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HUMAN CLONING

Scientific, Ethical and Regulatory Considerations
Relevant to Cloning of Human Beings

House of Representatives
Standing Committee on
Legal and Constitutional Affairs

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A. Introduction

The following comments are in response to the report of the Australian Health Ethics Committee of the National Health and Medical Research Council, *Scientific, Ethical and Regulatory Considerations relevant to Cloning of Human Beings* (December 1998).

B. Science of Cloning

Human cloning is the artificial formation of a human embryo which is genetically identical to another human being (embryo, foetus, child or adult). It may potentially be achieved using a number of methods: nuclear transfer from a human adult somatic cell to an enucleated human ovum; nuclear transfer from a human somatic cell into an enucleated bovine (or other animal) ovum; parthenogenetic activation of an ovum; and the fusion of two ova; use of embryonic stem cell lines to generate a number of identical embryos.

Embryo splitting is not technically cloning, but involves similar ethical issues since it also results in the creation of a blastocyst or embryo.

C. Purpose of Cloning

There appear to be a number of purposes for cloning technology:

- The production of babies for those such as infertile couples, single women, lesbian couples, couples whose children die or to avoid diseases carried by mitochondria. (For a number of reasons, the possibility of avoiding mitochondrial disease by cloning technology is dubious.)
- The production of embryos in order to obtain embryonic stem cells for culturing human tissue. This may be used for various kinds of research purposes, including the development of tissue for transplant.
- Embryo splitting is used for pre-implantation genetic screening.
- The production of histocompatible organs, which would require growth of the embryo in utero and abortion of the resultant foetus for organ harvesting.
- To enhance understanding of basic cell biology, ageing, cancer, embryology, human genes and for purposes of drug testing, gene therapy, and so on.

In all cases, cloning technology is used to create an embryo, but in the first case, the intention is for the embryo to be implanted, grow and be born as a new baby. In the

remainder, the embryo is destroyed, whether by the removal of embryonic stem cells or organs, or following experimentation or testing on the whole embryo.

D. Terminology

In order to increase public acceptability of human cloning, the terms “embryoids” and “reproductive” and “therapeutic” cloning have been introduced.

Embryoids The products of cloning by the methods mentioned above are termed “embryoids”. Whilst human embryoids have not as yet developed beyond the blastocyst stage, frog, sheep and mouse embryoids have developed into adulthood (eg. Dolly). Embryoids should therefore be given the status of embryo or foetus, even if it appears that the embryoid is disabled, unable to form a placenta. This disability may yet be overcome. The term “embryoid” serves merely to dehumanise the process.

Reproductive versus Therapeutic Cloning

The distinction between “reproductive” and “therapeutic” cloning is misleading. *Both* involve the production of an embryo and therefore of an early human life. The only difference is the fate of the embryo (embryoid). In reproductive cloning, the purpose is to bring about a live birth. In “therapeutic” cloning, the embryo is destroyed by removal of embryonic stem cells. In reality, *all* forms of human cloning are “reproductive”, but the resulting embryo is used for different purposes.

A further misleading notion, which has been perpetuated by the media, is that of “cloning organs” as though an isolated organ can somehow be reproduced in a jar. However, obtaining a whole organ from cloning technology would involve cloning an embryo, implanting it and allowing it to develop into the foetal stage. It would then be aborted and its organs harvested for use. I doubt that the public would be at all enthusiastic about “cloning organs” for transplant purposes if they understood the reality behind the words.

Even cloning tissue for culture and transplant requires the destruction of an embryo in order to obtain its embryonic stem cells, a fact of which the public is largely ignorant.

Proponents of human cloning attempt to infer that there is little difference between a differentiated somatic cell and a totipotent or pluripotent cell resulting from cloning technology. However, there is a vast difference. An ordinary body cell cannot develop into another whole body, whereas the cloned cell *does* potentially have that capacity. Cloning requires the use of an embryo or ovum, not just a somatic cell. If there was little difference between them, there would have been little excitement when “Dolly” was born.

E.Ethical Concerns

Contravention of Human Dignity

The cloning of human beings, whether to bring about the birth of a baby or to be suppressed within early embryonic life (such as for the purpose of obtaining embryonic stem cells), is an affront to human dignity. UNESCO declared human reproductive cloning to be contrary to human dignity. Clones are a means to an end and in being such, are treated with less dignity than other humans. Indeed, unconditional respect for human dignity, regardless of age, size, intellect or physical capacity is the cornerstone of civilized society. Human cloning contravenes this respect and violates the principles of equality and non-discrimination among human beings. It represents a line we should not cross.

Despite the semantic distinction between “therapeutic” and “reproductive” cloning, an embryo (or “embryoid”) is created in both cases and therefore should be treated in identical manner. So-called “embryoids” are clonal human organisms and to create and manipulate them at will is to treat them as human guinea pigs, without their consent and without even the protection afforded to experimental animals. It is unacceptable to render human beings at any stage of development or degree of disability to the level of mere research tool.

The production of human-animal genetic hybrids of any age, also a proposed area of research, crosses boundaries of nature that should not be approached. Such research contravenes the very nature and substance of humanity.

Destruction of human life

Cloning to gain embryonic stem cells for research or tissue transplantation purposes requires the sacrifice of the clonal embryo in order to obtain these cells. Creating and then destroying human life in this way is an abuse of power and control because embryos, even at this early stage of development, are deserving of special respect as human wholes.

As explained in the AHEC Report (2.40-2.44), it is extremely unlikely that whole organs will be able to be produced in vitro. Therefore, the generation of histocompatible whole organs would require that a foetus resulting from cloning technology grow in utero until the organ is well formed. The foetus would then be aborted in order to harvest the organ(s). This is, in effect, using one’s twin to grow body parts and is a gross exploitation of human life. The deliberate production of embryos with abnormally formed upper parts of the central nervous system as an attempt to overcome the obvious ethical problems with such a procedure is preposterous. Anencephalic embryos and foetuses are no less human than cephalic ones despite their extreme disability. The very idea of creating and using them for “spare part” manufacture is repugnant.

Pre-implantation genetic screening using the technique of embryo splitting is likewise a violation of the human dignity (and indeed the life) of the new twin which is created in order to be used for testing. Philosophically, pre-implantation screening is a modern form of eugenics and is therefore to be shunned.

The above uses of embryos and forced twins are examples of so-called "therapeutic" cloning. Whilst the goal might be said to be humanitarian, they treat human life as mere biological material. Our pursuit of new medical treatments should never sanction the destruction of human life in order to benefit other humans. This would be the ultimate discrimination. The taking of human life for research is never justified, even if to save other lives.

The Commercialisation of Human Beings

The push for human cloning comes from researchers and the biotechnical industry which stands to profit from the freedom to carry out human cloning research. The "industrial production" mentality in which human life is used for its tissue is dangerous, reducing the tiniest and most vulnerable members of the human family to mere "products". Human beings should not become a commodity, and commercial interest in human cloning should be withstood.

If human cloning is permitted for *any* purpose, no matter how specific, there will be pressure on IVF clinics to produce more "spare embryos", and on women to donate eggs and to offer their wombs as incubators. There is a serious potential for coercion. Allowing the cloning of human embryos even in very limited numbers and in special circumstances would inevitably lead to greater numbers and wider circumstances becoming accepted for cloning research.

If cloning of human embryos by nuclear transfer or parthenogenesis is permitted for research purposes, advances will overcome the technological barrier currently preventing cloning to produce new human babies. It will then be only a short step, done illegally in Australia or in a country lacking appropriate restrictions, to carry out such a procedure. It is important, therefore, to concentrate research elsewhere so that this technology is *not* perfected.

Safety

The production of "Dolly the sheep" was the final result of 277 cloning attempts. Since animal cloning experiments thus far have been fraught with many mishaps and failures, it would be unjustifiable to subject human embryos to such research. The risk of major structural abnormalities occurring would be high in surviving embryos. This would lead to further loss of the lives of embryos, and physical and psychological risk to mothers if induced abortions were then procured.

If cloning technology were to be used for gaining histocompatible tissue, the risk of malignant transformation of transplanted tissue is a concern. Malignant transformation

would cause individual patients' conditions to be far worse than they would have been if transplantation had not been carried out. There is also the possibility of severe unanticipated side effects occurring. Because cloning research in animals has been shown to be unsafe, it should not be undertaken on human embryos for the production of babies or for the treatment of diseased adults.

Cost

The cost of human cloning research both financially and in terms of the wastage of human life, would be enormous. The resources necessary to successfully clone and produce healthy babies, or develop useful tissue or organs for transplant would be exorbitant beyond justification given the other pressing needs of our society and the rest of the world.

F.Recommendations

NHMRC Guidelines and Legislation

A number of areas must be addressed in order to achieve the protection of the earliest forms of human life from cloning research for both "reproductive" and "therapeutic" purposes. Permitting so-called "therapeutic" cloning would still allow the cloning of an embryo or foetus and its necessary death. As already expressed, this would be exploitative and unacceptable use of human life and therefore should be banned nationally.

In order to achieve this end with consistency across the nation, legislation in Victoria, Western Australia and South Australia and NHMRC Guidelines should be amended, and legislation introduced in the remaining states and territories. The Guidelines and legislation should include the following:

- A clear and consistent definition of the term "cloning" should be developed for use by the NHMRC and all state and territory legislation in order to avoid confusion and legal loopholes.
- Cloning techniques (including somatic cell nuclear transfer, parthenogenesis and embryo splitting) which could be used to produce a human zygote, embryo or embryoid or a human-animal hybrid for *any* purpose, including for the purposes of developing embryonic stem cell lines, tissue cultures and organs for transplant, should be prohibited.
- *All* non-therapeutic research which involves the destruction of the embryo or which may otherwise not leave it in an implantable condition should be prohibited.
- No experimentation should be conducted on embryos produced specifically for research or on embryos excess to IVF requirements.
- Institutional Ethics Committees should not have the power to permit destructive research on embryos. All projects (if any) which have been granted permission by Institutional Ethics Committees to apply cloning techniques to human gametes/ embryos in states where no legislation exists to prohibit such activity, should cease.

- Experimentation with the intent to produce two or more genetically identical individuals, including the development of human embryonic stem cell lines with the aim of producing a clone of individuals should be prohibited. This prohibition should extend to the development of human embryonic stem cell lines with the aim of producing tissue and organs because it would involve the destruction of a human embryo.
- The Victorian prohibition on altering the genetic constitution of a gamete intended for use in a fertilisation procedure should be adopted in all other states and territories.
- The adoption of the NHMRC Ethical Guidelines by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia should continue, and also be made a legal requirement. Cloning technology should not be permitted in ART programmes.
- Statutory authorities similar to those in Victoria, South Australia and Western Australia should be established in all states and territories to approve and monitor research and developments in this area.
- Researchers should be prohibited from exporting Australian gametes, zygotes and embryos for research to be carried out overseas.
- Legislation is required to prevent importation of embryos or parts of embryos produced overseas.

International Standards

As noted by the AHEC Report, there is international consensus that human cloning should be prohibited.

- I endorse the Report's Recommendation 1 that the Commonwealth Government should reaffirm its support for the UNESCO *Declaration on the Human Genome and Human Rights*, in particular Article 11, which states that:

Practices which are contrary to human dignity, such as reproductive cloning, shall not be permitted.

- The Commonwealth Government should also sign the Council of Europe *Convention for the Protection of Human Rights and Dignity with Regard to the Application of Biology and Medicine* and the *Additional Protocol on Human Cloning*.

Primate Research Facility

I oppose the view of the AHEC Report that a primate research facility be established for the purpose of cloning experimentation. Even if such techniques were perfected in primates, there would still exist significant risk of adverse effects in humans because of inter-species differences. More importantly, since cloning techniques should never be applied to humans for any purpose, there is no point attempting to develop the technique in primates to the point of safer applicability in humans.

G. CONCLUSIONS

The Committee has a duty to support research which has the potential to benefit the lives of many people, but only as long as such research does not do so by harming or destroying other lives. Since human cloning *does* harm and destroy human life, all such research must be prohibited.

Research should be focussed instead upon efforts to culture adult stem cells eg. blood stem cells, skin cells and so on, in order to alter their type for use in tissue transplantation. There have already been some promising results in this area. This would avoid the ethical difficulties of cloning human embryos in order to obtain embryonic stem cells.

It is imperative that science be guided and upheld by ethical standards in order to discover new treatments for genetic and degenerative diseases which do not violate the dignity of human life.