

A Submission from
The Australian Catholic Bishops Conference
To
The Lockhart Review of
The Prohibition of Human Cloning Act 2002
And
The Research Involving Human Embryos Act
2002

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Executive Summary

- The subject matter of the Review is of great importance to the integrity of our nation and our community as well as to science.
- The legislation requires that the Review be established by the Minister “as soon as possible” after 19 December 2004 and report by 19 December 2005. However, the Review was not established until 17 June 2005, giving it only 6 months to complete its review and report.
- The Review has advised that it will concentrate its focus upon a number of changes since 2002 and will not consider threshold issues such as the rationale for the legislation. No reason is given for this decision. To ignore such important threshold issues threatens the credibility of the Review.
- Respect for human dignity, especially of the most vulnerable, is of paramount importance to our integrity as a nation and is a fundamental community standard. Respect for the human dignity of unborn children, including human embryos, is a measure of our integrity as a nation. If some people wish to ignore the human dignity of human embryos, they must prove that human embryos do not have such dignity. It is not merely a matter of “belief”. No such evidence has been presented and the Review has chosen to ignore these threshold issues.
- The Review proposes to assess “community standards” but does not advise the criteria against which such standards will be assessed.
- Respect for human dignity is a fundamental community standard. Such a standard would not allow cloning of a human and would require that the human dignity of the most vulnerable in our society be respected. Such a standard would not permit destructive research on human embryos and would definitely not permit further research than currently permitted by law.
- Many of the claimed scientific advances resulting from the use of embryonic stem cells are still unproven and most such advances are achievable via other means without the destruction of human embryos undertaken by some researchers.
- The issues being considered by the Review are not simply matters for scientists. These issues are integral to the fundamental values of our nation and our community standards. These issues warrant substantial discussion and consideration at all levels of our society.

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Introduction

On behalf of the Australian Catholic Bishops Conference, thank you for the opportunity to make a submission to this important review. The matters that the Review Committee (the Committee) has been asked to consider are of great importance to the integrity of our society as well as to science.

This submission does not seek to address all of the issues relevant to this important matter. It is proposed to briefly address a number of issues regarding the context of the review, in particular community standards, and also to address a number of technical issues of great importance. At a time convenient to the Committee, we would be happy to elaborate on the issues discussed or consider other issues that the Committee may wish to discuss.

Timing of the Review

The Prohibition of Human Cloning Act (the Cloning Act) requires the Minister to appoint an independent review “as soon as possible” after 19 December 2004 and that the review report by 19 December 2005. The Research Involving Human Embryos Act (the Human Embryo Act) contains a similar requirement. To undertake such an important review within a year would have been a formidable task. It is unfortunate that the Committee was not appointed until 17 June, almost 6 months after being required by legislation. This is not a criticism of the Committee but an acknowledgement that the Committee has a major task to adequately address many important issues by 19 December 2005. It is hoped that the short time frame does not encourage the Committee to ignore some important issues.

A Threshold Issue

In the Issues Paper, the Committee says in part “It is not the purpose of the reviews to revisit the underpinning debate and rationale for the legislation. Rather, it is to review the two Acts in light of changes in scientific or community understanding or standards since 2002, and any indications that the provisions are no longer appropriate and/or practical in their application.”

No explanation is given in the Issues Paper for this very narrow focus of the Review. It is unacceptable if the narrow focus is because of the short time frame for the review.

The relevant sections of the Cloning and the Human Embryos Acts that describe the review require the persons undertaking the review to take into account a number of matters including “developments in technology...in medical research and scientific research ...community standards..” etc. Nowhere in the legislation is the Committee limited to developments since 2002. Indeed, to understand and describe many of the current issues, one must understand and describe the debate and the rationale that resulted in the legislation that was passed in 2002. It may be inconvenient to consider issues that some people find uncomfortable. But that is not a valid reason for ignoring such issues.

Context

Australia is a wonderful country with strong democratic traditions. Relative to other countries, Australia is socially, politically and economically successful. Many claim that one feature of our nation of which we can be proud is the way in which victims of discrimination and disadvantage are protected. But the true measure of the success of our nation is when we can honestly say that, at every opportunity, we ensure that the most vulnerable in our society are protected. Christians have a simple guide to such an objective: “Just as you did it to one of the least of those, you did it to me” (Mt 25: 40).

Martin Luther King, in his Nobel Prize Acceptance Speech expressed the matter eloquently: “This evening I would like to use this lofty and historic platform to discuss what appears to me to be the most pressing problem confronting mankind today. Modern man has brought this whole world to an awe-inspiring threshold of the future. He has reached new and astonishing peaks of scientific success. He has produced machines that think and instruments that peer into the unfathomable ranges of interstellar space. He has built gigantic bridges to span the seas and gargantuan buildings to kiss the skies. His airplanes and spaceships have dwarfed distance, placed time in chains, and carved highways through the stratosphere. This is a dazzling picture of modern man's scientific and technological progress.

Yet, in spite of these spectacular strides in science and technology, and still unlimited ones to come, something basic is missing. There is a sort of poverty of the spirit which stands in glaring contrast to our scientific and technological abundance. The richer we have become materially, the poorer we have become morally and spiritually. We have learned to fly the air like birds and swim the sea like fish, but we have not learned the simple art of living together as brothers.”

Recent advances in science in general and genetics in particular have been truly amazing. We know that there are potentially many great advances still to come which will offer great benefit to many people by offering treatments of which humanity could previously only dream. But such advances are only amazing if they can be made while maintaining respect for the dignity of the

human beings who receive the treatment, who develop and administer the treatment and, most importantly, who provide raw material from which a treatment is produced or developed. Unless the human dignity of all human beings can be guaranteed then any such advance that results is at best tainted and at worst abhorrent.

Human Dignity

Blood transfusions and organ transplants are wonderful advances in medical science. But in all such processes, the dignity and integrity of the donor are maintained. It would be unacceptable if a donor was created and then destroyed in order to obtain an organ or a blood transfusion. It would be equally unacceptable if a donor was executed for the same reason. Human dignity is paramount in all such matters.

But some people consider it acceptable to create and then destroy a human in the form of an embryo in order to undertake research or a medical procedure. Some people will claim that an embryo is not human. But the onus is upon such people to prove such a claim. At what point does an unborn child become human? Most would agree that the day before birth he or she is human, but what about a month or six months before birth? Some will claim that an unborn child is only human from the time that he or she is viable outside the womb. But if such is the criterion then one's humanity is determined merely by advances in technology. A human embryo is a distinct yet integrated group of cells with a human genetic identity and the potential to develop into a human adult. An embryo must therefore be accorded the dignity of humanity.

Some people claim that an embryo does not become a human until some later stage in his or her development. But such people offer no proof for such a claim. If such a claim is accepted, then the humanity of one person is decided merely by the opinion of another. In the absence of such proof an embryo must be accorded the dignity of humanity and thus be protected from being considered a mere source of material which one might use for research or treatment.

Some people claim that debate about the human dignity of an embryo is merely a matter of differences in religious beliefs and that those who do not "believe" in the human dignity of an embryo are free to deal with embryos without respecting their humanity. Centuries ago, a similar argument was used to justify slavery. All humans, whatever their situation and whatever stage of their development, possess human dignity and deserve respect.

When one reviews legislation that deals with Human Cloning or Research Involving Human Embryos, it is imperative that the "underpinning debate and rationale for the legislation" be considered as a threshold issue prior to consideration of consequent issues. The Committee cannot "consider and report on the scope and operation of" the Acts, without considering and reporting on such matters. That the Issues Paper does not address such matters is a fundamental flaw in the Paper. It is suggested that the

Committee must urgently reconsider its threshold position regarding this matter and issue a revised Issues Paper. Unless the Committee adequately addresses these threshold matters then the report of the Committee cannot have the credibility so necessary for such an important review.

The following comments address a number of issues, some of which are identified in the Issues Paper. However, the fundamental flaws in the stated purpose of the Review and the consequent inadequacy of the Issues Paper provide an unfortunate background for consideration of these important issues. If the Committee decides to reconsider these threshold matters then we will provide further comment, either in writing or in discussion, whichever is most appropriate.

Community Standards

The Acts identify “community standards” as an important matter for consideration and report by the Committee. The Issues Paper advises that the purpose of the Review is “to review the two Acts in light of changes in scientific and community understanding and standards since 2002, and any indications that the provisions are no longer appropriate and/or practical in their applications”. The Issues Paper also advises that the “Committee must take into account ‘community standards’.”

The Issues Paper also identifies the importance of a common language in considering complex issues. But neither in the Terms of Reference nor in the Issues Paper is there any definition of the terms “community standards” or “community understanding and standards”. In particular, there is no description of such standards or the criteria against which such standards will be considered and assessed. This is another threshold issue that threatens the credibility of such an important review.

(It is emphasised that such criticism of the Review is not a criticism of the individual members of the Committee, all of whom are eminent in their fields. Rather it is an acknowledgement that the Committee has been handed a task with a timetable and parameters that will make it virtually impossible to produce a credible report.)

With the above caveat, some comments about community standards are provided below:

Previous comment has been made about the need for consideration of the threshold issues. In considering community standards, consideration of the threshold issues is very important. For example, the community standard regarding respect for human dignity must be an important consideration. Who decides whether or not an embryo possesses human dignity? Against which criteria is such a judgement made?

If we claim that our community standard includes respect for human dignity, then human cloning, for any reason, is unacceptable. We would be willing to define community standards’ criteria against which such an assessment

should be made. However, we would prefer to debate it, if necessary, within a context and criteria defined by the Committee and widely accepted as a community standard.

Similarly, if we claim that our community standard includes respect for human dignity, and there is not irrefutable proof that a human embryo is not human, then a human embryo must be accorded human dignity and thus protection. This is not merely a matter of individual opinion or religious belief. It is fundamental to our status as a civilised society.

In a society in which human dignity was respected, there would be no research or other activities that resulted in the destruction of human embryos or fetuses. Any further advances beyond that currently permitted by legislation are clearly unacceptable in our society.

The following discusses a number of issues identified in the Issues Paper. Given the threshold problems with the Review and the Issues Paper, it is not proposed to discuss all of the issues identified at this stage.

Issues – Definitions and Terminology

The definition of a human embryo in the legislation includes a requirement that it has “been developing for less than 8 weeks”. It is accepted that scientists and medical practitioners use 8 weeks as a distinguishing threshold between an embryo and a fetus. However, such a distinction is merely a scientific distinction and in no way affects the humanity of embryos and fetuses.

Issues – prohibited embryos and practices

The narrow focus of the Issues Paper is again evident in this issue. For example, the arguments described *for* human cloning do not mention that a precursor for such arguments is an unproven claim that human embryos do not have human dignity.

The threshold issues discussed above precede any consideration of how the ban on human cloning affects research.

It is almost certainly the case that the ban on all human cloning and the other prohibitions have not adversely affected research in Australia. Where research in these areas has proceeded overseas it has been beset by technological difficulties, not to mention, ongoing ethical controversy.

Embryonic stem cells have now been derived from cloned human embryosⁱ, parthenogenetically produced embryosⁱⁱ and hybrid embryos.ⁱⁱⁱ A recent article in the medical journal *The Lancet* reminds us, however, that four years after human cloning to generate stem cells was legalized in the United Kingdom:

...the technical difficulties and biological hazards inherent in cloning human embryos and developing treatments from their stem cells led

Richard Gardner, Chairman of the Royal Society Working Group on Stem Cells and Therapeutic Cloning, to doubt whether this would 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.’^{iv}

On the other hand, although difficult to measure, it is reasonable to suppose that the ban on human cloning and the other prohibitions in the Cloning Act has and will continue to exert a positive effect upon research in Australia through the preservation of the ethical integrity of researchers and scientific practice.

The alternative – to have scientists engage in a practice like human cloning which has been described by the United Nations as “incompatible with human dignity and the protection of human life”^v - would introduce an ethically confused and corrupt agenda to the Australian scientific community.

Issues — use of excess ART embryos

There appears to be an implication in the legislation and an attitude among some researchers that, because excess ART embryos will be disposed of eventually, they may as well be used for something useful and thus they can be destroyed during research. Such an implication and attitude fail to acknowledge the human dignity that should be accorded to embryos, whether excess or not. Taken to its logical conclusion, such an implication and attitude would allow research to be undertaken on terminally ill patients. Excess human embryos will be disposed of eventually but community standards expect that such disposal should be done with appropriate recognition of the human dignity of the embryo.

Issues – licensing and statutory arrangements

The Issues Paper advises that, of the applications for the use of human embryos in research, none have been rejected, though “some applications have required revision to meet Licensing Committee requirements”. Without evidence to the contrary, such an outcome would imply that the Licensing Committee requirements are inadequate and/or that the Licensing Committee is too close to the research community.

Issues – national stem cell bank

A national stem cell bank of adult stem cell lines for research and therapeutic developments would make an important contribution to biomedical research and healthcare, both in Australia and internationally.

Embryonic or fetal stem cell lines ought not be included in this bank as they have been obtained by unethical means.

Issues – research developments

The Issues Paper invites specific consideration of whether access to excess ART embryos for research has allowed a significant advance in knowledge in stem cell science and cellular therapy.

Scientific developments over the past 3 years confirm that adult-type stem cells show similar, and possibly, even greater potential for the development of stem cell therapies than embryonic stem cells.

Adult-type 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. An ever increasing number of adult stem cells have been isolated which are capable of transdifferentiation to become other types of cells^{vi} and stem cells with very similar properties to embryonic stem cells have also been found in human cord blood, placenta and amniotic fluid.^{vii} It is now clear that post-natal tissues are a more than adequate source of stem cells for research and regenerative therapies.

As was largely predicted in 2002, it is adult stem cell technology, not embryonic stem cell technology, which has proven to be of greater benefit to the sick and injured. It is estimated that there are currently over 80 therapies and around 300 clinical trials underway using adult-type stem cells.^{viii}

There are, however, no current therapeutic uses of embryonic stem cells for human patients. As one scientist recently 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.^{ix}

Therefore, to date in Australia, access to excess ART embryos for research has not led to a significant advance in knowledge in the areas of stem cell science and cell therapy research.

Conclusion

Science ought to be at the service of human life and human dignity.

There is no ethical justification for the subservience of the life and dignity of some members of our human family to biotechnology and biomedicine.

There is in fact, no scientific necessity for destructive embryo research, human cloning and other prohibited practices.

We thank the Committee for the opportunity to contribute to the legislative review process, and do so with the hope that this process will promote scientific research and medical treatments which respect the life and dignity of human beings at every stage of their development.

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- ⁱ Hwang WS *et al.*, Evidence of a pluripotent human embryonic stem cell line derived from a cloned blastocyst. *Science* **303(5664)**:1669-74, 12 March 2004.; Hwang WS *et al.*, Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts. *Science* **308**:1777-1783, 2005.; Hwang WS *et al.*, Human embryonic stem cells and therapeutic cloning. *J Vet Sci* **6(2)**:87-96, June 2005.; Highfield R, Scientists take a giant step forward in human cloning. *UK Telegraph*, 10 May 2005.
- ⁱⁱ Cibelli JB *et al.*, The first human cloned embryo. *Sci Am* **286(1)**:44-51, January 2002, and Cibelli JB *et al.*, Somatic cell nuclear transfer in human: Pronuclear and early embryonic development. *J Regen Med* **26**, 25-31, 2001.
- ⁱⁱⁱ Researchers at Advance Cell Technology in the USA fused a human cell with an enucleated cow's egg to produce an embryo that developed to the 32-cell stage. Stem Cell Sciences in Victoria, Australia conducted a similar experiment using a pig's egg to produce a 32-cell embryo that was destroyed before further development could take place.
- ^{iv} Scolding N, Stem-cell therapy: hope and hype, *The Lancet*: Jun 18-Jun 24, 2005; 365, 9477; Health and Medical Complete pg. 2073, citing Sample I, Is there hope behind the stem cell hype? *Guardian* Aug 19, 2004.
- ^v United Nations Declaration on Human Cloning, 2005.
- ^{vi} Crain BJ *et al.*, Transplanted human bone marrow cells generate new brain cells. *J Neurol Sci* **233(1-2)**:121-3, 15 June 2005.;^{vi} Yoon Y-S *et al.*, Clonally expanded novel multipotent stem cells from human 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.;^{vi} D'Ippolito G *et al.*, Marrow-isolated 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.;^{vi} Jiang Y *et al.*, Pluripotency of mesenchymal stem cells derived from adult marrow. *Nature* **418**:41-49 4 July 2002.;^{vi} 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.;^{vi} 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.
- ^{vii} McGuckin CP *et al.*, Production of stem cells with embryonic characteristics from human umbilical cord blood. *Cell Prolif* **38(4)**:245-55, August 2005; Miki T *et al.*, Stem Cell Characteristics of Amniotic Epithelial Cells, first published online in *Stem Cell Express* on 4 August 2005, <http://stemcells.alphamedpress.org/cgi/content/abstract/2004-0357v1> ; Prusa A-R *et al.*, Oct-4-expressing cells in human amniotic fluid: a new source for stem cell research? *Human Reprod* **18**:1489-1493, 2003.
- ^{viii} Editorial, Proceed with caution, *Nature Biotechnology* Vol 23 No 7 July 2005.
- ^{ix} Scolding N, Stem-cell therapy: hope and hype, *The Lancet*: Jun 18-Jun 24, 2005; 365, 9477; Health and Medical Complete pg. 2073.
- ^{ix} *Ibid.*