SUBMISSION of the CAROLINE CHISHOLM CENTRE for HEALTH ETHICS to the SENATE COMMUNITY AFFAIRS COMMITTEE on LEGISLATIVE RESPONSES TO RECOMMENDATIONS OF THE LOCKHART REVIEW

Our Centre is grateful for the opportunity given us by the Australian Senate to make a submission on the Lockhart Recommendations for National Legislation. We did make a rather lengthy submission to the Lockhart Inquiry. We do not wish to repeat here all that we wrote then, especially all the scientific details. We regret that the surprising statement in the Lockhart Review *Issues Paper* (August 2005, p.3) which unduly limited the Review's discussion on 'community standards': "It is not the purpose of the reviews to revisit the underpinning community debates and rationale of the two Acts." We thought such debates were pertinent, and history since then has shown the debates are still alive in the community and the media. Our detailed position is stated fully in our recent book, ***Stem Cells. Science, Medicine, Law and Ethics,*** a couple of copies of which have been posted to the Secretary of the Australian Senate's Community Affairs Committee.[1] We shall begin with a Preamble on our Centre's position on the moral inviolability of early human life from conception.

I. Preamble: Moral Inviolability of the Human Embryo

Many secular views on human embryos hold that they could not have any interests or intrinsic value beyond sentience - the seeking of pleasure and avoiding pain.[2]**.** Many others see embryos in a different light that dates back thousands of years to the Hebrew Scriptures. These portray God as the source and giver of human life in particular: "From the earliest Christian times it has been held that it was immoral to destroy a life that had been conceived because it belonged to God in whose image it was made. Catholic bishops of the world at the Second Vatican Council in 1965 confirmed this uninterrupted tradition on the moral inviolability of the basic good of human life from the formation of the human embryo --: "Life once conceived must be protected with the utmost care."[3]

As I have said in our Centre's book: "This *theological* insight expresses a widely shared value for human life, held also by many who do accord the Bible the respect that Christians do. There are also sound *philosophical*, i.e., rational, arguments in favour of the biblical and Christian tradition on absolute respect for the human embryo based on its natural actual and proximate potential, inherent in its formative process from conception, to form a human individual and person.[4] The moral necessity to show respect for human embryos is a profound human insight and reflects the respect for human life that from the beginning of time has taken its origin from a couple's mutual self-giving. It arises in our hearts and not only from religious sources. Human life is a

[1] N M Ford NM, and M Herbert M, *Stem Cells. Science, Medicine, Law and Ethics.* Strathfield, NSW: St Paul Publications 2003.

[2] Kuhse H, and Singer P. Individuals, humans and persons: the issue of moral status. In: Singer P *et al*. Embryo Experimentation. Cambridge: University Press; 1990, 73; see also Ford NM. The Prenatal Person. Ethics from Conception to Birth. Oxford: Blackwell Publishing; 2002, 69.

[3] Pastoral Constitution of the Church in the Modern World. Vatican II. The Conciliar and Post Conciliar Documents. Flannery A (Ed). Dublin: Dominican Publications; 1975. n. 51.

[4] Dave Wendler, Understanding the 'conservative' view on abortion, Bioethics 13 (1999) 32-55.

condition for the enjoyment of other values we cherish and protect. Adults have moral responsibilities for embryonic human life, but not direct dominion over life itself. There are no reasonable grounds for the reductionism that views human embryos as no more than genetic products, devoid of significance and value. The first fruit of human generation in the zygote has a claim to unconditioned moral respect. But the passive potency of a sperm or an egg to become a human embryo does not warrant moral respect.

"Moral respect due to human life from conception can also be argued by showing that the embryo at the zygote stage already is a human individual and a person. There are good and credible reasons supporting this position. The zygote is a *totipotent* cell whose newly constituted genetic package, in conjunction with exchanges of signals from the maternal reproductive tract, continuously directs, in a coordinated process, the multiplication of cells with unidirectional purposeful development. At the same time, the differentiation of tissues required for the growth of the one and the same living individual proceeds. The embryo and the resulting adult have practically the same genetic individuality. Clearly the embryo possesses the potential to develop and grow into an adult from the outset. This argues that the zygote and the adult are the same living individual. The zygote organises itself into a multicellular embryo and grows into a fetus, a child and then an adult. Once the human embryo is formed, naturally or artificially, it is owed a duty of unconditional moral respect, regardless of the potential therapeutic benefits that may be gained by their destruction."[5] This is not a moral principle that is based simply on utilitarian understanding of ethics.

Based on science and philosophy one can reliably say that the zygote or start of the embryo is the cell produced by the fusion of the male and female. This position of principle will influence our negative comments on many of the Lockhart Report's recommendations. In short we found no justification to reverse the ban on the cloning of human embryos.

II. Suggestions to the Senate Community Affairs Committee

A. Independent Expert Advice

We believe the Senate Community Affairs Committee should seek expert advice from scientists not involved in, and not in favour of, hES cell research – for example scientists working with mouse embryos. There are enormous risks if this measure is not adopted. Even sub-consciously scientists who support therapeutic cloning may exaggerate the likelihood of potential medical benefits resulting from therapeutic cloning and thereby needlessly raise false hopes of success and mislead both the public and members of Parliament to believe there is a need to amend the present **Prohibition of Human Cloning Act 2002** to permit the cloning of human embryos for research involving hES cells derived from their destruction. These hES cells are sought because they are *pluripotent*, i.e. sufficiently plastic to enable them to adapt and become any type of cell once transferred into an injured or diseased part of the human body for therapeutic purposes. One may legitimately ask where one can find published in scientific journals the successful animal, e.g. mouse, trials that provide proof of principle that therapeutic cloning and the use of hES cells will or could

[5] Ford and Herbert, *Stem Cells*, 77-78.

deliver the promised therapeutic benefits! Ordinary Australians may well be concerned about the hurry to "throw good money after bad" as the saying goes.

B. **Need of a Professional Survey of Australian's Views on *Therapeutic Cloning* and ES Cell Research**

Opinion polls on 'therapeutic cloning' and hES cell research published in newspapers are often not reliable. A recent ACNielssen poll taken for *The Age* newspaper and published on 12 September 2006 found that of 1415 respondents 62% answered positively to the question "do you support or oppose legislation which allows the cloning of stem cells for medical research?" The way the question was framed was quite inadequate because no mention was made of cloning embryos or of their destruction to obtain hES cells. No mention was even made of hES cells themselves. To their credit the journalist Katherine Murphy and Annabel Stafford stated at the conclusion of their article: "ACNielsen pollster John Stirton said that the survey results on stem cells needed to be treated with caution because the research was a complex field, and respondents had been asked only one question, which linked stem cells and medical research**."**

An earlier survey had been done by independent professional researchers to find out to what extent Australians support the destructive use of human embryos to obtain hES cells for research and therapies in 2004. Evidence was found that most Australians do not support creating human life destined for destruction in order to do medical research to develop therapies for accident victims or degenerative diseases such as Parkinson's or Alzheimer's. I wish to quote from my letter that was published in September 2005 in the *Internal Medicine Journal*: "Swinburne University of Technology researchers Dr Christine Critchley and Dr Lyn Turner have published the results of an Australia-wide survey of 1013 people conducted last year. Following an in-depth focus on stem cell research, they found that 'the majority (53.5%) indicated they would be comfortable using left over IVF embryos.' However, they also found that the majority (63.4%) of 'the Australian public do not feel comfortable with scientists cloning human embryos for research purposes'."[6] It is worth noting that this was a survey of people across Australia who had become informed by participating in focus discussion groups. Participants knew that therapeutic cloning involves the destruction of embryos, and, as I have mentioned above, not all surveys make that known. It is clear, properly informed Australians understand what 'therapeutic cloning' of embryos for research means, and they do not like it.

Our suggestion to the *Senate Community Affairs Committee* is to make their own survey, or better to commission a professional pollster to run a survey. The Committee would need to be in unanimous agreement on the wording of the question or questions to see if a majority of Australians across all States supports the cloning of human embryos destined to be destroyed to obtain hES cells for medical research into potential therapies for degenerative diseases. Unclear of ambiguous questions put to the Australian public on such an important issue is not good enough for legislators to rely on for legislation permitting this very practice.

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[6] Critchley C, Turney L.' Understanding Australians' perception of controversial scientific research', *Australian Journal of Emerging Technologies and Technologies and Society* 2 (2004) Accessed at http://www.swinburne.edu.au/sbs/ajets/journal/V2N2/pdf/V2N2-2-Critchley.pdf at pages 94 and 95.

B. Ethical Alternatives to the Use of Embryonic Stem Cells

There is evidence of success from clinical trials using AS cell therapies. Recently K **Takahashi and S Yamanaka** published in the scientific journal (*Cell*, 25 August 2006) explaining how in mouse models they produced pluripotent stem cells by introducing four key factors into adult cells. What is ethically interesting is that this procedure does not use eggs and does not create embryos. If this could be repeated with human cells, it provides an acceptable approach to preparing patient-specific pluripotent human stem cells without using human eggs and the destruction of human embryos or the cloning of human embryos. Admitted, more research is required here as it would also be with the unethical method of therapeutic cloning.

I recently wrote of another alternative ethical source of pluripotent stem cells: "Dr Gesine Kögler and her colleagues have identified some special adult somatic stem cells obtained from umbilical cord blood (CB) with great intrinsic pluripotent differentiation potential. These cells resemble ES cells because they are pluripotent and have similar differentiating capabilities to ES cells. It is thought that they may be able to provide the same valuable therapies sought by researchers using ES cells. Pluripotent CB cells could be stored in CB banks and be used to make a sufficiently close match to the tissue of patients in need of a transplant to repair cardiac muscle or nerve tissue." [7]

Again as I have published in *Kairos* 6 August 2006, pp. 5-6: "There are ethical alternatives to embryo destructive research, i.e. there are many possibilities of finding or developing stem cells of wide potentiality without involving embryo destruction**.** Human stem cells can be derived from umbilical cord blood, bone marrow (hematopoietic), fetal tissue, and even from the nose's olfactory-mucosa as done by Professor Mackay-Sims of Griffith University. These are *non-embryonic*, more popularly known as *adult* stem (AS) cells. They lack the universal plasticity of ES cells but they can adapt to certain parts of the body and repair damaged tissues. Dr Mary Horowitz reports "thousands of patients hematopoietic cell transplantations (HCTs) to treat life threatening malignant and non-malignant diseases. Current estimates of annual numbers HCTs are 45,000-50,000 worldwide. Reasons for wide spread use include proven and potential efficacy in many diseases …"[8]

"Pluripotent AS cells are rare and hard to find, e.g. in placental cord blood. However, recently it has been found that altered mouse body cell nuclei transferred to enucleated eggs formed pluripotent SCs. This was achieved by a gene called *Nanog* which encodes a transcription factor that is responsible for establishing and maintaining cells in the pluripotent state. Prior to transfer, the mouse cell nuclei were modified by manipulating them to acquire high levels of expression of *Nanog.* This resulted in the formation of pluripotent SCs which could be grown and multiplied in culture to produce a pluripotent SC line.

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[7] Ford, N M, "Human pluripotent stem cell research and ethics" *Monash Bioethics Review* Vol. 25, N.1, (2006) 31-41 at 33; see Kögler G, 'A new human somatic stem cell from placental cord blood with intrinsic pluripotent differential potential', *Journal of Experimental Medicine*, vol. 200, no. 2, (2004), 123—35.

[8] *Thomas' Hematopoietic Cell Transplantation*, eds. Blume, KG, et. al, Malden, MA, Blackwell Science Ltd., 2004, p.9.

"The same procedure could also be done using human cells. No human embryos would be formed and none would be destroyed. The ethics of this proposal has been endorsed by 35 eminent US scientists and Catholic academics. This promising research should begin with animal cells and not proceed to human cells unless it is morally certain a human embryo would not be created. This procedure is known as *altered nuclear transfer-oocyte-assisted reprogramming*. (*The National Catholic Bioethics Quarterly*, 2005, pp.579-83). This could result in human tailor-made treatments, without the risk of immune rejection."

Ethical aspects in practice

What is immoral is not justified by good effects: *the end does not justify the means*. Human embryos, conceived naturally, by IVF or by cloning, should not be created in order to be harmed or destroyed.

Once ethical sources of providing pluripotent AS cells become available there would be no ethical sense to seek to use hES cells. The Commonwealth of Australia banned human cloning in 2002 and there is no convincing evidence to justify why it should reverse its decision. As I said in the *Kairos*, 6 August 2006,

"Legalising the creation of IVF or cloned human embryos destined to be destroyed for medical research would be an awesome responsibility for law makers to assume. There is no ethical justification for making laws to authorise the creation of IVF or cloned human embryos. Instead, public funds should be provided for research on AS cells and non-embryonic pluripotent SCs.

"The ethical alternative approaches outlined above are the way forward for scientific and medical research on stem cells which would be socially advantageous and less divisive for the whole community."

III. Comments on the Lockhart Report's Recommendations

Many of the Report's recommendations are good. We will comment where we believe changes are to be made or dropped. For brevity, I do not repeat points already made on the Lockhart Recommendations that apply to Senator Patterson's draft legislation.

Rec. 15 & 16: We are morally opposed to these two recommendations. . I repeat what I wrote in our Centre's book: "Empirically verifiable human life begins with the fusion of two gametes, sperm and egg, resulting in the formation of a new diploid cell, the developing human zygote or embryo. It makes no difference whether the embryo is naturally conceived, an IVF or a cloned human embryo." [9] Clearly this first cell is an embryo as soon as it is formed, without waiting for the process of mitosis when the first cell divides into two cells, as Senator Patterson's draft legislation has in the definition of a human embryo. The formative process of human life begins with sperm entry into the egg and there should be no legal permission to damage human life's formative process.

[9] N M Ford NM, and M Herbert M, *Stem Cells. Science, Medicine, Law and Ethics.* Strathfield, NSW: St Paul Publications 2003.

Rec. 17: We are totally opposed to interspecies fertilisation and development up to the first cell division. Furthermore it is not really necessary.

Rec. 20: Disabled embryos should not be selected by any criteria for destruction.

Recs 21 & 22: Living preimplantation human embryos should not be selected for a 'death row' in ART procedures.

Rec. 23: For the reasons given in our submission to the Lockhart Inquiry last year we are morally opposed to the cloning of human embryos. There is a great moral difference between cloning a sheep embryo and a human embryo. This is unacceptable even if development is allowed only for some days.

Rec. 24: Likewise we oppose creating hybrid cloned human embryos for research. This shows a complete lack of respect for the inherent purpose of human gametes to join them with gametes of an animal. The same would apply for the case of a human nucleus to an animal egg.

Rec. 25: We also find this recommendation repugnant. Simply because human eggs, gametes and embryos appear like those of, say the mouse, the moral differences are enormous and remain, even if some people have reached the point of being mesmerised by the similarity of their appearances to concluding they all are morally same.

Rec. 26: What may be permissible to do with animal gametes and embryos does not transfer to a moral activity simply because they may be valuable for research.

Rec. 27: The reasons given above for respecting embryonic human life lead us to oppose this recommendation as well others above.

Rec. 28: The reasons given above for Recs. 15 & 16 also apply to our opposition to this recommendation. An embryo begins at the first cell stage well before it divides into two daughter cells. It is beyond human comprehension to hold that the first two cells formed following the division of the first cell formed after fertilisation constitute an embryo and at the same time hold that the first cell or zygote is not an embryo. It would be unethical to deny legal protection to the first human cell, the zygote, in legislation designed to provide legal protection for human embryos. The implication is that anybody could fuse human sperm and eggs to form live embryos up the two cell stage without a license and with impunity. This is not acceptable. It would be preferable for legal purposes to define an embryo beginning at the point of sperm entry if one is looking for legal clarity rather than delay it to the two cell stage and jeopardise the lives of human embryos prior to the two cell stage.

Rec. 29: Re second dot point: The onus of consent for donated embryos to be used for research should be on the donor. The consent could be unconditional for any approved research. The HREC members should not have the onus to "determine that the researcher need not ask for further consent to use embryos already declared 'excess'." Unless donors consent for their embryos to be used for research, they should not be used for any research. It would be preferable for such embryos to be

allowed to succumb if the donors do not re-claim them for implantation. People can or may change their minds about having consented for their embryos to be used for research. Provision should be allowed for this.

Rec. 30: see comments for Rec. 29. Donors, not the NHMRC, should consent. Being declared 'unsuitable for implantation' does not mean the 'couple' or one of the parties has consented to their embryos being used for research. Human embryos should not be 'up for grabs' for the NHMRC to rule on their destiny. There is lurking in these recommendations a mentality that unused embryos may be treated as commodities by the State, NHMRC or HREC's. *Recommendation 30 should be suppressed, being superseded by an enhanced Rec. 29***.**

Rec. 42: This should be suppressed since human embryos are not to be commercially exploited.

Rec. 45: to be read in agreement with amended Rec. 29.

Rec. 46: There is need for mandatory provision that any pharmaceutical product developed with the use of embryos or hES cells should be clearly labelled. Citizens have a right to know if products they buy have been 'morally tainted' by the destruction of human embryos in any way.

Rec. 50: Parliament should not give an 'open' mandate to the Licensing Committee. The Licensing Committee should implement not only legal provisions but also some suitable guiding principles to be inserted in the Preamble of the Act of Parliament. The Licensing Committee does not have the powers of Parliament. The default position should be respect for human embryos, without commodifying or exploiting them.

Rec. 54: Provision should be made that science education does not become a market exercise for further exploiting human embryos.

PROHIBITION OF HUAMN CLONING for REPRODUCTION

Comments

Title:. Insert before present title: 'Authorisation of Human Cloning and' as amended, the title is misleading.

25A: 6. Include 'the general public' in the review as well as experts.