22nd November 1999

The Secretary, Legal and Constitutional Affairs Committee, Parliament House, Canberra, ACT 2600

Dear Sir/Madam,

The Murdoch Institute for Research into Birth Defects welcomes the Minister's call for observations on the AHEC document on "human reproductive cloning" which was issued about twelve months ago, immediately after cloning of sheep, cattle and mice made it likely that similar procedures could work for humans. If the document is to be redrafted, we hope it will be shortened and simplified.

We define reproductive cloning as cloning which gives rise to a living person who has the complete nuclear genome of a previously existing person using procedures for assisted reproduction. Staff of the Murdoch Institute are not carrying out research in this field of study, but we are very interested in the area because of our commitment to developing new forms of treatment for serious genetic disorders which are currently untreatable. Over 50% of perinatal and neonatal deaths involve a genetic birth defect. We believe that a combination of cell therapy and gene therapy might lead to very much better treatment for many of these babies and children. Cancers also can be regarded as genetic diseases, even though most are not inherited, and their treatment should benefit from research in this area. These new therapies may involve studies which parallel (but need not duplicate) aspects of reproductive cloning technology. Therefore, our clinicians, scientists and ethicists have all discussed and studied these issues.

We believe that reproductive cloning, particularly if the donor of the genetic material is an existing person, would involve a diminution of autonomy and a weakening of traditional parenting roles. Twinning is not a model for reproductive cloning, as twins have their own genome that is distinct in time for those of others, and of their own parents. We know that other developments also lead to diminution of autonomy and weakening of parental roles, but these are based on social rather than medical interventions. It is necessary to examine whether there is any medical reason that could provide the very strong justification that would be required to permit reproductive cloning, in view of the arguments against its introduction.

Our clinical service offers care to all children born with genetic disorders in Victoria, and to their families, and we are familiar with their problems and their desire to have healthy children. We have concluded that there are no circumstances where there is a medical reason for reproductive cloning. Any couple who wish to avoid the

birth of a child with a serious medical condition of a genetic nature can do so using methods which are not thought to be unethical in these circumstances by the great majority of the profession and the community. Where these methods are not yet available, reproductive cloning of an existing adult or child has, in our view, no medical advantages as against other options.

There are those who argue that same sex couples, or individuals who are not in a relationship, should be permitted reproductive cloning, or who put forward other reasons of a personal nature for permitting cloning, or who argue on libertarian grounds that cloning should be permitted. We do not agree with this, because of the diminution in autonomy, and for two further reasons. First, there is a real possibility that cloning will be medically unsafe, in that the cloned individual will be more prone to diseases associated with ageing than an individual conceived in the normal way. Second, there are strong arguments on the grounds of resource allocation that there are better ways to spend our limited health resources.

The senior staff of the Murdoch Institute is divided as to whether reproductive cloning should be made illegal. Arguments against making cloning illegal include the view of some staff believe that cloning should be discouraged but is ultimately within the area where an individual has a right to make the final personal decision. Others argue that the field is moving so quickly that it may prove difficult to define the terms in law, and the law may restrict in ways that are not envisaged at present. (This is the case for some of the State laws governing IVF.) However, the majority of the staff thinks that reproductive cloning to give a liveborn human could be made illegal.

However, we recognise that there are very great potential benefits in continuing research into ways in which somatic cells from living individuals can become totipotent. These benefits are most clear in the field of transplantation medicine. Transplants are limited by risk of rejection, which also requires the use of highly dangerous and cytotoxic drugs. Almost all of those who die after attempts at transplantation do so from the effects of immuno-incompatibility or the drugs used to attempt to control it. There are also not enough tissue donors. If it were possible to take a cell from an individual (say, a child suffering from leukaemia) and dedifferentiate/redifferentiate this cell into a bone marrow cell with normal properties, these problems would be solved. This is such a stunning prospect that it would be highly unethical NOT to pursue it.

The dedifferentiating of a somatic cell turns it into what is known as an embryonic stem cell (ES cell), which could in theory form an embryo. However, it is now clear that almost any cell, if put through a series of procedures, can become the equivalent of an ES cell. At present, the easiest way to do this is to pass the cell nucleus through a fertilised egg from which the nucleus has been removed. However, it seems likely that this step will not be essential, and other techniques will succeed in the future in dedifferentiating somatic cells to totipotency.

We believe that reproductive cloning to give a living individual is not ethical and should not be permitted. However, we believe that research to allow the use of dedifferentiated somatic cells as tissue for transplantation, in the first instance for those with leukaemias or liver disease, is of the highest medical importance, and ways should be found to permit and encourage this research. We do not think that ES cells grown as cells in culture are in any way equivalent to human embryos.

We would suggest:

- 1. That a National Regulatory Committee for Reproductive and Genetic Technology (NRC) should be established, to which all groups (public or private) should be legally bound to submit any proposal for research with human material in this field.
- 2. That the NRC should determine that no reproductive cloning procedures that could lead to a viable human being (or a fetus of more than 28 days) should be permitted.
- 3. That the NRC would be directed to permit a limited number of procedures (subject to the usual rules of consent) on "spare embryos" which would otherwise be destroyed, to allow methods to be developed which can yield cells for transplantation from somatic cells, provided such procedures do not breach the rules against reproductive cloning procedures above.
- 4. That the government make available grants as a matter of urgency through NHMRC and ARC, for which all groups can apply (public and private), to support studies which involve the reestablishment of totipotent cells for transplantation from somatic cells without going through a step involving the destruction of an embryo.
- 5. That whatever recommendations are made, they should be in force throughout all States and Territories in Australia.
- 6. That Australia acknowledge that these issues would be best dealt with by international agreement, and support (and consider convening) an international meeting, with WHO and UNESCO, to attempt to agree an international code of practice.

Yours sincerely,

Bob Williamson, FRS,

Director and Professor of Medical Genetics, University of Melbourne