SUBMISSION

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1. Legal regimes at federal and state level

1.1 State legislation.

Embryo splitting and nuclear transfer <u>for the purpose of cloning human beings</u> is prohibited by legislation in Victoria, South Australia and Western Australia. Relevant provisions in the Victorian Act are as follows:

Infertility Treatment Act 1995 (Vic)

- s 47. A person must not carry out or attempt to carry out cloning.
- s 3: "clone" means to form, outside the human body, a human embryo that is genetically identical to another human embryo or person.
- s 22 (1): A person may only--
 - (a) carry out research, outside the body of a woman, involving the formation of a zygote; or
 - (b) carry out research, outside the body of a woman, involving a zygote or embryo--
- *if--* ...
 - (d) the research is approved research ...
- s 25. The Authority must not approve the carrying out of research outside the body of a woman involving the use of an embryo if it considers that--
 - (a) the embryo is unfit for transfer to a woman; or
 - (b) in the case of an embryo which is fit for transfer to a woman, the research would--
 - (i) harm the embryo; or
 - (ii) make the embryo unfit for transfer to a woman; or ...
- s 39 (2) A person must not alter the genetic, pro-nuclear or nuclear constitution of ... an embryo except to alter the somatic cells for therapeutic purposes.

Penalty: 480 penalty units or 4 years imprisonment or both.

s 44. A person must not carry out ... research involving the use of a zygote or an embryo removed from the body of a woman.

Penalty: 240 penalty units or 2 years imprisonment or both.

s 49(1) A person must not knowingly or recklessly form or attempt to form an embryo outside the body of a woman except for...a treatment procedure...

Penalty: 480 penalty units or 4 years imprisonment or both.

1.2 Federal regulation: NHMRC, Ethical Guidelines on Assisted Reproductive Technology

Cloning is also prohibited by the National Health and Medical Research Council's *Ethical Guidelines on Assisted Reproductive Technology*. Although the NHMRC document distinguishes between cloning of humans and cloning of human <u>parts</u>, it does not advocate that the latter should be allowed. The NHMRC guidelines, like the Victorian and South Australian legislation, prohibit the production of embryonic stem cell lines.

2. Desirability and practicability of implementing a national legal regime

2.1 Should we have a legal (legislative) regime?

- 2.1.1 Legislation has many advantages:
- paramount overrides common law
- clear and conclusive
- prospective
- carefully planned systematic
- necessary to establish new government bodies; to impose penalties
- public participatory states values
- freely available
- reflects community attitudes
- flexibility can be increased by delegating functions
- 2.1.2 However, legislation also has disadvantages:
- Constitutional issues
- State legislation inconsistent forum shopping
- Inflexible
- Difficult to change
- Hard for rapid change areas like biotechnology
- 2.1.3 If we do not legislate, that does not mean that there is no law. It means that legal issues that arise will be decided by common law principles developed by judges in cases that come before them. This has advantages and disadvantages.
- 2.1.4 Advantages of leaving legal issues to the common law:
- slow changes
- similar throughout Australia
- fits with other law
- sensitive issues considered outside political arena

2.1.5 Disadvantages of leaving legal issues to the common law:

- piece-meal cases must arise no "grand scheme"
- conservative
- retrospective
- no community consultation
- often uncertain standard like "reasonable"

2.2 If legislation is enacted, should there be a <u>national</u> regime?

There are advantages in federal legislation. It is universal throughout Australia; promotes equality for residents of all states; and prevents forum shopping. However, states often take different views, particularly on such sensitive issues. Federal legislation, given the constitutional power (see below), will require careful political handling.

3. Whether the application of international and domestic human rights law affect issues involving human cloning

3.1 Relevant international instruments

Several international instruments prohibit human cloning. Sometimes, the intention is to ban cloning of humans; but in some cases, the wording is so wide that it covers all types of cloning, even cloning of tissues and cells. They are based on human *dignity*. Two examples are:

The European Convention on Human Rights and Biomedicine

Convinced of the need to respect the human being both as an individual and as members of the human species and recognising the importance of ensuring the dignity of the human being

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine..."

<u>UNESCO: Universal Declaration on the</u> <u>Human Genome and Human Rights 1997</u>

Article 11: "Practices which are contrary to human dignity such as reproductive cloning of human beings shall not be permitted".

Other Articles protect individuals from discrimination, abuse or harm on the basis of genetic factors:

Article 2: "everyone has a right to respect for their dignity and for their human rights regardless of their genetic characteristics"

Article 6 bans "discrimination based on genetic characteristics" where the discrimination is "intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity".

3.2 Effect of provisions in international instruments in Australian law

3.2.1 The European Convention is not part of Australian law.

3.2.2 The UNESCO Declaration is likely to become codified like the Universal Declaration of Human Rights 1948 (ICCPR, ICES&CR) – a binding international treaty. However, that does not make it part of Australian law. That requires specific municipal legislation. However, in the case of uncertainty in the law, a court (especially the High Court of Australia) might take account of the international treaty in deciding what the law should be.

The same is true of more general international instruments, such as the International Covenants on Civil and Political Rights; and Economic and Cultural Rights (1966); and the UN Convention on the Rights of the Child (1989), which Australia has signed and ratified. However, there is very little jurisprudence to support the approach of the courts in this area and the treaties, even if signed and ratified, create no rights or duties in themselves.

- 3.2.3 Even if a court were to take account of the international instruments in this field, it is difficult to imagine how that would arise. Terms like "dignity" are so imprecise and open to interpretation. Even if one regards reproductive cloning as contravening huamn dignity, surely the same is not true of therapeutic cloning. A person's "dignity" is best respected by trying to save the person's health and life. Even if embryonic sells are used, I do not believe that any "dignity" interest of the embryo outweighs the interests of a dying or diseased person.
- 3.2.4 It is conceivable that an application might be made to the UN Human Rights Committee pursuant to Australia's participation in the First Optional Protocol to the International Covenant on Civil and Political Rights. I cannot think, however, of circumstances in which that might occur in relation to cloning.

4. Scope of Constitutional power to legislate on cloning

I believe that the Federal Parliament could legislate to establish a federal body to oversee developments in cloning and like technology (cf the regulatory scheme replacing the Genetic Manipulation Advisory Committee). This could be achieved under the External Affairs power.

5. Ownership and control of cloning technology

There is no reason why

My view: In my view, there are real dangers in trying to legislate specifically in a rapidly developing area like biotechnology. It is inevitably difficult to anticipate new discoveries and to provide for them. A more flexible system would be to establish a supervisory body with broad terms of reference to provide advice as needed. This body would need to be established by legislation, for the reasons given above. It should be federal, for reasons of consistency and equity. I believe federal legislation would be constitutionally possible under the External Affairs power. The new body should be multi-disciplinary but not representative. It should be established in the Department for Health and Aged Care and should report annually to the federal Parliament.