SOUTH AUSTRALIAN COUNCIL ON REPRODUCTIVE TECHNOLOGY

ENQUIRY INTO SCIENTIFIC, ETHICAL AND REGULATORY ASPECTS OF HUMAN CLONING

HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON LEGAL AND CONSTITUTIONAL AFFAIRS

1. Regulation of reproductive technology in South Australia

1.1 Reproductive Technology Act 1988

In 1988 the Parliament of South Australia enacted the Reproductive Technology Act, 1988. In this Act various mechanisms were set up to control the practice of reproductive technology.

1.1.1 A Council was appointed that consists of 11 members appointed by the Governor, including nominees of the universities, the College of Obstetrics and Gynaecology, the College of General Practitioners, the heads of churches, the Law Society and 5 nominated by the Minister.

1.1.2 The functions of the Council include advising the Minister on questions arising from reproductive technology, carrying out research, promoting information and informed public debate, advising the Commission on conditions to be included with licensing and the establishment of the Code of Ethical Practice.

1.1.3. Licensing of reproductive technology units occurs through the South Australian Health Commission (now Department of Human Services) who set the conditions under which a licensee may operate.

1.1.4. Penalties are prescribed for the breach of any Regulation and several practices, including embryo flushing, and destructive research on embryos are proscribed.

1.2 The Code of Ethical Research Practice

The Reproductive Technology (Code of Ethical Research Practice) Regulations of 1995 were established in accordance with Section 20(4) of the Reproductive Technology Act 1988. This code sets out conditions for ethical research and clinical practice, including a section (Part 2) on prohibited practices.

1.2.1 Prohibited practices

The Reproductive Technology Code of Ethical Research Practice has several prohibitions listed which include embryo flushing, culturing or maintaining embryos outside the body, research on embryos more than 14 days old, altering the genetic structure of reproductive material, replacing the nucleus of embryo cells, placing reproductive material in animals, mixing reproductive material from different sources, mixing of human and animal reproductive material, giving

value for gamete donation. Amongst these prohibited practices is a prohibition on cloning.

1.2.2 A ban on cloning

The Code states "A licensee may not carry out, or cause, suffer or permit to be carried out, the procedure of cloning". In Part 1, Section 2, cloning is defined as "any procedure directed at producing two or more genetically identical embryos from the division of one embryo".

2. Review of the definition of cloning

2.1 Background to the Council's concerns

The scientific advances on cloning, conducted in Scotland, led the Council to readdress the issues of the definition of cloning in the Codes of Research Practice. Council noted that the definition in the Codes might imply that cloning experimentation on cells is permissible, despite the guidelines of the National Health and Medical Research Council (NHMRC) that do not allow such research. The NHMRC in its Ethical Guidelines on Assisted Reproductive Technology, prohibited

"experimentation with the intent to produce two or more identical individuals, including development of human embryonic stem cell lines, with the aim of producing a clone of individuals".

It was considered by Council that cloning undertaken in a similar manner to the procedure used to create a cloned sheep was prohibited under Section 9 of the Regulations

"A licensee must not replace, or cause, suffer or permit the replacement of, the nucleus of a cell of an embryo, or of an ovum in the process of fertilization, with any other nucleus".

Similarly, any other interference was prohibited under this statement

"A licensee must not alter, or cause, suffer or permit to be altered, the genetic structure of a cell while the cell forms part of an embryo or an ovum in the process of fertilization".

While these prohibitions were quite satisfactory for the technology currently available, the Council was mindful that scientific advances in cloning techniques in the future could alter this. It was particularly noted by the Council that South Australian law does not legislate against the cloning of human organs or tissues. The Council therefore established a cloning working party whose brief was to develop a new definition of cloning in the Code of Ethical Research Practice which reflects current research and therapeutic needs and preserves the spirit of the legislation.

2.2 A working party on cloning established

This cloning working party was constituted in April, 1999 and met in October of that year. Members of the cloning working party included 5 members of Council and 4 scientists with expertise in animal cloning. Some members of

the Committee had concerns that “back door” methods might be used to clone humans. There was unanimous agreement that cloning of whole humans was not permissible under legislation nor was this in any way envisaged by the Committee. Expert opinions on current technology for cloning of animals was presented and a definition of cloning agreed upon.

2.3 Council’s definition of cloning

This is as follows:

“Cloning is defined as the practice of forming an embryo or an entity capable of embryogenesis which is genetically identical to, or substantially identical to, another human being, living or deceased”.

2.4 Limitation of this definition

It should be noted that the ambit of the Council includes human reproductive technology relating to gametes and embryos. While this definition will therefore exclude the use of human gametes for cloning, it does leave open the possibility of using somatic cells for cloning with methods that do not incorporate human oocytes. The Committee was given an opinion by the experts that the potential is still open for human somatic cells to be placed in animal oocytes to form human embryonic stem cells or, alternatively, for mature cell lines to be de-differentiated. These would be outside of the terms of reference of the Reproductive Council and not included in the Reproductive Technology Act 1988. If these styles of cloning were to be prevented, other legislation would have to be utilised or introduced to prohibit cloning if the methods do not use human gametes.

The Committee was sympathetic to the concept of human embryonic stem cells being established for therapeutic use, either as a generic stem cell line or as a personalised stem cell line. It did not seek to prohibit the use of human somatic cells for this purpose provided that no human gametes were utilised in the production of these stem cell lines. There also exists a theoretical possibility that cells obtained from the inner cell mass of an embryo could be used to establish embryonic stem cells provided that there was not destruction of the embryo from which these were derived. In terms of South Australian law, destructive embryo research is not permitted and embryos so biopsied would have to be transferred to a human uterus, rather than destroying it.

3. Conclusion

South Australian regulations prohibit the use of sperm or oocytes for human cloning. Destruction of embryos to produce embryonic stem cells is also banned. The Council has not taken a position on the use of other methods to produce such cell lines. It has also not opposed the potential use of biopsied embryonic cells for this purpose, provided destruction of the embryo from which they are obtained does not occur. The Council recognises the potential benefits to humankind of embryonic stem cells and their differentiated cell lines, but will not permit the use of human gametes or destructive use of human embryos to achieve this aim.

Prepared by: R.J. Norman

February, 2000