo is a human being in the early stages of development. This accepted fact is neither a religious nor a philosophical statement: it would be equally correct to make an analogous statement of the fact that a canine embryo is a dog, not 'capable of becoming a dog'.

The Lockhart Committee significantly was not structured with any Term of Reference that simply advocated retaining the current definitions and prohibitions on certain practices. Consequently it was dismaying to read of the Chairman of the Review Committee, Justice John Lockhart, declaring that its task was "… to strike a balance between emotional reaction and rational progress".[12] The words "emotional reaction" could easily be taken as a gratuitous and prejudicial reference to any view that supported the current legislative provisions.

The Senate Committee must consider whether "rational progress" was code for the presumption that the 'scientific imperative' must lead to the removal of at least some restrictions on human research as proposed in the present amendment Bills. Certainly the Lockhart Committee was regaled with submissions which essentially did appeal to the 'scientific imperative' which, simply put, amounts to "whatever can be done must be done" – and preferably before others do it! Nazi era medical experiments such as those conducted on children by Dr Joseph Menegle should haunt us all; and Orwell's warning about deceptive language is still to be heeded.[13]

Further, to dub "progress" as necessarily "rational" is to beg the question. Progress to those who push for the adoption of some policy or procedure is always rational in their terms; history is littered with havoc wrought by 'visionaries'.

> "When one hears of progress one should ask for whom."[14]

The pejorative reference to "emotional reaction" implies that an emotional reaction to some proposal is unsupportable by reason: does horror at the Holocaust preclude reasoned moral objection to such a course of action?

Similarly the Federation finds puzzling that, while the Review stated that it was not its purpose to revisit the underpinning community debate [preceding passage of the two items of legislation in 2002], the Issues Paper stresses throughout that it "must take account of 'community standards'".[15] Did the Lockhart Committee presume that the input of the community to the decisions of the Federal Parliament some mere three years before had substantially altered or even become obsolescent? Surely fundamental ethical positions are not likely to prove so ephemeral.

---

[11] *Issues Paper* p 15.
[12] *The Australian*, 2 September 2005 p 15.
[13] George Orwell, *Nineteen Eighty-Four*. Newspeak, the language of the tyrannical State of Oceania, was designed to narrow the range of thought and to make impossible interpretations of reality not favourable to the ruling Party.
[14] Robin Skelton. *A Devious Dictionary*. 1991.
[15] For example, see Issues Paper p 12 and p 15.

Consequently it was not out of character that the Lockhart Committee decided, after submissions closed early in September 2005, to adopt a definition radically different from both accepted knowledge and legal usage. This gave no time for public comment and consultation on a redefinition that would, if adopted, increase dramatically the availability of human embryos for experimentation, both embryos created through IVF procedures and those produced by cloning procedures. This questions the much proclaimed independence and expertise of the Committee and is at odds with the insistence in its Issues Paper of the importance of a common language for use in the debate on the current legislation.

When the Lockhart Committee first opened its website it invited prospective submitters to register and provide e-mail addresses which were used for communication with the Committee. It could have informed those registered of the crucial changes they were intending to adopt in these definitions. **It did not do so**.

The Lockhart hearings took place in all State and Territory capitals, and 1035 submissions were received from the community representing a diversity of viewpoints. In addition, the Committee met with a range of scientists and other stakeholders. Remarkably, though some 80% of submissions were opposed to radical changes like producing human embryos for any purpose, the Lockhart *Reports* gave those scientists wanting to engage in cloning and associated practices everything they wanted. The membership of the Committee casts light on this predictable outcome.

F. Membership of the Lockhart Review Committee

Membership of the Lockhart Review Committee was constituted as required by the *POHC Act* which gives State Premiers veto powers over the selection of its members by the Federal Minister.[16]

Well before the Lockhart Committee was appointed Premiers Beattie, Bracks and Carr had expressed their support of cloning. It is not surprising, therefore, that three of the five academic members of the Committee had expressed pro-cloning views well before their appointment:

- **Associate Professor Ian Kerridge** (Universities of Sydney and Newcastle) had been quoted to that effect that: "There are strong moral imperatives to do stem cell and cloning research."[17]

- **Professor Peter Schofield** (University of NSW) commended proposed NSW legislation allowing research "…including embryonic stem cells and their use in human therapeutic cloning."[18]

- **Professor Loane Skene's** (University of Melbourne) stated: "Even if one regards reproductive cloning as contravening human dignity surely the same is not true of therapeutic cloning".[19]

- More recently, on 13 July 2006, **Professor Barry Marshall** (University of Western Australia) addressed the National Press Club. In answer to the first question Professor expressed his unreserved support of the cloning of human embryos for destructive research on the principle that the scientific community had in the past

---

[16] Section 25 of the *POHC Act* provides that the review is to be undertaken by persons chosen by the Minister, with the agreement of each State.

[17] ABC Science Online on 12 June 2001: abc.net.au/science/news/health/HealthRepublish_311098.htm

[18] Letter dated 9 October 2001 to Ms Jillian Skinner (then Shadow Minister for Health, NSW Parliament).

[19] Submission dated 1 March 2000 to a Public Forum (in Melbourne) of the House of Representatives Standing Committee on Legal and Constitutional Affairs *Inquiry into the Scientific, Ethical and Regulatory Aspects of Human Cloning.*

been too slow to accept advances in medical science like his work on stomach ulcers. His response showed complete ethical confusion: his work did not involve the destruction of human life as does cloning for research.

G. The Lockhart Committee's dissatisfaction with current legislative restrictions

The IVF lobby had not been shy in pursuing their demands through the developing work of the NHMRC Working Party and the Lockhart Committee was not at all slow to concede to those self-serving interests. The first indication of the Committee's sympathies was revealed in the Introduction to its *Reports*:

> However, the Committee was concerned to hear that this provision [*ie the prohibition on creation of an embryo by fertilisation other than in an ART treatment*], combined with the current definition of a human embryo as starting from the appearance of two pronuclei — a very early stage in fertilisation before the male and female genetic material combine — has had the apparently unintended consequence [**Note 1**] of impeding valuable research and clinical practice in ART clinics.
> ……..
> Adopting an independently developed definition [**Note 2**] of a human embryo to a slightly later stage in the fertilisation process (the first cell division) would allow much of the research described above to occur without falling outside the scope of the RIHE Act.[**Note 3**]This change would also maintain a very broad definition of an embryo, in line with all the community views expressed during the reviews, including that a new and unique genetic entity is formed only after the genetic material from the male and female pronuclei combine. [**Note 4**] This stage is known as 'syngamy' and occurs about one to three hours before the first cell division (cleavage).
> ……..
> To achieve this change, the Committee has recommended that the definition of a human embryo created by fertilisation of a human egg by a human sperm should include the fertilised egg from the first mitotic cell division (cleavage). In addition, the current prohibition of the creation of hybrid embryos has prevented the use of a standard test for sperm maturity by experimental fertilisation of animal eggs. The Committee has therefore also recommended that hybrid fertilisation should be permitted, under licence, up to, but not including, the first cell division.[20]
>
> **Notes**
>
> Note 1.The bland assumption that these consequences were "apparently unintended" is not explained.
>
> Note 2. This "independent definition of a human embryo" is referenced in a footnote to: NHMRC (2005) *Discussion Paper: Human Embryo – a Biological Definition*, NHMRC, Canberra (from January 2006). Risible, when one considers the composition of the Working Party which produced the document.
>
> Note 3. "without falling outside the scope of the RIHE Act" is a strange way of expressing the legal consequences of such a definition of t 'human embryo'. What clearly is meant is that the RIHE Act would not apply to experimentation on these human entities once they have been defined out of the definition of 'human embryo'.
>
> Note 4 **Correct.** It *is* the accepted fact that fertilisation is complete when the chromosomes of the sperm and the egg combine to form the zygote which is a genetically unique individual. Some1-3 hours later the zygote will undergo the first cleavage division. Yet the Lockhart Committee abandoned the "commonly accepted view" and went for a later stage in the developmental process, the first mitotic cell division.

In pursuit of the Lockhart Committee's 'insight' there emerged the crucial shift from the current legislative definition of the human embryo to the redefinition of the embryo in Recommendation 28 of the Lockhart Reports:

---

[20] Lockhart Legislation Review Committee: *Reports.* December 2005, p xv.

Recommendation 28 - *Definition of a human embryo*

A human embryo is a discrete living entity that has a human genome or an altered human genome and that has arisen from either:

(a) **the first mitotic division when fertilisation of a human oocyte by a human sperm is complete**; or

……

and has not yet reached 8 weeks of development since the first mitotic division.[21]

H. Redefinition of the 'human embryo' by Working Party of the NHMRC

The Working Party originated from a decision taken at the 154th Session of the NHMRC on 16-17 September 2004. The Meeting noted that the Council's Australian Health Ethics Committee had discussed the definition of "human embryo" and comment was recorded that there were "no loopholes' in the current legislated definition. As if to make good that regrettable situation, it was agreed that the Licensing Committee would "do some work on the definition of embryos issue". The Working Party was the result.

At the 158th Session of the NHMRC, 8-9 September 2005, Professor Findlay (Chair of the Licensing Committee) outlined the progress of the Working Party; it was decided that further work was to proceed out of session. At its 159th Session 8-9 December 2005 the Council decided that the work on the definition of a human embryo should be produced as a discussion paper. The NHMRC *Discussion Paper* was released in January 2006. At its 160th Session in March 2006 the NHMRC noted "plans to publish the definition in the peer reviewed literature".

Senator Stott Despoja's Explanatory Memorandum refers to the membership of this NHMRC Working Party as comprising three members of the NHMRC Licensing Committee and "**three other Australian experts**".[22] The three members of the Licensing Committee were Professors Jock Findlay and Peter Illingworth and Dr Graham Kay.

Professor Illingworth is also Clinical Director, IVF Australia; he recently referred to an embryo newly created in the IVF process as "just four cells in a dish",[23] a comment designed more to advocate than to enlighten. The "**three other Australian experts**" co-opted to the Committee all occupy prominent positions in the IVF industry. They were:

- Dr Adrianne Pope is Director of Laboratory Services Monash IVF, President of Fertility Society of Australia (2004);
- Dr Leeanda Wilton is Head of the Genetic and Molecular Research Lab, Melbourne IVF as at 23 Sep 06; and
- Dr Stephen Junk, is Scientific Director in the Hollywood Fertility Centre, Perth, Western Australia.

It is therefore not surprising that this 'stacked' group, dominated as it was by persons significantly engaged in the commercial IVF industry, adopted a redefinition of the ***human embryo*** which opened to scientists large areas of research which would escape regulation by excluding many human embryos from this redefinition. This redefinition, arrived at by a group of individuals whose conflict of interest is all too evident, is the definition of the

---

[21] Lockhart Legislation Review Committee: *Reports.* December 2005, p xxiv.

[22] Draft *Explanatory Memorandum* to the Bill, Schedule 1, Item 1.

[23] "Maybe baby: the fertility issue". Sydney Morning Herald, Magazine supplement *Essential*, 28 September 2006 p 5.

human embryo copied exactly by both Senator Stott Despoja and Senator Patterson in their respective amendment Bills:

- Item1 in both Schedules 1 and 2 of the Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006 ; and
- Item 3 in Schedule 1 and Item 2 in schedule 2 of the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006.

I. Definition of 'human embryo' in both amendment Bills proposed in relation to embryos created by fertilisation

> ***human embryo*** means a discrete entity that has arisen from either:
>
> (a)the first mitotic division when fertilisation of a human egg by a human sperm is complete; or
>
> ……..
>
> and has not yet reached 8 weeks of development since the first mitotic division.

(a) Redefinition of ***human embryo*** by NHMRC Working Party

The NHMRC *Discussion Paper*, the source of this definition and adopted without significant change by the Lockhart Committee, is a masterly exposition of how to avoid scientific objectivity when promoting the interests of an agenda enthusiastically shared by at least four of its six authors. The NHMRC *Discussion Paper* in examining stages of the human embryo's biological development advances two types of definition of the embryo:[24]

- **Broad definition**: That a conceptus is an embryo from the moment of its creation (eg fertilisation) to the end of the eighth week (56 days), by which time the beginnings of all major structures are present, the organs are developed and the embryo becomes a foetus. The Paper concedes that this definition is commonly used by the general public and "could lead to misunderstandings" between the general community and the interests of some scientists.
- **Restricted definition**: That a conceptus should be referred to as an embryo only after it had completed various stages of its development. The NHMRC indicates preference for this approach to the definition.

The *Discussion Paper* gives no justification for choosing the second option rather than retaining the first, commonly accepted definition. The justification appears to be a concern that the current definition (which denotes an 'embryo' from fertilisation) has led governments to legislate inappropriately in restricting 'embryo research'.[25] In support of this view the *Discussion Paper* criticises legislation that provides protection to the whole fertilised egg on the grounds that some parts of the fertilised egg will not form the actual body of the developing human, but rather will later become other essential structures necessary for sustaining the embryo eg the placenta, zona pellucida. This analysis is advanced to justify legislation which would allow destructive experimentation on the newly fertilised egg up to the time of the first mitotic cell division (some time in the second day after fertilisation).

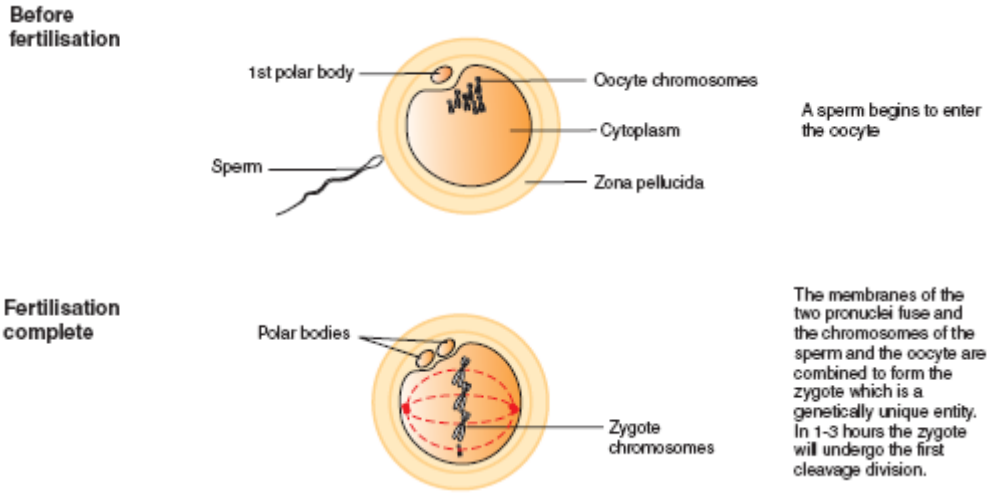
---

[24] NHMRC *Discussion Paper* p 3.

[25] NHMRC *Discussion Paper* p 4.

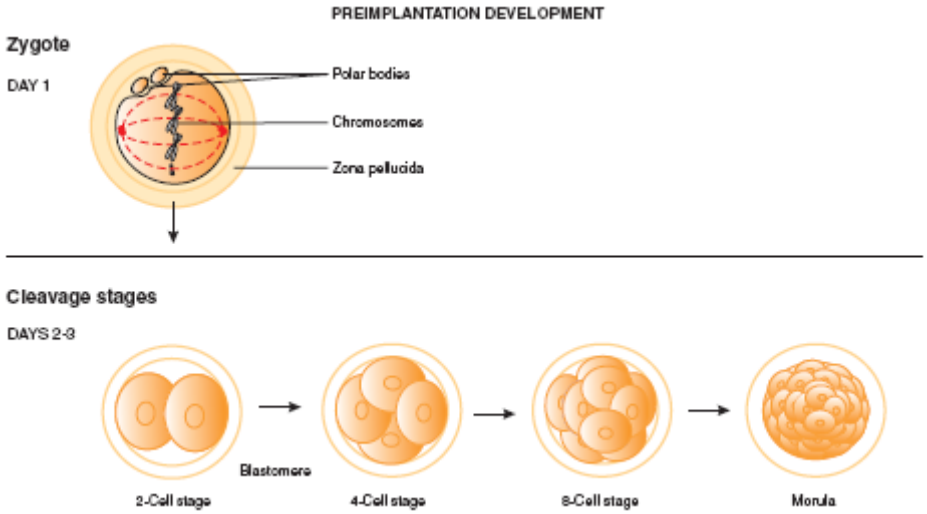
This approach to legislation is a nonsense. If experimentation conducted on the embryo in its earliest stages destroys the whole fertilised egg, then it obviously destroys all possibility of further development of the embryo.

In fact, **Figure 1** of the NHMRC *Discussion Paper* provides a valuable illustration and lucid explanation of embryonic development.[26]



The "Fertilisation complete" diagram clearly identifies the process of fertilisation to be complete when the membranes of the two pronuclei (provided by the nuclei of egg and sperm) fuse to from the zygote described as a "genetically unique entity".

Nonetheless, in a bewildering turn-about, the NHMRC *Discussion Paper* expresses a *choice* to deny the term 'embryo' to this human entity even at this stage of development. Remarkably the authors choose a significantly later stage of the embryo's development in order to achieve a 'biological' redefinition of the human embryo resulting from fertilisation of human egg. They selected the first mitotic cell division, an event which occurs at some time during the second day after the sperm penetrates the egg (see diagram below).



The basis for moving the goalposts in this manner is:

> "Based on the biology of the early mammalian developmental processes (see Figure 1) the term 'human embryo' is not applicable before the completion of fertilisation of a human

[26] NHMRC *Discussion Paper* pp 7-8.

> oocyte by a human sperm (ie syngamy) because this is when the new genome of the new individual is created. ……
> A definition of 'human embryo' based on syngamy, however, excludes reproductive technologies that do not involve the fertilisation of a human egg by a human sperm."[27]

When a technological reproductive process, like SCNT, is used the successful production of an embryo can only be identified when the transferred somatic cell nucleus activates and divides. However, an embryo created by the combination of egg and sperm is a distinct genetic entity (zygote) well before cell division can be detected. Therefore it is totally inappropriate to use the same criteria to define as embryos both those genetic entities created by fertilisation and those resulting from technologies not involving fertilisation.

This unjustified approach is adopted *in toto* by Senators Stott Despoja and Patterson in the definition of a human embryo produced by fertilisation proposed in their respective Bills. Those Senators must acknowledge that the adoption of such a definition would remove all legal protection from human embryo for a period extending into the second day after fertilisation occurs.

(b) Definition of the human embryo recommended in the Lockhart Reports

The Explanatory Memorandum to Senator Stott Despoja's Bill says that the NHMRC Licensing Committee "passed their definition [of the 'human embryo'] to the Lockhart Committee"[28] who adopted it in Recommendation 28 of its Reports.[29] This provides no reassurance as to the value of the definition offered in both Bills. Given its provenance, explained above, it is rather a matter of deep concern in its permissive legislative effect.

The manner of consultation between the Lockhart Review Committee and the NHMRC Working Party was quite inappropriate. The details of the membership of these bodies and their collaboration in arriving at this new definition are explored in Part XXX of this Submission.

J. Definition of 'human embryo' in both amendment Bills proposed in relation to embryos created by means other than fertilisation.

> ***human embryo*** means a discrete entity that has arisen from either:
>
> …….
>
> (b) **any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;**
>
> and has not yet reached 8 weeks of development since the first mitotic division.

This is identical with the second paragraph of the definition of ***human embryo*** contained in **Recommendation 28** of the *Lockhart Reports* which in turn draws inspiration again from the NHMRC Working Party's work in progress on embryo definition, work not yet publicly available when the Lockhart Committee published its *Reports*.

The origin of this part of the redefinition of the ***human embryo*** is also revealed in the NHMRC *Discussion Paper*, especially in those parts which explain the various embryonic entities which 'reproductive technologies' can produce.

---

[27] NHMRC *Discussion Paper* p 25.

[28] Draft *Explanatory Memorandum* to the Bill, Schedule 1, Item 1.

[29] The Lockhart Reports adopts the same definition with only some insignificant differences in the perambulatory sentence**: "**a human embryo is a discrete [living] entity that has [a human genome or an altered human genome and that has] arisen from either: …… Differences indicated [ ]

Reproductive Techniques – Current and Conjectured

Table 1 of the NHMRC *Discussion Paper*[30] sets out seventeen "**Reproductive Techniques**" by which an embryo might be produced (see Appendix 1 pp…..). In addition to fertilisation sixteen other methods are listed including the now well-known Somatic Cell Nuclear Transfer (**Technique 2**). Other techniques include: pronuclear transplantation (**Technique 3**); parthenogenesis (**Technique 4**); parents of the same gender (**Techniques 7** and **8**).

The Table includes prediction of the potential (established either in fact or conjectured where the matter has not been tested) for development of each of these embryonic entities through various stages from fertilisation to live birth. Some of these embryos cannot reach gastrulation (those produced by **Techniques 4, 9, 14** and **15**); the potential for development of other human embryos is still a matter of conjecture (those described against **Techniques 6, 8, 16** and **17**).

Notably, embryos resulting from **Techniques 14** and **15** are deliberately prevented from development past a certain stage because the experiment has included genetic alteration designed to remove the potential for implantation ensuring their death.

With this information as a guide, the NHMRC *Discussion Paper* then indicates its preference for taking "potential for continued development" as another "key consideration for any definition of 'embryo'". It concludes that a "more productive approach to the development of a biological definition of human may be one that does include a reference to a specific developmental point, but in the context of the potential for continued development".[31]

Therefore adoption of the second paragraph of the definition of ***human embryo*** in the two amendment Bills would permit any number of grotesque experiments which could produce a living new human entity which would be excluded from that definition of ***human embryo***, either because of a developmental incapacity resulting from the method of producing this entity or because of a deliberate disabling of that capacity by genetic manipulation.

K. The NHMRC Working Party relationship with the Lockhart Committee

It is evident that the definition of ***human embryo*** proposed in the amendment Bills proposed respectively by Senators Stott Despoja and Patterson relies upon that crafted by the NHMRC Working Party which was recommended in the Lockhart *Reports*. This definition patently serves the interests of scientists dissatisfied with the current legislative provisions which prohibit the deliberate creation of human embryos by fertilisation or any other method for destructive experimentation.

This outcome is hardly unexpected considering the weighted composition of the NHMRC Working Party detailed above. The Lockhart Committee also was obviously partial in approaching its Review; despite the popular description of it as independent and expert. There is no scientific justification for the proposed change other than to open research to certain scientists and to remove legal protection of whole classes of human embryos.

[30] NHMRC *Discussion Paper* pp 16-20.
[31] NHMRC *Discussion Paper* p 25.

L. Abuse of language - Playing the name game

An examination of public statements by some scientists who chafe under the present legal restrictions on cloning human embryos suggests that if their ambitions cannot be realised by changing the legal definition of 'human embryo' they might well be achieved by denying the status of the human clone or by resort to linguistic obfuscation. The most significant linguistic victory has been the adoption by the media generally of the phrase 'somatic cell nuclear transfer' (or just 'SCNT') rather than 'cloning'. SCNT is simply the basis of a particular cloning technology that ultimately is capable of producing a clone; it is undeniably the very process that produced cloned sheep, calves, and even a dog.[32]

An example of such disinformation is Professor Trounson's statement that "somatic cell nuclear transfer" is simply the process which allows scientists to obtain embryonic stem cells.[33] This disingenuous description of the process is that "somatic cell nuclear transfer" (SCNT) omits to say that SCNT is followed by the creation of an embryo from which the stem cells are then taken, thus ensuring the destruction of the embryo.

The resort to this misleading language can have no purpose other than to deliberately mislead and confuse the Australian community and distort evaluation of 'community standards' which the Lockhart Committee was asked to address in relation to the accepted definition of an embryo.

This game is an international one that anyone can play; and one is well advised to look out for the rule makers. In 2004 the International Society for Stem Cell Research formally adopted the term 'somatic cell nuclear transfer' to describe the procedure in which an adult cell nucleus is transplanted into an egg in order to be able to harvest the stem cells from the destruction of the resulting embryo. This decision provoked unfavourable comment from a leading scientific journal:

> It is true that embryo is an emotive term, but there is little scientific justification for redefining it. Whether taken from a fertility clinic or made through cloning, a blastocyst has the potential to become a fully functioning organism. And appearing to deny the fact will not fool the die-hard opponents of this research. If anything, *it will simply open up scientists to the accusation that they are trying to distance themselves from difficult moral issues by changing the terms of the debate*.[34] [italics added]

The deliberate obscurantism fostered in this 'name game' is even surpassed by the inept ontological assertions by scientists like Professor Bob Williamson, University of Melbourne. He has argued that, since the organisms created by nuclear transfer lack the social context of entities created by the usual process of fertilisation, **he** does not "regard this as an embryo in any sense".[35]

As proof that this was not some isolated instance expressed in the sometimes hyperbolic style of academic debate, Professor Williamson recently advanced identical views in a bid for the hearts and minds of television viewers:

> When it comes to therapeutic cloning, it's a pity that term has got out there because in my view what we're talking about is not cloning at all. Indeed, scientists want to have the permission from society to take a nucleus from a skin cell, a liver cell, any cell in the body of anyone in this room and put it into an egg, not in order to clone it, but in order to give it

---

[32] The cloning of a male dog was achieved in South Korea after some 1000 unsuccessful attempts.
[33] *The Australian*, 5 July 2005.
[34] Nature Vol 436 7 July 2005 p 2.
[35] Bob Williamson, *Striving for an ethical way forward for stem cell research in Australia.* Australian Academy of Sciences Annual Symposium 6 May 2005.

> a little kick backwards so that it can turn in to a pancreatic cell for diabetes or a lung cell for cystic fibrosis. *My view is that that has nothing in common with an embryo*.[36]

This 'name game' is an international one; overseas players are recruited to give support to claims like those of Professor Williamson.[37] For example, in a flying visit to the Antipodes, Oxford University's Sir Walter Bodmer, informed us colonials that human embryos created by cloning for research purposes are not really embryos at all.[38] The reason: because they will not be allowed by the researcher to develop fully, the proposed research inevitably destroying them.

This ontological sleight-of–hand, whereby meaning is determined solely by the user's intention without reference to any agreed denotation, precludes discussion based on a common terminology. Such reasoning enabled whole classes of human beings to be denied status and protection in totalitarian regimes of the last century: no capital crimes were committed against Jews in the last years of the Third Reich as the victims were not legally defined as persons.

This self-serving and self-validating approach to meaning is not new, though it is scarcely of good repute and has long been the target of satire:

> "When I use a word," Humpty said in a rather scornful tone, "it means what I choose it to mean – neither more nor less."[39]

This crude ontology which holds that the nature of something is changed by what someone intends to do with it should be dismissed with contempt by principled lawmakers.

M. Misinformation and bias in the Media

With this kind of assistance from some scientists it is little wonder that media accounts of what is involved in cloning are characteristically misleading as to the relationship between cloning and the attempted recovery of embryonic stem cells. The following account is typical:

> **"Therapeutic cloning-nuclear transfer:**
>
> Used to create embryonic stem cells for research or therapeutic use. Genetic material from an adult, say skin or blood, is put into a donor egg emptied of its genetic material. After a few days ES cells are extracted and used to create a research stem cell line (colony), or re-injected into the donor to repair defective organs without rejection. Prohibited in Australia. Allowed in Britain, US, South Korea and Japan."[40]

This article, published in a national newspaper with wide circulation, is typical of the misleading propaganda designed at the time to influence the outcome of the Lockhart review. Firstly, it states as accomplished fact that ES cells will "repair defective organs without rejection", whereas the claim is purely conjectural; secondly, it omits the critical step between nuclear transfer and the extraction of ES cells ie the creation of an embryo.

The errors are repeated time and again; below are samples from two newspapers only:

> Therapeutic cloning, also known as somatic cell nuclear transfer (SCNT), involves injecting the nucleus of an adult cell into a human egg and harvesting the resulting stem cells to treat disease or conduct research into its causes.[41]

---

[36] Transcript of TV Channel SBS, *Insight*. 8 March 2005

[37] Professor Williamson was co-author of the submission of the Australian Academy of Sciences' submission to the Lockhart Review.

[38] *Australia urged to allow cell cloning*, Canberra Times, June 22, page 13.

[39] Carroll, Lewis, *Through the Looking-Glass*. Chapter 6

[40] *The Australian*, 2 September 2005, p19.

[41] Matthew Franklin and Samantha Maiden, 'PM grants free vote on cloning' *The Australian* 16 August 2006 p 2.

> …..cloning involves "remov[ing] cells from unwanted human embryos and replac[ing] the DNA in those cells with DNA from another human"[42]
>
> The technique [of therapeutic cloning] involves taking genetic material from a cell in an adult's body and fusing it with a woman's **empty** egg to produce stem cells for research.[43]

The egregious errors in these statements are breathtaking in their ignorance of nuclei, the cytoplasmic contents of the egg, etc. Cronin is a repeat offender,[44] her most recent contribution as follows**:**

> The [cloning] technique involves taking genetic material from a cell in an adult's body and fusing with a woman's empty eg to produce stem research for research.[45]

Leaving the vagueness of "genetic material" (it should be the nucleus) and the "fusing" (ie substitution of nucleus), where has the cloned human embryo gone? The embryo must be produced and allowed several days to develop before stem cells can be extracted.

The general ignorance among journalists, even those who style themselves as science and/or health writers, is ubiquitous. It is scarcely excusable when the whole process of cloning is clearly described early in the *Issues Paper* produced by the Lockhart Committee (lockhartreview.com.au) in August 2005.

Such misunderstanding and/or misrepresentation of the cloning process fosters even greater ignorance. Statements by journalists and politicians occasionally reveal complete ignorance of the fact that an embryo can be created without fertilisation of an egg by a sperm. For example, there is the assertion that because there "is no sperm involved" in cloning, the living human entity produced by somatic cell nuclear transfer is not an embryo.[46] Similarly:

> There are no sperm involved in this process. The embryos the scientists talk about are not a fertilised egg. They can't make a baby.[47]

and, in similar vein, Senator Stott Despoja:

> It is important to emphasise that SCNT does not involve sperm or fertilisation or making genetically identical fetuses or making a baby. Implantation of an embryo created through SCNT is illegal and will continue to be prohibited under this bill.[48]

It is obvious to all that an embryo created through the SCNT process "does not involve sperm". This new human entity is a human embryo in the terms of the definition given in her Bill. Why the reassurance that the SCNT process does not involve "making a baby". A 'baby' is simply a developmental stage on the human journey, as is the 'embryo', the 'fetus', the 'infant', the 'child', the 'adolescent', the 'adult'. Of course, the embryo destroyed by experimentation such as that allowed in the amendment Bills of Senators Stott Despoja and Patterson will not reach those further milestones.

---

[42] Simon Grose, Science Reporter, *Canberra Times*, 28 June 2006, Opinion, p 11.
[43] Danielle Cronin, Health Reporter, *Canberra Times* 23 September 2006 p 14.
[44] Danielle Cronin, *Canberra Times* 30 August 2006 p 7 and 1 September 2006 p 1.
[45] 'Stem cell expert warns of alarmists', *Canberra Times* 23 September 2006 p 14.
[46] Danielle Cronin, Health reporter, 'Stemming a great divide' *Canberra Times* 19 Aug Forum B3.
[47] Senator Jeannie Ferris at a Liberal Party meeting at Parliament House, *Weekend Australian*, Inquirer, August 2006 p 22.
[48] Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006, Senator Natasha Stott Despoja Tabling Speech p 4.

N. The Lockhart Review Committee *Reports* and the Government response

Professor Loane Skene, Deputy Chair of the Lockhart Committee, has been reported as saying

> Naturally we're disappointed that **none** of the recommendations were taken up.[49]
>
> [Bold added]

This statement does not match the facts: the Committee made 54 recommendations (see pages xxii to xxvi of its 19 December 2005 Reports). In fact, 18 of those recommendations (1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 14, 34, 37, 39, 40, 43, and 44) and, in part, two others (6 and 13) address matters which are currently in effect through the operation of the POHC and RIHE Acts. The Government, in a statement issued by the Prime Minister on 23 June 2006 said it had considered the Committee's recommendations and approved those recommendations which required no change to current legislation:

> *After careful reflection, the Government is not disposed to make any changes to the existing national legislative framework for research involving human embryos, agreed in 2002.*
>
> The Government also indicated that it would support other recommendations [Recommendations 47 and 49] relating to: administrative improvements in the current licensing scheme operating under the RIHE Act; a register of excess embryos donated for research from IVF programs; the establishment of a national stem cell bank.

Perhaps the Professor means to say that the Government does not support those recommendations calling for radical change in the treatment of human embryos.

The same article attributed to Professor Skene the extraordinary statement:

> "Most people don't know this type of research is prohibited …… If you wanted to do research on changing the medium in which the fertilised egg is developing, it's not possible for the researchers to do that research."

In fact, that type of research is permitted under the RIHE Act and is being done, for example, under licences 309701 and 309702A issued to Sydney IVF Limited on 16 April 2004 by the Embryo Research Licensing Committee of the National Health and Medical Research Council. The first licence enables the use of "up to 670 excess ART embryos"; the second licence involves access to the same embryos.[50]

Professor Skene's apparent lack of knowledge of the recommendations of the Committee of which she was a member does not assist accurate reporting in the media on the Federal Cabinet's response to the Lockhart Reports:

> that Australian researchers will not be able "to remove cells from unwanted human embryos to grow new human tissue."[51]

In fact, such practices are currently entirely lawful if conducted under licence as provided for by the RIHE Act.

---

[49] Canberra Times 8 July 2006 p 8 and B4

[50] See NHMRC website: www.nhmrc.gov.au/embryos/monitor/database/index.htm.

[51] Diana Streak, *Abbott stacks health boards*, *Canberra Times*, 5 July, page 1.

O. Cures for all ills – extravagant claims by ES cell researchers

Embryonic stem cell scientists promise the community all manner of cures for human conditions if only they were to be allowed to destroy human embryos created in the laboratory for research purposes. It is relevant to refer here to a press report of the First Consultation Meeting of the Lockhart Committee held on Thursday 1 September 2005 in Adelaide. At that meeting Professor Peter Rathjen, head of the University of Adelaide's Department of Molecular Biosciences, is reported as saying that stem cell technology had vast applications; further, a stem-cell bank would aid in creating a new generation of Australians who had high quality lives until they died:

> "If this sort of technology is adopted in its broadest sense, then my view is it will be an utter paradigm shift in the way we think about medicine".[52]

Whether through omission or deliberation, either by Professor Rathjen or by the media reports, what typically is not made clear is the source(s) of the proposed stem-cell bank. If the stem-cells are derived other than from prohibited embryos (for example, embryos neither from excess ART embryos nor from cloned embryos), then there is no conflict between the proposal and the present legislative constraints. If the stem-cells referred to are derived exclusively from mature cells (for example, cord blood cells, other somatic cells), then there is no ethical issue to be resolved. The lack of information is typical of the reporting of promised cures; it does not promote community understanding of the issues.

In 2003 the late Christopher Reeve, suffering from a spinal cord injury, urged acceptance of deliberate creation of human embryos for research.. He asserted that "there are no distinguishing human characteristics whatsoever" when the embryo is at the 100 cell stage; such an abysmal ignorance of the process of human development, can charitably only be accounted for by his hope for a cure. Indeed when he said:

> if scientists are allowed to use stem cells that derived by nuclear transfer, my body is likely to receive them and the lesion that keeps me sitting in a wheelchair would probably be cured[53]

his uncritical faith in the scientists, for whom he had become a mouthpiece in his declining years, had little foundation in reality.

"The enormous distortion of hope that's not tinged with reality" is how Professor Jack Martin describes the hyperbolic language used by those who promise sure cures, if only they are allowed to remove all boundaries on their research.[54] So far there have been no cures for such ailments from embryonic stem-cell research; yet there have been numerous, impressive beneficial applications achieved from stem cells harvested from mature cells.

Nonetheless extravagant claims are still being made by proponents of such research. A recent Victorian State Government-commissioned report claims that:

> The amount of progress that has been made in a scant years with human embryonic stem cells is breathtaking. Australian scientists have been prominent in this global endeavour, and should not be excluded from the next exciting step.[55]]

This claim is remarkable because the licences issued by the NHMRC's Licensing Committee under the *RIHE Act* have been overwhelmingly granted for improvement in the outcome of IVF procedures, that is, industry R & D rather than directed to curing injury or

---

[52] Professor Rathjen, *The Age* 1 September 2005.
[53] *Making Connection*. NSW Premier's Forum on Spinal Cord Injury and Conditions. Sydney 27-28 January 2003.
[54] Transcript of TV Channel SBS, *Insight*, 8 March 2005.
[55] 'Billions lost by cloning ban: Bracks', *The Australian*, 2 Oct 2006 p 6.

disease which was the reason repeatedly advanced in support of human embryo research during the Federal Parliamentary debates of 2002.

Professor Martin's estimation of the hype that is characteristic of the claims by scientists working with embryonic stem cells is supported by Michael Good, director, Queensland Institute of Medical Research, who said:

> …therapeutic cloning does raise a number of ethical issues which are different from those involving stem cell tissues derived from IVF embryos. I am not aware of any clinical trials being undertaken or being planned using stem cells derived from IVF embryos, which was a major reason put forward in support of the legislation passed in 2002. The scientific hurdle was, and remains immunological rejection and the scientific community is no closer to solving that dilemma. Until it does, I, as an immunologist, cannot foresee any clinical use for IVF-derived ES cells tissues without the concurrent use of powerful immunosuppressive agents.[56]

P. ES cell researchers and the law

Professor Rathjen is reported to have said that Australia's laws must reflect the potential of the technology.[57] This attitude to law is unfortunately not uncommon among embryonic stem cell researchers. Professor Bob Williamson, clearly chafing under the current legislative restrictions, is dismissive of ethical restraints, states in this context:

> Research is inherently of value to society. It is inherently ethical.[58]

From this novel standpoint he accuses many health research ethics committees of being "risk averse". In pursuit of ethical hegemony for researchers, Williamson objects to even lawyers' holding positions on Human Research Ethics Committees (HREC) and deplores the necessity of researchers' having to wait upon access to embryos excess to ART programs. The clear conclusion is that Professor Williamson wishes to create embryos expressly for research; he should simply say so without overreaching 'ethical' claims.

Q. Who will make the final decision?

The Lockhart *Issues Paper*, in addressing the issue of who will make the final decision, fortunately was in no doubt: it is the Australian Government in consultation with State and Territory governments.[59] That of course is the way of a parliamentary democracy. It seems not to be the way of scientists such as Professor Williamson who sees the parliamentary process as no more than a road-block to his hubris born of scientific megalomania:

> …. we must not allow parliament 'open slather' to regulate research that is carried out in laboratories. … This research [cloning embryos for research purposes] is of great potential value, and is not embryo research.[60]

Of course not all scientists are so dismissive of ethical concerns nor so contemptuous of accepted scientific definitions. Others acknowledge the community's right to decide the issue by democratic means:

> *Professor Jack Martin* – There is an ethical issue for our community …. it's throughout our society. It's not just one religion, it's throughout the Christian religions and the non-Christian religions and people of no religion at all. So there is an ethical barrier and yet

---

[56] LRC Submission 364.
[57] *The Age*, 1 Sept 2005.
[58] *Striving for an Ethical Way Forward for Stem Cell Research in Australia*. Australian Academy of Sciences Annual Symposium 6 May 2005.
[59] *Issues Paper*, p 4.
[60] See footnote 58.

that barrier is being influenced by the enormous distortion of hope which is hope that's not tinged by reality."[61]

R. Conclusion and recommendation

We are confident that the Committee will consider with great caution representations from researchers who do not concede that science should be conducted within ethical parameters consistent with respect for human life. Parliamentarians have the responsibility to ensure that those parameters are expressed effectively in legislation. The two amendment Bills proposed by Senator Stott Despoja and by Senator Patterson, respectively, demonstrably fail to meet this responsibility. The Committee therefore should not recommend the Bills to the Senate.

[61] Transcript of TV Channel SBS, *Insight*, 8 March 2005.

Appendix

Table 1 from *Discussion Paper*: Human Embryo – A Biological Definition, NHMRC 2006

Table 1 – The developmental potential and genetic contribution of entities produced either by natural processes of fertilisation or as a result of emerging technologies in reproductive science

Reproductive technique / Functional element	Male gamete	Fertilisation	Syngamy	Cleavage	Morula	Blastocyst	Potential to implant	Gastrulation	Potential to develop into a foetus	Potential for live birth	Genetic contribution: Nucleus	Genetic contribution: Mitochondria
Processes that occur naturally in humans												
fertilisation – naturally occurring	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Both gamete donors	Oocyte donor
Chimera – embryo fusion[1,2]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Both gamete donors	Oocyte donor
Embryo splitting – monozygotic twins	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Both gamete donors	Oocyte donor
Experimental techniques that have been successfully conducted using human material (shaded boxes indicate theoretical assessments as the entity has not been demonstrated experimentally to proceed to the developmental stage indicated)												
1) Cloning by embryo splitting[3,4]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Both gamete donors	Oocyte donor
2) Somatic cell nuclear transfer (SCNT) – human somatic cell and human oocyte[5]	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Somatic cell donor	Oocyte donor

Functional element / Reproductive technique	Male gamete	Fertilisation	Syngamy	Cleavage	Morula	Blastocyst	Potential to implant	Gastrulation	Potential to develop into a foetus	Potential for live birth	Genetic contribution: Nucleus	Genetic contribution: Mitochondria
3) Pronuclear transplantation – transfer of pronuclei from fertilised human oocyte to enucleated donor human oocyte[6]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Donors of gametes used for fertilisation	Oocyte donor
4) Parthenogenesis – human oocyte activation[5]	No	No	No	Yes	Yes	Yes	No	No	No	No	Oocyte donor	Oocyte donor
5) Chimera – generated by aggregation of individual viable blastomeres obtained from non-viable embryos[7]	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Multiple origin depending on origin of blastomeres	Multiple origin depending on origin of blastomeres
Experimental technique that has been successfully conducted using human and animal material (shaded boxes indicate theoretical assessments as the entity has not been demonstrated experimentally to proceed to the developmental stage indicated)												
6) SCNT – human somatic cell and enucleated animal oocyte[8,9]	No	No (enucleated oocyte)	No	Yes	Yes	Yes	?	?	?	?	Human somatic cell donor	Animal oocyte donor

Reproductive technique / Functional element	Male gamete	Fertilisation	Syngamy	Cleavage	Morula	Blastocyst	Potential to implant	Gastrulation	Potential to develop into a foetus	Potential for live birth	Genetic contribution: Nucleus	Genetic contribution: Mitochondria
Experimental techniques that have been successfully conducted in animal models involving no human material												
7) Gynogenesis – as for pronuclear transplantation but using 2 maternal pronuclei[10,11]	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Oocyte donor	Oocyte donor
8) Androgenesis – as for pronuclear transplantation but using 2 paternal pronuclei[11,12]	Yes	No	Yes	Yes	Yes	Yes	Yes	?	?	No	Sperm donor	Oocyte donor
9) SCNT – mouse somatic cell genetically altered to remove implantation potential and enucleated mouse oocyte[13]	No	No	No	Yes	Yes	Yes	No	No	No	No	Mouse somatic cell donor	Mouse oocyte donor
10) Chimera – injection of mouse blastocyst with mouse embryonic stem (mES) cells	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Host embryo or mES cells (but not in same cell)	mES cells and host blastocyst cells (but not in same cell)

Reproductive technique / Functional element	Male gamete	Fertilisation	Syngamy	Cleavage	Morula	Blastocyst	Potential to implant	Gastrulation	Potential to develop into a foetus	Potential for live birth	Genetic contribution: Nucleus	Genetic contribution: Mitochondria
Proposed and theoretically possible experimental techniques (shaded boxes indicate theoretical assessments as the technique has not been published as successfully conducted)												
11) Fertilisation – human gametes generated *in vitro* from differentiating human embryonic stem (HES) cells[14, 15, 16]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Derived from HES cells used to generate sperm	Derived from hES cell used to generate oocyte
12) Fertilisation - human gametes produced *in vitro*[17]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Male and female human tissue donors	Female human tissue donor
13) Human oocytes produced by animals containing human ovarian tissue grafts fertilised with human sperm[18]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Male and female human tissue donors	Female human tissue donor
14) SCNT – human somatic cell genetically altered to remove implantation potential and enucleated human oocyte (or oocyte generated *in vitro* from differentiating hES cells)	No	No	No	Yes	Yes	Depends upon genetic alteration	No	No	No	No	Human somatic cell donor	Human oocyte donor

Reproductive technique / Functional element	Male gamete	Fertilisation	Syngamy	Cleavage	Morula	Blastocyst	Potential to implant	Gastrulation	Potential to develop into a foetus	Potential for live birth	Genetic contribution: Nucleus	Genetic contribution: Mitochondria
15) SCNT – human somatic cell genetically altered to remove implantation potential and enucleated animal oocyte	No	No	No	Yes	Yes	Depends upon genetic alteration	No	No	No	No	Human somatic cell donor	Animal oocyte donor
16) Chimera – injection of hES cells into animal blastocyst	Yes	Yes	Yes	Yes	Yes	Yes	?	?	?	?	Host embryo or hES cells (but not in same cell)	hES cells and host blastocyst cells (but not in same cell)
17) Chimera – injection of animal ES cells into human blastocyst	Yes	Yes	Yes	Yes	Yes	Yes	?	?	?	?	Host embryo or animal ES cells (but not in same cell)	Animal ES cells and host blastocyst cells (but not in same cell)

[1] Strain et al., 1998. [2] Yu et al., 2002. [3] Footnote 25 in Daar and Sheremeta, 2002. [4] Chan et al, 2000. [5] Cibelli et al., 2001. [6] Zhang et al., 2003. [7] Alikani and Willadsen, 2002. [8] Chen et al., 2003. [9] Chang et al., 2004. [10] Kono et al., 2004. [11] Surani, 1986. [12] Barton et al., 1984. [13] Meissner and Jaenisch, 2006. [14] Hubner et al., 2003. [15] Toyooka et al., 2003. [16] Geijsen et al., 2004. [17] Bukovsky et al., 2005. [18] Gook et al., 2003.