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HUMAN CLONING:  
Scientific, Ethical and Regulatory Issues

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### 1. Introduction

The birth and survival to adulthood of "Dolly the Sheep" has led to serious consideration of the risks and benefits of cloning technology, particularly as applied to human beings. It was with great interest, therefore, that I read the Australian Health Ethics Committee's Report, "Scientific, Ethical and Regulatory Considerations Relevant to the Cloning of Human Beings". The following comments are a response to this report and are written in the light of my background as a vascular surgeon.

### 2. Scientific Considerations and Potential for Human Applications of Cloning Technology

#### Assisting in Reproductive Technology (ART) Programs

The AHEC Committee noted the almost universal condemnation of cloning post-natal human individuals (2.1). The AHEC Committee also noted, however, that there has been some consideration of cloning babies for the purposes of artificial reproduction for infertile couples, lesbian

couples and single women. It has also been suggested that the technology could be used to prevent the inheritance of mitochondrial disease (2.30-1) or to provide a donor of bone marrow for a sibling with leukaemia.

Despite these seemingly humanitarian reasons for cloning babies, their production is still unethical. Cloning human babies is a contravention of human dignity, would involve high wastage of embryos (as evidenced by the production of Dolly after 277 attempts) and the risk of congenital malformation and long-term adverse effects would be significant. It would be dangerous even to allow reproductive cloning for the very tiny number of women who might wish to avoid transmitting mitochondrial disease to their children. This is because it would be followed by questionable causes for reproductive cloning and the slippery slope phenomenon would occur. (It is also unlikely to be effective as it appears that some mitochondrial diseases also involves defects in nuclear DNA.) Given the strain on the health care budget, it is unjustifiable to fund research into reproductive cloning since it is essentially unproven and unnecessary, and most likely could only ever be afforded by a small elite.

#### Embryos, Embryonic Stem Cells and Embryoid Bodies

In 2.7, the AHEC Committee states that the Report deals with proposals for the application of cloning techniques to generate new human subjects (whether pre or post-natal) rather than cloning of genes or cell lines. The Committee then makes the crucial point that there may be situations in which the development of cell lines requires "the production of a new human subject as a preliminary step". It is when a new human subject, whether embryo, foetus or post-natal, is produced that ethical difficulties with cloning arise. In ethical terms, an embryo, foetus and new born baby are all human entities or wholes, and as such, must be given special status and protection. The international condemnation of cloning post-natal human individuals must surely extend to pre-natal humans also as the only difference between the two is merely a matter of time and the right environment in which to grow.

In my work in vascular surgery, I am faced daily with the ravages of degenerative disease. The prospect of having increased supplies of tissue and organs, especially if histocompatible, is exciting. However, as a doctor, I am also equally aware that my treatments should not pose unacceptable risk of harm to patients and neither should they be at the expense of the wellbeing or lives of other human beings.

Human embryoid bodies and the embryonic stem cells from which they are derived may, given certain conditions, have the potential to develop in utero and live on into post-natal existence. Even though at present the technology to bring about placental development is in its infancy, the fact that it is possible in animals (eg. Dolly) and may yet be in humans means that the result of somatic cell nuclear transfer and parthenogenesis should be regarded as equivalent to a conceptus (zygote). It also means that an embryoid body and the result of embryo splitting are ethically equivalent to embryos formed in the conventional manner.

It is my view that zygotes, embryos and fetuses should be awarded the

dignity and protection given to post-natal human beings. Based on this premise, one must not use them as research material or as sources of cell lines or tissue if this will damage or destroy them so that they are not able to be implanted and develop in the normal way to birth.

#### Projected benefits from Cloning and Cloning-Related Technologies

The benefits suggested from the production of human ES cells, including studies of normal and abnormal embryogenesis, aging and cancer, gene discovery, drug testing, a source of transplantable tissue and so on, appear laudable. However, these benefits should only be sought by means which do not involve the sacrifice of the smallest and most vulnerable of humans - embryos. Unfortunately, obtaining ES cells requires the destruction or damaging of an embryo (or embryoid body) and this is one of the aspects which would make the research and practice of such techniques unethical. Another ethical objection is that embryonic stem cells are equivalent to zygotes in their potential capacity to form an embryo. As the earliest forms of human wholes, they also should not be used in destructive research or in research which is not for their benefit and does not allow them to develop, be implanted and brought to term.

These ethical obstacles could be overcome by focussing efforts instead upon the de-differentiation of adult cells or of pluripotent stem cells found in post-natal humans (such as pluripotent blood cell precursors normally found in the blood stream). If such cells could be de-differentiated to the pluripotent precursor cell stage of particular cell types, they could be useful sources of histocompatible tissue or of cell lines for other studies. Since these cells would have the capacity to give rise to cells from only one germ cell layer, there would be no ethical dilemmas to be overcome. Their use in tissue transplantation may also reduce the likelihood of malignant transformation or the development of inappropriate mature cell types compared to the use of ES cells.

#### Human Cloning for Transplantable Organs

The AHEC Committee has explained in paragraph 2.42 of the Report some of the reasons why it is unlikely that organs could be grown in vitro. Given the incredible complexity of the processes involved in organogenesis and the fact that it is still poorly understood, I think that organogenesis in vitro is an impossibility. The obvious, and truly horrifying, alternative is to clone embryos, implant them and allow them to grow well into the foetal period until their organs are suitable for harvesting. The idea of growing babies for their organs or other tissues alone is made no less barbaric by, as the AHEC Committee suggested, deliberately inducing anencephaly (2.43). I was appalled to see such a suggestion as a serious solution in print. Even if successful "artificial wombs" were to be developed, sacrificing foetuses grown in this way would still be an atrocity.

#### Testing on Non-Human Primates

The establishment of a new non-human primate research facility would be of great benefit for many types of research. However, I do not think it necessary or wise to use non-human primates to experiment with

cloning technology or ES cells when such procedures should never be applied to human beings for ethical reasons, even if perfected.

### 3. Ethical Issues

The maintenance of a civilized and peaceful society rests upon the foundation of respect for the inherent dignity and value of all humans, and the wrongfulness of discriminating against them for innate aspects of their being; for example, race, sex, age, disability, and so on.

If one respects human life in this way, one cannot discriminate against zygotes, embryos or fetuses even though they are “undeveloped” and completely dependent. It is my view that cloning research contravenes the basic human rights of these vulnerable members of the human family.

The ethical significance of the objectives sought through cloning

A To investigate and understand human biology and pathology

In paragraph 3.11, the AHEC Committee refers to the fact that cloning techniques for use in human reproductive programs will ultimately require experimentation on human embryos. The questions are then asked: “How many human embryos may be experimented on and then destroyed? What degree of risk to embryos will be acceptable (if any)? To what stage of development may they be experimented on? If cloned embryos are brought to term, what kinds of developmental abnormalities in these embryos (and their offspring) will be acceptable? Acceptable to whom? What will be an acceptable trade-off between ‘certainty of normality’ and ‘numbers of embryos experimented on’?”

It is not acceptable for any human embryos to be experimented on and then destroyed. Research which is not for the benefit of the embryo and which is not likely to leave it in a state fit for implantation and development into post-natal life should be prohibited. Human life should not be exploited in this way.

Given the eugenic rejection of abnormalities diagnosed pre-natally by ultrasound and other techniques and high uptake of abortion amongst parents of disabled unborn babies, I doubt very much that any abnormalities would be acceptable to “parents” of cloned babies. This would frequently occur given that participants in reproductive programs using cloning techniques would inevitably be paying very large sums and would expect perfection. There will never be certainty of normality even if every possible pre-natal test is performed. Even a seemingly normal cloned baby may have problems which do not appear until later life or in his or her offspring. “Parents” may sue for failure to produce perfection in the cloned child.

B To assist in reproductive technology programs:

I sympathise with infertile couples who desire a genetically related child, and for whom cloning may be the only option by which this may be accomplished. However, having a child who is genetically a twin of one parent may present psychological difficulties as a result of the expectations of how this child should be. The child herself, upon discovering her origins may experience identity problems. However, even

if these relationship difficulties were to be overcome, I still believe that this type of cloning is unethical in itself as a contravention of human dignity, and that the wastage of embryos which the process would involve is practically and ethically unacceptable.

As mentioned earlier, it is unlikely that mitochondrial disease could be completely avoided in offspring by the use of somatic cell nuclear transfer. Even if it were possible, there remains the risk of other abnormalities arising as a result of the artificial means of the baby's production. Above all, there remains the ethical problem of destroying many human embryos to fulfill a couple's desire for a healthy genetically related child. There are many orphans in desperate situations overseas who could be adopted rather than wasting embryos and vast sums of money on reproductive cloning for this purpose.

I am opposed to cloning technology being made available at great expense to people whose "infertility" is a product of their own choice of lifestyle eg. single women, lesbian women. It would also be wrong to deliberately bring a child into a situation which does not provide a family with both a mother and father.

#### C To produce transplantable organs and tissues

I stated earlier that one cannot produce and then sacrifice another human organism for the sake of taking his organs or tissues for another's benefit. This would be a barbaric injustice. If the public were aware that so-called "therapeutic cloning" involved the killing of an embryo or foetus either to gain its ES cells or organs, I am quite sure there would be very little enthusiasm for carrying out this form of cannibalism.

#### E To copy a human being

Copying a human being so that he or she can be a source of tissue or organs is ethically untenable. Storing a twin of one's child in embryo form or allowing the twin to be born in order for it to supply bone marrow or other tissue is using a human being as a mere means to an end is an affront to human dignity. Attempting to "replace" a lost loved one is a false hope and also uses humans as a means to an end. Help with the normal grief process is a far superior alternative.

The ethical significance of the circumstances in which cloning takes place

The AHEC Committee is right in stating in paragraph 3.22 that none of the objectives for cloning technology should "be pursued without regard to the ethical acceptability of the means employed towards its achievement and the circumstances in which it is pursued". Since non-therapeutic and destructive experimentation on embryos is unethical, then cloning technology, which necessitates this type of research, is also unethical.

I agree entirely with the AHEC Committee's comments in paragraph 3.27(a) in which some of the substantial ethical objections to somatic cell nuclear transfer and parthenogenesis are outlined. These objections are the risks of the technique, confusion of identity, eugenic manipulation

of the next generation and a violation of the meaning of the parent-child relationship.

The use of the term “embryoid body”, as rightly expressed by the AHEC Committee (3.27(b)), should not be a means of hiding the fact that developing embryonic stem cell lines involves embryo experimentation. Whether termed an “embryo” or “embryoid body”, non-therapeutic experimentation on these human wholes is a contravention of the rights they have to be treated with dignity as members of the human family.

The ethical significance of cloning in itself

I agree with the argument of Leon Kass considered by the AHEC Committee in paragraph 3.28, namely that asexual reproduction does violate nature’s boundaries, confounds the understanding of normal human relationships and reduces human beings to mere products to be manufactured at another’s will and for another’s purposes.

The ethical significance of a policy which permits or prohibits cloning in some circumstances

Human cloning should be prohibited in all circumstances. It would be impossible to restrict cloning research for some purposes and not others. The strict purposes for its use would soon be forced to be widened as claims of discrimination would inevitably be made and as researchers push the boundaries in order to compete with others for opportunities for research publication. I would also contend that even if it was possible to contain cloning research within narrow bounds, the ethical objections to the procedures which would be undertaken on human embryos and zygotes are significant enough that all such research should be prohibited for that reason alone.

#### 4. Australian Legislation and Guidelines relevant to Cloning in Existence at November 1998

At present, legislation and the NHMRC Guidelines relevant to human cloning are inadequate. Legislation should be introduced in the states and territories other than Victoria, South Australia and Western Australia which as yet have no relevant legislation. This legislation should be nationally consistent and include the points listed below, and existing legislation and NHMRC Guidelines should also be amended to reflect these recommendations:

“ A concise definition of cloning should be agreed upon and used consistently within all state and territory legislation and the NHMRC Guidelines.

“ Somatic cell nuclear transfer, embryo splitting, parthenogenesis and any other cloning techniques which may be developed in the future should be prohibited. It should become an offence to use cloning to produce a zygote, embryo, embryoid body or foetus for any purpose, including for the purposes of production of embryonic stem cell lines, tissue culture or organs for transplantation.

“ 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 also be prohibited.

- “ The production of a human-animal hybrid to any stage of development 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.
- “ It should become an offence to conduct experiments on embryos produced specifically for research or on embryos excess to IVF requirements.
- “ All other states and territories should adopt the Victorian prohibition on altering the genetic composition of a gamete intended for use in a fertilisation procedure.
- “ 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.
- “ Cloning technology should not be permitted in ART programs.
- “ Institutional Ethics Committees should not have the power to permit non-therapeutic or destructive research on embryos. They should also not have the power to grant permission for research involving human cloning of any type. If there are projects involving destructive embryo research or cloning technology at present, then these should cease.
- “ Legislation should be introduced to prohibit importation of embryos or parts of embryos produced overseas.
- “ Researchers should be prohibited from exporting Australian gametes, zygotes, embryos or foetuses or parts thereof for research to be carried out overseas.

#### 5. International Legislation and Guidelines Relevant to Cloning in Existence at November 1998

Consistent with the international condemnation of human cloning and the AHEC' Recommendation, I urge the Commonwealth Government to reaffirm its support for the UNESCO Declaration on the Human Genome and Human Rights, especially Article 11 which states:

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organisations are invited to co-operate in identifying such practices and in determining, nationally or internationally, appropriate measures to be taken to ensure that the principles set out in this Declaration are respected.

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.

#### 6. Conclusions

I hope that my submission has been helpful. I believe that human cloning for any purpose represents a serious affront to the dignity and inherent value of human beings and I urge the Committee to take a strong stance against it for the protection of our society.