Submission to

The Australian Senate Community Affairs Committee

- Legislative Responses to Recommendations of the Lockhart Review.

From

The Life Office Catholic Archdiocese of Sydney

Prepared by

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Executive summary

The Catholic Church is a well known advocate for respect and protection of the human embryo. As science clearly demonstrates that human embryos are complete, though immature, human beings, justice requires that embryonic human beings are protected by law in the same way that other human beings are.

At the same time, institutionally and individually, Catholics make a substantial contribution to health care and medical research. As the sponsor of the oldest and largest network of healthcare institutions in the world and being the largest nongovernment provider of healthcare in Australia, we recognise the potential benefits of biotechnology to the health and wellbeing of the Australian and International community.

Therefore, the Catholic Church supports biomedical research and therapy which is undertaken within an ethical framework which respects human life and dignity at every stage and in every condition. In so doing, we join other Christian denominations, major religious traditions and many people of good will of no religion who propose that medical and scientific research should be at the service of human life and dignity.

To this end, the Life Office opposes any expansion of destructive human embryo experimentation as both unethical and scientifically unnecessary. In particular, we oppose the intentional creation of research human embryos, whether by in vitro fertilisation, human cloning or other currently prohibited practices.

This submission recommends that legislative responses to the Lockhart Review should NOT:

- Allow any expansion of destructive human embryo experimentation for ART research and stem cell research through amendments to the Research Involving Human Embryos Act 2002 and Prohibition of Human Cloning Act 2002;
- Allow the creation of human embryos, by any means, for any purpose other than attempting to achieve pregnancy in a woman;
- Allow changes to the definition of human embryo which would define an embryo as commencing existence at a later point in time.

4 October 2006

1. Introduction

The Life Office of the Catholic Archdiocese of Sydney is grateful for the opportunity to make a submission to The Australian Senate Community Affairs Committee, *Legislative Responses to Recommendations of the Lockhart Review.*

The Life Office is an agency within the Catholic Archdiocese of Sydney, established to extend the research, policy and educational activities the Church undertakes in life and related issues. Currently there are some 589,000 Catholics in the Archdiocese of Sydney, constituting 32.3% of the general population living within the geographical boundaries of the diocese. Over one million Catholics live in the greater Sydney area.

2. The Lockhart Committee Recommendations

2A. General comments

In 2002 the *creation* of human embryos for the purpose of research or therapy was banned by Federal Parliament without a dissenting voice. Now, less than four years later, the Lockhart Committee has recommended that this ban be lifted without a dissenting voice, and despite the fact that the great majority of the 1000 written submissions to the Committee were opposed to expanding destructive embryo research and permitting the creation of research embryos by human cloning and other forms of reproductive technology.

The majority of the Lockhart Recommendations contravene basic ethical and community standards governing research involving human beings. The Lockhart Report proposes a radical departure from a range of international declarations and covenants, notably the 2005 *United Nations Declaration on Human Cloning*, which calls on all member states to 'prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life' and Article 18 of the *European Convention on Human Rights and Biomedicine* which also specifically forbids the creation of embryos for use in research.

The Lockhart Recommendations are also out of proportion to scientific developments and expectations in this area. While some commentary on this appears in this Submission, this case has been well made in the Analysis of Advice on Developments in Assisted Reproductive Technology and Related Medical and Scientific Research, prepared by mpconsulting for the Department of the Prime Minister and Cabinet, June 2006.

2B Proposals to allow the creation of human embryos for research or therapy.

The Life Office opposes the logic and recommendations of the Lockhart Report which seek to loosen current restrictions on destructive human embryo research, and in particular, any move to overturn the legal prohibition of the creation of human embryos, by any means, for any purpose other than attempting to achieve pregnancy

in a woman. We strongly reject the recommendations 15-17, 20-27, 30 and 42 $^{\circ}$ for the following ethical and scientific reasons.

(i) Ethical considerations

Submissions from the Catholic Archdiocese of Sydney have previously noted that the law should educate, protect and regulate biotechnology on the basis of the following reasoning and objective ethical principles.

1. That human life is always a good and human beings are to be valued precisely because of the kind of entities they are. All human beings are equal

¹ 15 Research involving fertilisation of human eggs by human sperm up to, but not including, the first cell division should be permitted for research, training and improvements in clinical practice of ART.

16 Testing of human oocytes for maturity by fertilisation up to, but not including, the first cell division or by parthenogenetic activation should be permitted for research, training and improvements in clinical practice of ART.

17 Certain interspecies fertilisation and development up to, but not including, the first cell division should be permitted for testing gamete viability to assist ART training and practice.

20 An expert body should formulate objective criteria to define those embryos that are unsuitable for implantation.

21 Fresh ART embryos that are unsuitable for implantation, as defined by the objective criteria, should be permitted to be used, under licence, for research, training and improvements in clinical practice.

22 Fresh ART embryos that are diagnosed by preimplantation genetic diagnosis (according to the ART guidelines) as being unsuitable for implantation should be permitted to be used, under licence, for research, training and improvements in clinical practice.

23 Human somatic cell nuclear transfer should be permitted, under licence, to create and use human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

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

25 Creation of human embryos and human embryo clones by means other than fertilisation of an egg by a sperm (such as nuclear or pronuclear transfer and parthenogenesis) should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

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

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

30 The NHMRC should develop ethical guidelines for the use of embryos that are unsuitable for implantation for research, training and improvements in clinical practice (see Recommendations 20–22).

42 The import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority.

in dignity and this dignity is intrinsic and does not depend on any accidental characteristics such as maturity or presently exercised capacities.

- 2. Respect for the dignity of every human being gives rise to the recognition of the so-called 'sanctity' or 'inviolability' of human life and a series of human rights. While respecting human life and rights is a duty of every individual—including research scientists—protecting human life and rights is especially a duty of the state and an irreplaceable condition for ensuring the common good of all. The *International Convention on the Rights of the Child* provides that "the child, by reason of his or her physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before as well as after birth"."
- 3. Science confirms that human embryos are complete, though immature, human beings. Ethics requires that all human beings be treated with respect for their human dignity and that their basic human rights be observed. Sound research ethics therefore concludes that the destruction of human embryos for experimental, commercial or therapeutic uses is gravely unethical. As the World Medical Association's *Declaration of Helsinki* (2000) points out: "in medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interest of science and society."

The Catholic Church has consistently opposed any form of destructive human embryo experimentation for these reasons. Now we are deeply concerned by the Lockhart Committee's advocacy for the creation *and* destruction human embryos for experimentation. This would expand the pool of human embryos at risk of destruction. It would also take society beyond the *designation* of a group of living human beings (excess ART embryos) for research, as is currently allowed, to the more objectionable stage of *creating* a group of living human beings solely for the purpose of exploitation as biological material. This would embody the ultimate form of commodification of human life. It could radically alter societal attitudes towards human dignity, equality and community. As an editorial in *The Lancet* declared in 2001: "...the creation of embryos solely for the purpose of producing human stem cells is not only a unnecessary but also a step too far."

Additionally, the Lockhart Committee makes recommendations which would expand the range of ways in which human embryos are created, such as human cloning, the mixing of animal and human gametes, and the creation of hybrid embryos by introducing the nucleus of a human cell into an animal egg. These procedures are also incompatible with human dignity, as well as our shared and valued societal understanding of the human nature, procreation and family.

We specifically reject any distinction between 'therapeutic' and 'reproductive' cloning as arbitrary and misleading. A cloned human embryo, it must be remembered, is a living human being. It is human in kind, possessing a human nature, and therefore, innate human dignity. As such, all cloning is reproductive if it results in a new living human being. Ironically, cloning is never genuinely therapeutic if it results in the destruction of the living human being so created. In many ways, therefore, 'therapeutic cloning' is a more serious violation of human dignity than 'reproductive cloning'. 'Reproductive cloning' would usually at least involve the intention to nurture

the life of the human clone through the prenatal stage and beyond. 'Therapeutic cloning' is characterized by the intention to create life in order to use and destroy it.

We also reject the logic of the Lockhart Committee that:

"...the moral significance of such a cloned embryo is linked more closely to its potential for research to develop treatments for serious medical conditions, than to its potential as a human life." (Lockhart Report, p. xvii)

This reasoning departs radically from the widely held understanding that the moral significance of embryonic human beings is derived from what they *are* - very young human beings. These embryos do not gain or loss their humanity on the basis of how or why they are created. Yet the Lockhart Report suggests that a human embryo only counts as 'someone' if it will be nurtured and brought to birth. Otherwise it's just 'something' to be studied in the lab, used for drug testing, dismembered to obtain stem cells, and ultimately destroyed. This attitude towards early human life is inherently illogical and unjust.

We also disagree with the Committee where they suggest:

Furthermore, the production and destruction of such an embryo is not dissimilar to the production and destruction of excess ART embryos, which is permitted by the legislation and widely accepted by society. Thus to permit one (production and destruction of ART embryos) but not the other (production and destruction of nuclear transfer and other bioengineered embryos) would be inconsistent and appear to attach more importance to the treatment of infertility than to the treatment of other diseases and conditions that could be helped as a result of this activity. (*Lockhart Report*, p. xvii)

It is misleading for the Committee to justify the creation and destruction of human embryos for research by conflating this with the creation of excess human embryos for reproductive purposes (ART). Creating embryos for reproductive purposes is radically different to creating embryos for research. Even though couples undergoing ART know that some embryos may be destroyed in the ART process, this is not something that they intend and want. The likelihood that some embryos will perish is accepted as a regrettable, but unavoidable side effect of ART.

Research ethics is very clear about the relative roles of human subjects and animals in experimentation. Both the Nuremberg Code and the Declaration of Helsinki stipulate that any allowed experimentation involving human subjects should be capable of being supported by the relevant research literature and preceded by corresponding humane work in animals if necessary. Serious doubts exist about whether the rationale behind proposed research is scientifically plausible and sufficiently validated by corresponding studies in other species. ^v

(ii) Scientific considerations

As well as there being serious ethical objections to the creation of human embryos for research, there is also no compelling scientific case for these practices. Embryonic stem cell research remains beset by serious scientific problems such that there are still no therapeutic uses of embryonic stem cells in human patients. As one scientist has explained in *The Lancet*:

Techniques for culturing human embryonic cells have advanced...but an increasing appreciation of the hazards of embryonic stem cells has rightly prevented the emergence or immediate prospect of any clinical therapies based on such cells. The natural propensity of embryonic stem cells to form teratomas, their exhibition of chromosomal abnormalities, and abnormalities in cloned mammals all present difficulties. VI

Meanwhile, scientific developments continue to point to the fact that adult stem cells show similar, if not greater potential for the development of cell-based therapies than embryonic stem cells. Adult stem cells have been found in almost every major body tissue type, constituting a source of 'ready-made-to-order' replacement cells for damaged tissues. VII Stem cells with very similar properties to embryonic stem cells have also been found in human cord blood, placenta and amniotic fluid. VIII In fact, there is now evidence of a substantial body of adult stem cells which are capable of transdifferentiation to become other types of cells. IX The Catholic Archdiocese of Sydney has been pleased to offer a substantial grant to support a research team led by Professor Alan Mackay-Sim at Griffith University, Queensland which has shown that adult stem cells from the human olfactory mucosa are able to give rise to new nerve, glial, liver, heart, kidney and muscle cells. X In his summary, the principle researcher states that:

It is often argued that adult stem cells would not be as useful as embryonic stem cells for stem cell therapies. This new research turns this argument on its head.*i

It is estimated that there are currently over 80 therapies and around 300 clinical trials underway using adult stem cells.***

The therapeutic potential of adult stem cell technology is augmented by the fact that adult stem cell therapies pose less threat of tumour formation and genetic instability. Autologous adult stem cell transplantation also overcomes hurdles associated with immune-incompatibility.

There is still no evidence that stem cells can be readily obtained from a cloned human embryo, let alone be used for a treatment. Experience in mammalian cloning to date has shown that genetic disorders and non-viability are the most likely results for these embryos and so for any stem cell derived from them.xiiii The cloning of human embryos to obtain stem cells for therapies is likely to be too impractical for routine clinical use and prohibitively expensive. xiv The Chairman of the Royal Society Working Group on Stem Cells and Therapeutic Cloning, Richard Gardner doubts whether 'therapeutic cloning' will ever be:

...a procedure that becomes widely available...There are concerns about the efficiency and elaborateness of the procedure, and it's going to be very time-consuming and very expensive. **

Other practical (and ethical) problems surround the fact that many of these procedures depend upon the invasive 'harvesting' of eggs from women xvi placing women at risk of instrumentalisation and exploitation. As one scientist explains in *The Lancet*:

...in practice the specific issues of the source of oocytes used for any embryos created for the purpose of research is a major problem, in view of the well documented imbalance between needs and supply in egg donation. If there is a limited number of oocytes available should they preferentially be allocated to reproduction? Potential abuse of vulnerable women who might be enticed to sell their oocytes for research is a grave concern as it has been for several years in gamete donation.**

Alternatively, many scientists think that developments in adult stem cell research and therapy will overcome the need to create human embryo clones and extract matched human cells for research and cell replacement therapies.xviii

2C Proposal to redefine the human embryo.

The Committee's attempt to redefine the 'human embryo', Rec 28, should be rejected.

A human embryo is a discrete entity that has arisen from either:

- (a) the first mitotic divison when fertilization of a human oocyte by a human sperm is complete; or
- (b) any other process that initiates organised development of a biological entity with a human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;

While the current definitions in the Acts are far from ideal ², the proposed definition arbitrary assigns a later stage in human development, the first cellular division, as the moment when the embryo comes into existence. An alternate view is that the new human entity that we call an 'embryo' comes into existence when the first cell is formed by the fusion of the human oocyte and human sperm. The later process of mitosis that occurs in order to replicate that first cell (the first cell division) happens in an already existing unicellular organism. The cell division is not the beginning of the new entity (the embryo), but something that occurs in an entity which already has a completed human genome and which is already organised for further development.

The intended effect of the new definition is to allow the creation of human research embryos by the fertilization of eggs with sperm, but to conceal this by not defining the resulting unicellular human being as an embryo. Although the Report does not appear to recommend lifting the prohibition on creating embryos by fertilization of eggs with sperm for research use, (Rec 12), the proposed definition of the embryo facilitates the subsequent recommendation that research involving fertilisation of human eggs by human sperm up to, but not including, the first cell division should be permitted for research, training and improvements in clinical practice of ART (Rec 15). In reality, therefore, the Report merely shifts the point at which the new human being is called an embryo to a later stage in development (the first cell division, rather than the appearance of the two pronuclei) to allow the creation, and subsequent research with unicellular human organisms formed by fertilisation of human eggs by human sperm.

The Committee noted that changing the definition 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 breaking the law, while still maintaining a very broad definition of an embryo in line with all the community views expressed to them during the reviews. (*Lockhart Report*, p. 167)

Essentially, this definition would remove the embryo, for the first 16 hours or so of development, from the scope of any ethical or legal regulation.

² "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."

The second part of the proposed definition is also problematic because it 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 (a developmental event which depends upon implantation). There is a possibility, therefore, that this part of the definition would allow an interpretation that a cloned embryo was only an embryo if it is to be implanted, placing unimplanted cloned embryos completely outside any ethical or legal regulatory framework. The second part of the proposed definition at least needs the qualification: "...potential to develop if placed in a suitable environment."

2D Proposals to expand the power of licensing committees

We oppose recommendations 50 and 51 which seek to reinforce a 'regulatory approach to legislation'. ³ Unelected licensing committees should not be authorised to make binding rulings on the interpretation of an Act, or the regulations made under that Act, when these matters touch upon crucial public issues of protection for human life and dignity. This represents a dangerous encroachment upon the Court's and elected parliamentary representative's rights and responsibilities.

3. Comments upon current Bills and Draft Bills

The Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Ammendment Bill 2006 amends the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002 consistent with the recommendations of the Lockhart Committee. As such, our critique of the Lockhart recommendations has direct application to this Bill. We additionally note that:

- The Bill employs the misleading and illogical distinction between cloning for therapies/research and cloning for reproduction. As we have previously noted, all human cloning involves the 'reproduction' of another human being.
- The Bill replaces the current legislative definition of the human embryo with the definition proposed by the Lockhart Report (3). In addition to already outlined scientific and ethical deficiencies, this is problematic because despite the Bill's explanatory memorandum attributing this definition to the NHMRC, this 'proposed' biological definition has only been made available as a discussion paper prepared by a NHMRC Working Party and not formally promulgated. The formal position of the NHMRC continues to be stated in the Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, developed by the Australian Health Ethics Committee (the body with statutory responsibility for developing ethical guidelines for medical research). The new

³ 50 The Licensing Committee should be authorised under the Prohibition of Human Cloning Act to give binding rulings on the interpretation of that Act, or the regulations made under that Act, on condition that it reports immediately and in detail to the NHMRC and to parliament on such rulings.

⁵¹ The Licensing Committee should be authorised by the Research Involving Human Embryos Act to give binding rulings and to grant licences on the basis of those rulings for research that is not within the literal wording of the Act, or the regulations made under the Act, but is within their tenor, on condition that the Committee reports immediately and in detail to the NHMRC and to parliament on any rulings it gives, or any licences it grants, in that way.

proposed biological definition of the human embryo, is therefore, in conflict with existing guidelines.

- The Bill's redefinition of the human embryo allows them to adopt the tactics of the Lockhart Committee and claim to prohibit the creation of a human embryo for a purpose other than achieving pregnancy in a woman (12) and creating or developing a human embryo by fertilisation that contains genetic material provided by more than two persons (13), when it actually allows embryos to be created by fertilisation for non-reproductive purposes so long as they are destroyed before the two cell stage.

The Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006 (exposure draft) also seeks to amend the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002 to 'capture' the 'scientific recommendations of the Lockhart Review' (Draft Explanatory Memorandum). Our previous comments also apply to this Bill, but we draw the Committee's attention to the use of the term 'somatic cell nuclear transfer' in the title of the Bill, and the following passage from an editorial in the scientific journal, Nature:

...the (International Society for Stem Cell Research) decided to formally adopt the term 'somatic cell nuclear transfer' to describe the procedure in which an adult cell nucleus is transplanted into an egg to produce embryonic stem cells. This procedure had been called 'therapeutic cloning' to distinguish it from 'reproductive cloning', which would use the same technique in an attempt to make a baby. But the work is far from yielding any therapies, and scientists realised that the word 'cloning' was generating public concern. So they decided to adopt a more technical term less likely to stir up strong emotions.*

4. Conclusion

The Catholic Church operates in a pluralist environment here in Australia and understands that not all of her morality will be adopted by the state as law. The Church will remain, however, a vigorous defender of the life and dignity of every human being.

While we welcome the possibility that advances in biotechnology could improve the health and wellbeing of our community, this will be best achieved by ethical research which embodies respect for embryonic as well as adult human subjects.

The Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Ammendment Bill 2006 and The Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006 (exposure draft) fail to protect and uphold the dignity of nascent human life.

We recommend that current federal and state legislation in this area is NOT subject to any amendments that would allow:

• Expansion of destructive human embryo experimentation for ART research and stem cell research through amendments to the Research Involving Human Embryos Act 2002 and Prohibition of Human Cloning Act 2002.

- The creation of human embryos, by any means, for any purpose other than attempting to achieve pregnancy in a woman;
- Changes to the definition of human embryo which would define an embryo as commencing existence at a later point in time.

Thank you, again, for the opportunity to make this submission. I would be pleased to discuss this issue further should that prove useful.

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Endnotes

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ⁱ European Council of Europe. Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine. *Convention On Human Rights And Biomedicine*, Oviedo, 4.IV.1997.

ii Convention on the Rights of the Child, United Nations General Assembly resolution 44/25, 20 November 1989.

World Medical Assocation, *Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects*, 52nd WMA General Assembly, Edinburgh, Scotland, October 2000 A.5

iv Editorial. Stem-cell research: drawing the line. *Lancet* 2001; 358:163.

^v N Cobbe. "Why the apparent haste to clone humans?" *Journal of Medical Ethics* 2006; 32:298-302.

Scolding N, Stem-cell therapy: hope and hype, *The Lancet:* Jun 18-Jun 24, 2005; 365, 9477; Health and Medical Complete pg. 2073.

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bone marrow regenerate myocardium after myocardial infarction. J Clin Invest 115:326-338, February 2005.; Moriscot C et al., Human bone marrow mesenchymal stem cells can express insulin and key transcription factors of the endocrine pancreas developmental pathway upon genetic and/or microenvironmental manipulation in vitro. *Stem Cells* **23**:594-604, 2005.; D'Ippolito G *et al.*, Marrowisolated adult multilineage inducible (MIAMI) cells, a unique population of postnatal young and old human cells with extensive expansion and differentiation potential. J Cell Sci 117:2971-2981, 15 July 2004.; Mezey E et al., Transplanted bone marrow generates new neurons in human brains. Proc Natl Acad Sci USA **100**:1364-1369, 4 February 2003.; ^{ix} Jiang Y *et al.*, Pluripotency of mesenchymal stem cells derived from adult marrow. *Nature* **418**:41-49 4 July 2002.; Krause DS *et al.*, Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell. Cell 105:369-377, 4 May 2001.; Kruse C et al., Pluripotency of adult stem cells derived from human and rat pancreas. Applied Physics A 79:1617-1624, November 2004.; Li H et al., Pluripotent stem cells from the adult mouse inner ear. Nature Med 9:1293-1299, October 2003.; Zhao Y et al., A human peripheral blood monocyte-derived subset acts as pluripotent stem cells. Proc Natl Acad Sci USA 100:2426-2431, 4 March 2003.; Howell JC et al., Pluripotent stem cells identified in multiple murine tissues. Ann New York Acad Sci 996:158-173. 2003.: X Bjorson CR et al., Turning brain into blood: a hematopoietic fate adopted by adult neural stem cells in vivo. Science 283:534-7, 22 January 1999.: Eglitis MA & Mezey E. Hematopoietic cells differentiate into both microglia and macroglia in the brain of adult mice. Proc Natl Acad Sci USA 94:4080-4085, 1997.

^x Murrell W *et al.*, Multipotent stem cells from adult olfactory mucosa. *Developmental Dynamics* **233**:496-515, June 2005.

xi Summary prepared by principle researcher, Professor Alan Mackay-Sim,

xii Editorial, Proceed with caution, *Nature Biotechnology* Vol 23 No 7 July 2005.

xiii "Some studies published by Advanced Cell Technology and others have been touted as showing benefits from stem cells harvested from cloned animal embryos—but in each case, the study had to achieve its therapeutic goal by implanting the embryo in an animal's uterus and growing it to the fetal stage, then killing the fetus for more developed *fetal* stem cells. Such "fetus farming" is now apparently seen by some researchers as the new paradigm for human "therapeutic cloning," and some state laws on cloning (e.g., New Jersey's) are crafted to allow just such grotesque practices in humans. It may be that "therapeutic cloning" cannot be made to work without conducting the "reproductive cloning" that almost everyone condemns—placing embryos in women's wombs, in this case in order to abort them later for their more developed tissues." Richard Dorflinger, "The Many Casualities of Cloning," *The New Atlantis*, Spring 2006, pp. 61.

The Chairman of the Royal Society Working Group on Stem Cells and Therapeutic Cloning, Richard Gardner doubts whether 'therapeutic cloning' will ever be: "...a procedure that becomes widely available...There are concerns about the efficiency and elaborateness of the procedure, and it's going to be very time-consuming and very expensive." Sample I, Is there hope behind the stem cell hype? *Guardian* Aug 19, 2004. Similarly, Ruth Faden, John Gearhart, and eighteen other ethicists and scientists favoring ESC research, in the *Hastings Center Report*, November-December 2003 write: "Although [cloning by somatic cell nuclear transfer (SCNT)] might, in theory, solve the rejection-biological access problem, it can do so only one person at a time. The amount of time and money needed to create these uniquely cloned solutions makes it unlikely that SCNT will provide a practical, widespread solution to the biological access problem."

xv Sample I, Is there hope behind the stem cell hype? Guardian Aug 19, 2004.

There are serious concerns within the community that the authorization of human cloning and other prohibited practices that require oocyte donation, would place women at risk of instrumentalisation and exploitation. As one scientist explains in *The Lancet*: "...in practice the specific issues of the source of oocytes used for any embryos created for the purpose of research is a major problem, in view of the well documented imbalance between needs and supply in egg donation. If there is a limited number of oocytes available should they preferentially be allocated to reproduction? Potential abuse of vulnerable women who might be enticed to sell their oocytes for research is a grave concern as it has been for several years in gamete donation." Shenfield F, Semantics and ethics of human embryonic stem-cell research, *The Lancet*: Jun 18-Jun 24, 2005; 365, 9477; Health and Medical Complete pg. 2071.

Shenfield F, Semantics and ethics of human embryonic stem-cell research, *The Lancet*: Jun 18-Jun 24, 2005; 365, 9477; Health and Medical Complete pg. 2071.

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xix Nature Editorial. "Playing the name game," Nature 436, 2 (7July 2005).