

Opinion

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ACHIEVING NATIONAL REGULATION OF HUMAN CLONING

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The Status Quo

In 1997, Dolly the cloned sheep was a world first that took the scientific and ethics communities by surprise, and it was not long before cloning was replicated in several other species including in primates such as marmosets and rhesus monkeys. But the event has also caused some confusion over terminology - what is cloning, what is a human embryo, what is a human being?

In December 2000 the Commonwealth Parliament passed the *Gene Technology Act 2000* which established an Office of the Gene Technology Regulator to manage a licensing system with which all those institutions and corporations undertaking genetic modification in Australia, whether using plant, animal or human material are required to conform. The legislation created some new offences in relation to cloning a whole human being.

However, the new offences do not have any impact on what is popularly known as cloning, the procedure used in the case of Dolly the sheep. The Dolly process is known to the scientific and ethical debate as somatic cell nuclear transfer into an enucleated ovum. The outcome is a close but not identical genetic copy of the animal from whom the somatic cell is taken. There are some discernible genetic differences because the ovum retains its extra-nucleic genetic material and this becomes part of the genetic constitution of the cloned individual.

The human cloning offences in this respect failed to prohibit applying the Dolly process to humans because the definition of cloning was based on genetic identity.

The offences also referred to "whole human beings", a phrase that is highly ambiguous and likely to generate confusion in the context of applying a criminal law offence.

In 1997, human reproductive cloning, understood as inclusive of applying the Dolly process to humans, was condemned by the United Nations as a practice contrary to human dignity and to be prohibited.

Currently, Australia has no effective regulation of human cloning. Even those three States that do have legislative offences for human cloning have failed to achieve that goal. The problem in their case is over the definition of a human embryo and the definition of cloning. All define the embryo in terms of the product of fertilisation of a human ovum by human sperm. The fact of the matter is that a cloned human embryo is

not the product of fertilisation. There are restrictions on using embryos produced by fertilisation but none in relation to embryos produced by cloning. Second, they all refer to cloning in terms of genetic identity which is not inclusive of the Dolly process.

Cloning human beings is almost universally condemned

Why and what is condemned?

The human genome, according to the United Nations, underlies the fundamental unity of all members of the human family, as well as underlying the recognition of their inherent dignity and diversity. Human reproduction using the new cloning technology is, according to the *Universal Declaration on the Human Genome and Human Rights*, a practice that is contrary to human dignity and not to be permitted.

Some have argued that it is because cloning represents a challenge to identity and uniqueness through being a genetic copy of someone else. But these are relatively weak considerations because a person is much more than their genetic identity: from the moment that their first cell is formed they follow a different path in their environment and in their nurturing, and in the later choices that they make of their own free will. The clone of Ian Thorpe may well choose not to subject himself to Ian Thorpe's punishing training regime. As an individual develops there are even subtle changes in their genetic make-up. Even identical twins have discernibly different genetic fingerprints.

The harm to identity and uniqueness as a result of cloning is likely to be in the expectation of others, based on genetic determinism, that the individual will be a copy of the personality of their genetic predecessor: the child born as a clone of grandpa will be expected to have his abilities and personality attributes. That would thus be very limiting for the child. But the belief would be a false belief and one that would soon be understood to be mistaken.

But the major issue of respect for human dignity, identified by the United Nations, is much more complex. It is the issue of the manner of a person's coming to be.

What links us all together as a human family, each with inherent dignity and equal and inalienable rights, is that we share the human genome. Each individual human genome is the dynamic program for a rational being. That capacity for rationality may be damaged by disease, injury or deprivation, but inherently each human being is the kind of being who has the capacity for rationality, the capacity to doubt, believe, wonder and love that seems to be peculiar to humans.

Normally the protected status of human beings is inherited by being born into a family, and being the child of parents who are strongly linked to the child through

- sharing genetic inheritance,
- the child being the issue and hence the symbol and extension of the parent's own loving unity, and

- the suffering and hardships of child birth and the demands of nurturing.

By being the natural child of human parents a child has an inheritance of a protected status whatever his or her actual capacities or disabilities.

Human cloning breaks that link. The status of a being produced in a laboratory process using human genetic material is likely to depend on whether that being is shown to develop human capacities. That is to say, the protected status of a cloned human being is likely to be acquired rather than inherent.

If allowed to develop to become a born child that being will not have natural parents, and not be the issue of parental love. Gestational and social parenthood may be chosen for the developing cloned human being, but that is assigned parenthood rather than inherent. If that child is disabled then he or she will be seen as a product of a defective laboratory process and not the responsibility of the commissioning would-be parent or parent couple.

We have seen recently that medical laboratories have access to human organs and tissues, and often that tissue is no longer identified with the source individual. It would seem possible, if cloning techniques are applied, for such tissue to be used to generate human beings who have no known familial connection with any human being. The capacity would exist to develop unlimited numbers of embryos with a human genome, using human or even animal eggs as the carrier of the human genome, without the need to seek anyone's consent, with no parents to answer to about how those embryos may be used.

Many scientists, including the Australian Academy of Science, while disavowing any intention to allow a cloned human embryo to have a mother and hence to be born, are claiming a right to be able to produce human embryos who have no parents, for whom they have to answer to no-one. This is the issue that needs to be addressed by the Australian Commonwealth and the States and Territories.

What should be prohibited?

The Australian Academy of Science published a statement which urged that "therapeutic cloning" should be permitted. By therapeutic cloning the academy meant cloning human embryos for the purposes of obtaining tissues from them for research and the development of therapies. The Australian Health Ethics Committee (AHEC) rejected this position. On December 15th, Dr Kerry Breen, the Chairman of AHEC wrote to the State and Territory Health Authority:

"...In the *Ethical Guidelines*, AHEC reaffirmed and applied the well-accepted distinction between (a) therapeutic research and (b) non-therapeutic research. Therapeutic interventions are interventions directed towards the well-being of the individual embryo involved and non-therapeutic interventions are interventions that are not directed towards the benefit of the individual embryo but rather towards

improving scientific knowledge or technical application. Non-therapeutic experimentation includes both non-destructive procedures (which include observation) and destructive procedures.

“The *Ethical Guidelines*, and in particular the section on research on embryos (section 6) and the list of prohibited/unacceptable practices (section 11), rely upon and apply this distinction between therapeutic and non-therapeutic research. The more-recently-coined term 'therapeutic cloning'¹ collapses both (a) the distinction between therapeutic and non-therapeutic research on embryos and (b) the distinction between destructive and non-destructive experimentation on embryos. The creation of embryos specifically for research purposes, experimentation on those embryos and their subsequent destruction, etc, all fall under this term. It was because of the lack of transparency of the term 'therapeutic cloning', because the term concealed rather than revealed these ethically-significant differences, that AHEC rejected its use. AHEC said that, in the matter of cloning and related technologies, the fundamental distinction was between the production by cloning of whole human entities (such as human embryos) and the production by cloning of the component party of those entities (such as cells, DNA, etc.). AHEC held that, whereas the latter has been an accepted part of medical and scientific research for over fifty years, the former should take place only in exceptional circumstances.”

The Australian Health Ethics Committee in its 1996 *Ethical Guidelines* stated

“Section 11 Prohibited/unacceptable practices:

- 11.1 Developing embryos for purposes other than for their use in an approved ART treatment program.
- 11.2 Culturing of an embryo in vitro for more than 14 days.
- 11.3 Experimentation with the intent to produce two or more genetically identical individuals, including development of human embryonal stem cell lines with the aim of producing a clone of individuals.
- 11.4 Using fetal gametes for fertilisation.
- 11.5 Mixing of human and animal gametes to produce hybrid embryos.
- 11.6 Mixing of gametes or embryos of different parental origin so as to confuse the biological parentage of the conceptus.
- 11.7 Placing an embryo in a body cavity other than in the human female reproductive tract.
- 11.8 Embryo flushing.
- 11.9 Commercial trading in gametes or embryos.

- 11.10 Paying donors of gametes or embryos beyond reasonable expenses.
11.11 The use in ART treatment programs of gametes or embryos harvested from cadavers.

As well as therapeutic and non-therapeutic research on embryos, there has been the distinction, referred to by AHEC at 11.1 (above), between producing embryos for the purposes of experimentation and conducting research and experimentation on embryos that have been produced for the purposes of achieving pregnancy in woman on an Assisted Reproductive Technology treatment programmes. There has been a view consistently held that embryo experimentation, if it occurs, should be limited in this way. In Australia, destructive or non-therapeutic embryo experimentation when it occurs has thus been limited to those embryos that are “spare” or left over on ART programs.

Producing human embryos solely for the purpose of research and experimentation would add another dimension to the current practices and would be in breach of the AHEC recommendation that embryos not be produced for the purposes of experimentation.

In its report on human cloning to the Commonwealth Minister for Health in December 1998, AHEC recommended that there be national uniform legislation to prohibit the practices listed in section 11 of its guidelines on reproductive technology including section 11.1 in relation to producing embryos for purposes other than for use in an ART treatment program and section 11.3 on cloning.

A way of achieving regulation of this area would be to legislate, as AHEC has recommended, to:

- (a) Prohibit producing human embryos for purposes other than to achieve pregnancy in an Assisted Reproductive Technology program; and
- (b) Prohibit producing a human embryo or embryonal stem cell line for the purposes of creating an individual human being who is a clone.

AHEC published those guidelines in 1996 prior to the advent of the Dolly process and the surprising possibility that somatic cell nuclear transfer to an enucleated ovum would work. As we have seen (above) this produces a near genetic copy but not strict genetic identity. The ethical and legal discussion has now to take into account that it is the method of reproduction - asexual reproduction resulting in an individual with no natural parents, rather than absolute genetic identity that is significant.

Second, the definition of an embryo has to be revised to allow for the fact that an embryo can be produced other than by fertilisation. The significant feature is the creation of an entity that has the capacity of a human embryo or zygote (the cell formed by the fusion of a human sperm with a human ovum) to develop to human adulthood if placed in a suitable environment.

This then would separate cloning a human embryo from cloning human cells or tissues which lack the specific capacity that an embryo or zygote has of being able to develop to human adulthood. There would be no ban on cloning somatic cells in order to develop treatments. In fact it is much more likely that treatments will be developed from that source than by following the complicated embryo route which involves harvesting large numbers of human ova from women.

Different Legislative Models

The Commonwealth has open to it a number of options for achieving regulation in this area:

(i) The Human Tissue Act Model

A uniform separate cloning Bill to be accepted and passed by each State and Territory. This model was adopted in relation to various State Human Tissue Acts in 1981 after the latter had been developed by the Australian Law Reform Commission. Though at the time Tasmania and Western Australian left out the clauses dealing with brain death. The issue in this respect is to gain acceptance from each State. There is a danger that what results will be a less than ideal compromise.

(ii) The Office of Film and Literature Classification Model

The establishment of a Commonwealth legislative standard with limited direct application to the States and Territories (perhaps based on the corporations, customs and excise, and possibly the external affairs powers in relation to the Convention on the Rights of the Child), but which would then be supplemented by the individual States passing legislation that adopted the Commonwealth standard. Something like this has been done in relation to censorship in which the standard is a Commonwealth standard and determined by a Commonwealth instrumentality, but the actual applicable offence in each State or Territory is established by the State or Territory law which refers to the Commonwealth standard. This could perhaps be done using the Australian Health Ethics Committee in a role such as is exercised by the Office of Film and Literature Classification. Currently the AHEC guidelines are limited to medical research matters, not clinical matters, and they only apply to medical research projects in receipt of funding for medical research from the Commonwealth Government. That accounts for only 25% of Australian medical research.

(iii) Licensing

The establishment by the Commonwealth of a national licensing system for human ART and genetic modification with the co-operation of each State and Territory passing legislation requiring those engaged in human ART and genetic modification in each State or Territory to hold a licence under the Commonwealth legislation. AHEC might be the appropriate body to establish, vary and monitor compliance with the licensing conditions. The Commonwealth Bill could specify a list of prohibited procedures such as the list that AHEC has provided, including

- (a) producing human embryos for purposes other than to achieve pregnancy in an Assisted Reproductive Technology program; and

- (b) producing a human embryo or embryonal stem cell line for the purposes of creating an individual human being who is a clone;

Where “**embryo**” means the cells or cells resulting from the fertilisation of a human ovum by human sperm and all stages of development until a foetus forms, or “**embryo**” means an entity formed other than by fertilisation of an ovum by sperm which possesses a human genome and, if placed in a suitable environment, a capacity to develop similar to the capacity to develop of a human embryo that results from fertilisation; and “**a clone**” means an entity which is genetically similar to another and produced other than by fertilisation of a genetically unaltered ovum by genetically unaltered sperm.

(iv) Gene Technology Act 2000

Further revision of the *Gene Technology Act 2000* to use the Office of the Gene Technology Regulator as the licensing body for ART and embryo research and amendment of the existing cloning offences under the Act in accordance with the above. Model (iii) is to be preferred because it involves national uniformity, State and Territory co-operation and a soft way of achieving regulation using licensing powers rather than creating criminal offences and engaging the cumbersome machinery of the criminal law. Its disadvantage would be that it duplicates the licensing system under the *Gene Technology Act 2000*. Those engaged in genetic modification research involving human embryos would be required to be licensed under both bodies and to meet the requirements of both.