Submission to

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

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Dear Members of the Lockhart Committee

Further to my appearance before the Legislative Review Committee on the 9th of September 2005, and the questions raised by some members of the Committee, I submit the following with respect to definitions used in the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning Act 2002*.

1. Definition of human embryo [and lack of definition of embryo].

• The current definition.

Both Acts define the human embryo as follows:

Human embryo means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of development by other means. [PHC Act, s 8(1); RIHE Act, s 7(1)]

This definition of the human embryo is open to various interpretations as there is no further explanation within the legislation as to *what* an 'embryo' *is*.

The result of this omission is that the definition cannot distinguish between a human cell (or collection of cells) that possess some 'embryo-like' qualities and a genuine human embryo.

This requires urgent correction. Processes such as somatic cell nuclear transfer, parthenogenesis, altered nuclear transfer and other alternatives to fertilisation have become increasingly refined in animal models since 2002 and they are already being undertaken with human cells in some countries. The definition needs to specify what capacity a cell that results from these processes, or even a human fertilization process, must have for it to be considered a human embryo under the Act.

Effects of the current definition.

The legislation currently prohibits the intentional creation or development of a 'human embryo' by a process other than the fertilisation of a human egg by a human sperm, but without a clear definition of the term 'human embryo' one could justify undertaking these prohibited processes on the grounds that the biological product so created is not a 'human embryo'.

Furthermore, the ethical and legal status of the newly created 'cells' or biological entity would be unclear. Human embryos whom the legislation ought to protect could be 'redefined' and subjected to destructive research, while biological

material which could constitute an ethical source of cells for useful research could be given unnecessary protection.

This is a matter of great concern, and one which the Committee appeared to be aware of during our meeting.

Unless the human embryo is properly defined, the legislation does not adequately achieve its intended ban on human embryo cloning, the use of prohibited embryos or the formation of hybrid or chimeric embryos, nor effectively regulate the use of excess ART embryos.

Recommendation

That the legislation is amended to include a definition of 'embryo' which recognises what must be present for the product of fertilization or other prohibited practices, to exist as an embryo, and not as a cell/ group of cells.

• A proposed definition of 'embryo', to be used in conjunction with the current definition of a 'human embryo' would be:

Embryo means a uni- or multicellular biological entity, however formed, that has the intrinsic orientation to develop in an integrated way towards forming a foetus, given a suitable environment.

This definition, when read with the existing definition of 'human embryo', would seem to achieve the goal of the Acts.

2. Definition of hybrid embryo.

The definition of *hybrid embryo* would seem to allow researchers to create an organism by fusing *segments* of the human nucleus with *segments* of an animal nucleus.

It is recommended that the definition be altered so that the term "hybrid embryo" also includes:

- a human egg into which a whole or a substantial part of the nucleus of an animal cell has been introduced.
- an animal egg into which a whole or a substantial part of the nucleus of a human cell has been introduced.

3. Appendix

As the definition of the human embryo was of particular interest and concern to the Committee, I also submit an article from *The National Catholic Bioethics*

Quarterly outlining a way of distinguishing between normal human embryos, defective human embryos and non-organismal entities of human origin.

Maureen L. Condic and Samuel B. Condic, Defining Organisms by Organization, *The National Catholic Bioethics Quarterly* Summer 2005 Vol. 5 No. 2., 331-353.

Notably, this article points out that a lack of 'potential' to develop is not sufficient to define an entity as non-organismal. Failure to fully realize a developmental program may be due to intrinsic limits in potential (defects) that do not affect the underlying organizational principle (e.g. infants with congenital heart defects; and arguably, the products of some forms of altered nuclear transfer).

By this account therefore,

...the relevant criterion is not whether an entity has the capacity (i.e. the 'potential') to actually mature to normal adult stages, but rather whether an entity exhibits an intrinsic pattern of organisation characteristic of an organism. (340)

To adequately define an entity as non-organismal, the sole criterion would be the failure to *organize* along an overall, coordinated pattern of human development.

I hope that this submission will further assist the deliberations of the Committee, and I would be pleased to engage in any further discussion with the Committee.

Yours sincerely

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