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Submission to

The Legislation Review Committee - *Prohibition of Human Cloning Act 2002* & the *Research Involving Human Embryos Act 2002*

From

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Executive summary

The Catholic Church through its several institutions and the many professionals who are believers, makes a substantial contribution to healthcare, health education and medical research in Australia. We encourage the promotion of ethically acceptable forms of biotechnology that would protect and promote the health and wellbeing of *every* member of the human family, and give proper expression to the dignity of human life.

By authorising the use of excess ART embryos for research, the *Research Involving Human Embryos Act 2002* contravenes the basic community standard of respect for human life and dignity.

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. There is no strong scientific case for expanding access to ART embryos, by allowing the deliberate manufacture of human embryos for research purposes. In fact, the scientific justification for *any* further use of excess ART embryos for research into cell-based therapies has weakened since 2002. The *Research Involving Human Embryos Act 2002* should be amended to at least recover the situation up until April 2005 and ideally to prohibit all forms of destructive human embryo experimentation.

The *Prohibition of Human Cloning Act 2002* should not be amended to allow any form of human cloning or other currently prohibited practices.

So-called 'therapeutic cloning' is unlikely to surpass the application of adult-stem technology for routine clinical use. There is no evidence that the deliberate creation of human embryos for research or therapy would be consistent with community standards. It is clearly inconsistent with International ethical standards.

Therefore, in line with scientific developments and community standards, this submission recommends that the combined effect of the two Acts ought to be:

- to prohibit all forms of destructive human embryo research or, at least, not to extend the class of human beings at risk of such manipulation;
- to prohibit the creation of human embryos, by any means, for any purpose other than attempting to achieve pregnancy in a woman;
- to prohibit human cloning and all other unacceptable practices identified in the *Prohibition of Human Cloning Act 2002*;
- to facilitate the development of alternative sources of stem cells such as through a national adult stem cell registry and bank for cells derived from cord blood or other non-destructive sources.

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Introduction

The Catholic Archdiocese of Sydney is grateful for the opportunity to make a submission to the Legislation Review of Australia's *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002.* We record our disappointment, however, that this Review did not occur before the so-called sunset clause came into effect in April 2005.

In this submission, each Act has been considered separately, in light of the Legislative Review Committee's terms of reference and questions raised by the Issues Paper, with particular attention being paid to:

- developments in medical research and scientific research and the potential therapeutic applications of such research [TOR 1 (i) b)]
- community standards [TOR 1 (i) c]

Research Involving Human Embryos Act 2002

1a) Considerations with respect to developments in medical research and scientific research and the potential therapeutic applications of such research.

(i) Scientific developments over the past 3 years confirm that adult stem cells show similar, if not greater potential for the development of cell-based therapies than embryonic stem cells.

(ii) 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. [i]

Stem cells with very similar properties to embryonic stem cells have also been found in human cord blood, placenta and amniotic fluid. [ii] A multipotent adult progenitor cell has been isolated from bone marrow and hailed by *New Scientist* as the 'ultimate stem cell."[iii] 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. [iv] Here in Australia, a research team at Griffith University, Queensland, led by Professor Alan Mackay-Sim 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. [v] 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.[vi]

The Catholic Archdiocese of Sydney made a $50 000 grant to Professor Alan Mackay-Sim's research team in 2002. Heartened by the results of this research, as well as other developments in adult stem cell technology here and overseas, a further research grant of $100 000 has been offered, on a competitive basis, to further support and foster research on the therapeutic potential of adult stem cells. [vii]

(iii) It is estimated that there are currently over 80 therapies and around 300 clinical trials underway using adult stem cells.[viii] 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.

(iv) In stark contrast to these developments with adult stem cell technology, there are no current therapeutic uses of embryonic stem cells in human patients.

Scientists around the world have been able to prepare stem cell lines from human embryos since 1998, but they are yet to develop any therapeutic applications of embryonic stem cells for humans. 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]

(v) Another development within stem cell technology since 2002 is the growing interest and emergent potential of alternative sources of human pluripotent stem cells. This has been the subject of a recent White Paper of The President's Council on Bioethics, Washington, D.C.,[x] that summarizes several current proposals for obtaining pluripotent human stem cells that do not require destroying human embryos. These include dedifferentiating somatic cells back to pluripotency, deriving stem cells from organismically dead embryos, developing stem cells from blastomeres extractable from living embryos and seeking to derive stem cells from genetically engineered artificial entities.

Since the publication of this White Paper, some members of the President's Council on Bioethics, in consultation with scientists, philosophers and theologians have presented a specific proposal that envisions the reprogramming of a somatic cell nucleus before introducing

it into an oocyte so that it immediately becomes a pluripotent stem cell without passing through any embryonic stage of development. [xi]

1b) Considerations with respect to community standards

(i) Regrettably, the Legislative Review's Terms of Reference and Issues Paper do little to promote further ethical analysis and debate about this legislation. For example, the Issues Paper seeks to exclude revisiting the underpinning community debate and rationale for the legislation.

We have been invited, however, to take 'community standards' into account, and we note that such standards ought to be based upon sound reasoning and objective ethical principles and that the law should educate, protect and regulate society on the basis of such principles. We therefore recommend as 'community standards' upon which the Committee should base its reflections:

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 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".[xii]

(ii) 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."[xiii]

The *Research Involving Human Embryos Act 2002* created, for the first time in Australian political and legal history, a class of human life which is statutorily expendable. We reject the argument that because excess ART embryos *are going to die anyway*, it is acceptable to use them for *something*. Many frail elderly people, prisoners on death row, and

terminally ill patients are 'going to die soon anyway', but we hold back from killing and using them because human dignity deserves better.

Law ought not endorse the deliberate killing of human beings and to the extent that it now does, the Act already stands in opposition to fundamental community standards. To propose the widening of the class of expendable humans, as some have done, would worsen this situation.

(iii) When this legislation was enacted in 2002, supporters of the legislation argued that the overriding 'community standard' was 'necessity'. It was argued that destructive human embryo research was justified by the 'need' to obtain embryonic stem cells for research and therapy for the 'greater good' of human health and welfare.

These pragmatic or utilitarian assertions, driven by supposed 'necessity', can now be rejected not merely on philosophical or ethical grounds but also for purely scientific reasons.

(iv) According to the Database of Licenses authorizing the use of excess ART embryos (29 Jun 2005) 1,731 human embryos have been consigned to destructive research under the Act. Of these, only 550 human embryos will be used to create new human embryonic stem cell lines, the remaining embryos being used to improve IVF culture of human embryos, train technicians in the techniques of embryo biopsy and develop pre-implantation screening techniques.

At the time of passage of this legislation, the range of matters for which a license could be granted, was not satisfactorily disclosed to the public. This situation has not improved. The vast majority of the community remains unaware of the purposes to which the excess ART embryos have actually been consigned.

It is likely that if the public were aware that the majority of excess ART embryos have been consigned to destructive research for reasons that are *not* directly related to the development of much promised and hoped for medical treatments, they would oppose the current legislation where arguments of 'necessity' have trumped sound democratic principles such as respect for human life and human dignity.

1c) Applicability of establishing a national stem cell bank. [TOR1(i)d)]

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 if they have been obtained by unethical means.

1d) Concluding comments

There are good scientific and ethical reasons why destructive research involving human embryos should not be endorsed by Australian law.

By authorizing the use of excess ART embryos for destructive research, the *Research Involving Human Embryos Act 2002* contravenes the fundamental standards of *primum non nocere* and respect for human life and dignity.

Access to excess ART embryos for research has not led to significant advance in knowledge in the areas of stem cell science and cell therapy research. There is no strong scientific case for expanding access to ART embryos, by allowing the deliberate creation of human embryos for research purposes. In fact, the scientific justification for *any* further use of excess ART embryos for research into cell-based therapies has weakened since 2002.

Prohibition of Human Cloning Act 2002

2a) Considerations with respect to developments in medical research and scientific research and the potential therapeutic applications of such research.

(i) The cloning of human embryos to obtain stem cells for therapies is likely to be too impractical for routine clinical use.

Women would have to be subjected to hormones and invasive procedures to 'harvest' the eggs for each treatment. A recent editorial in *Nature Biotechnology,* making reference to the June 17 issue of *Science* where Woo Suk Hwang and his team describe the generation of multiple embryonic stem cell lines via human embryonic cloning, stated that:

> Of course it will be many more years before cloned ES cells can be turned into routine clinical treatments for patients. From a practical standpoint, although Hwang's tenfold more efficient derivation of cloned ES cells is impressive, the shortage of fresh human eggs to reprogram somatic cell nuclei and derive ES cells remains a considerable drawback.[xiv]

It is also likely to remain prohibitively expensive for general use. 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."[xv]

(ii) Further developments in adult stem cell research and therapy should overcome the need to create human embryo clones and extract matched human cells for research and cell replacement therapies.

(iii) At any rate, while there is still no evidence that human embryonic stem cells can be used in therapies, there is absolutely no medical justification for the creation of additional human embryos by cloning.

2b) Considerations with respect to community standards

(i) There is no evidence that community standards have fallen to endorse the creation of human embryos with the intention of utilizing and destroying them in research or cell based therapies, whether by IVF, methods of human cloning such as somatic cell nuclear transfer, or other currently prohibited practices.

To allow human cloning would move us beyond the *designation* of a group of living human beings to the class of biological material for research, as we already see with the *Research Involving Human Embryos Act 2002*, to the even more objectionable stage of *manufacturing* a group of living human beings solely for the purpose of utilization and 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.

One Australian survey has found that public support for human cloning remains at under 10%. [xvi]

(ii) The prospect of cloning human embryos to achieve pregnancy and the live birth of a child, so called 'reproductive cloning', has been greeted with almost universal ethical condemnation. On the other hand, some countries, and some scientists here in Australia, think that it is acceptable to clone human embryos for biomedical research or cell based therapies, so called 'therapeutic cloning'.

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.

Ironically, 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.

(iii) There are also 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.[xvii]

(iv) The current prohibition on all forms of human cloning is consistent with International standards.

In March 2005, the United Nations General Assembly endorsed the *United Nations Declaration on Human Cloning*, thereby calling 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". The General Assembly made this declaration:

"*Guided* by the purposes and principles of the Charter of the United Nations,

Recalling the Universal Declaration on the Human Genome and Human Rights…

Aware of the ethical concerns that certain applications of rapidly developing life sciences may raise with regard to human dignity, human rights and the fundamental freedoms of individuals,

Reaffirming that the application of life sciences should seek to offer relief from suffering and improve the health of individuals and humankind as a whole,

Emphasizing that the promotion of scientific and technical progress in life sciences should be sought in a manner that safeguards respect for human rights and the benefit of all,

Mindful of the serious medical, physical, psychological and social dangers that human cloning may imply for the individuals involved, and also conscious of the need to prevent the exploitation of women, [and]

Convinced of the urgency of preventing the potential dangers of human cloning to human dignity."

Article 18 of the *European Convention on Human Rights and Biomedicine* also specifically forbids the creation of embryos for use in research. [xviii]

(v) Other practices currently prohibited in the Act reflect community standards about the need to protect and promote the dignity of human life in its transmission and expression.

(2 c) Concluding comments

The prohibition of all forms of human cloning and other practices described in the *Prohibition of Human Cloning Act 2002* remains scientifically appropriate and ethically necessary, in light of developments in biotechnology and community standards. So called 'therapeutic cloning' is unlikely to surpass the application of adult stem cell technology for routine clinical use. There is no evidence that the deliberate creation of human embryos for research or therapy would be consistent with community standards. It is clearly inconsistent with International ethical standards.

The *Prohibition of Human Cloning Act 2002* should not be amended to allow any form of human cloning or other currently prohibited practices.

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Therefore, in line with scientific developments and community standards, the Catholic Church in Sydney submits that the combined effect of the two Acts and any subsequent legislation following upon the present Review ought to be:

- to prohibit all forms of destructive human embryo research or, at least, not to extend the class of human beings at risk of such manipulation;
- to prohibit the creation of human embryos, by any means, for any purpose other than attempting to achieve pregnancy in a woman;
- to prohibit human cloning and all other unacceptable practices identified in the *Prohibition of Human Cloning Act 2002*;
- to facilitate the development of alternative sources of stem-cells such as through a national adult stem-cell registry and bank for cells derived from cord blood or other non-destructive sources.

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. The Church gives expression to this in Australia through its substantial contribution to healthcare, health education and scientific research. We join all Australians in hoping for new developments in biotechnology and medicine that will improve the health and wellbeing of Australians. We believe there are ways of achieving such results without compromising research ethics or further polarising the Australian community; ways which protect and promote the health and wellbeing of *every* member of the human family.

Endnotes

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