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Appendix D - AHEC Report

Terms of reference, executive summary and recommendations and resolutions

TERMS OF REFERENCE FOR THE AHEC REPORT

In providing advice to the Minister for Health and Aged Care, the Hon. Dr Michael Wooldridge MP, on the issue of cloning of human beings, the Working Group (under the aegis of the Australian Health Ethics Committee) will:¹

- 1. distinguish between the cloning of human beings and human tissue and identify the considerations for each technique;
- 2. identify potential risks and benefits as well as ethical considerations in approving the cloning of human beings;
- 3. examine the current state of the cloning of human beings nationally and internationally;
- 4. identify the current legislative position of cloning of human beings in Australia and the implications for the NHMRC *Ethical guidelines on assisted reproductive technology*;
- 5. recommend the appropriate regulatory framework
 - through uniform legislation; or
 - other further pronouncement; and
- 6. in accordance with the recommendations arising from TOR 5, recommend the most appropriate model of legislation or pronouncement.

In providing the above advice, the Working Group is to identify/consider:

- the current legislative position nationally and internationally on the cloning of human beings;
- guidelines and other codes or pronouncements on the cloning of human beings; and
- the ethical issues underpinning the potential support for cloning of human beings.

EXECUTIVE SUMMARY FROM THE AHEC REPORT²

- E1 The Commonwealth Minister for Health and Aged Care requested the Australian Health Ethics Committee to advise him on the potential and need for further pronouncement or possible legislation regarding cloning of human beings. The Terms of Reference of this request are set out in a later section of this [AHEC] report.
- E2 The Australian Health Ethics Committee set up a Working Group to consider the issues. In the course of its deliberations the Working Group conducted a limited consultation and did not receive any support for the application of any technique with the aim of intentionally cloning an individual human being. Names of the individuals and organisations who responded to the Working Group's invitation are listed at Appendix 2 [of the AHEC report].
- E3 In Chapter 1 of this [AHEC] Report, the Australian Health Ethics Committee responds to the Terms of Reference and advises that:
 - A basic distinction should be drawn between the cloning of a *whole* human individual and the copying (also referred to as 'cloning') of the component *parts* of a human (such as DNA and cells);
 - The cloning of individual human beings is prohibited by State legislation in Victoria, South Australia and Western Australia and is prohibited by National Health and Medical Research Council guidelines;
 - Legislation should be introduced in the remaining States and Territories to regulate human embryo research and to prohibit research on human embryos except as it is permitted in the NHMRC's *Ethical guidelines on assisted reproductive technology*
- E4 In addition to recommending a regulatory framework to prohibit cloning of a human being, Chapter 1 [of the AHEC report] discusses how basic research work may be supported, for instance by the establishment of a non-human primate facility.

- E5 Chapter 2 [of the AHEC report] outlines relevant scientific considerations and their potential for human application. Background embryology is sketched. Several techniques for cloning human embryos are outlined. Issues of technical applicability and feasibility are considered. This chapter outlines projected benefits of cloning techniques which have the potential for supporting transplantation and tissue and organ repair. Possible risks of these techniques are identified.
- E6 Chapter 3 [of the AHEC report] identifies a series of ethical issues associated mainly with cloning techniques involving human embryos. This chapter reflects on the possible objectives for cloning techniques involving human embryos, the circumstances in which such cloning may take place, the significance of such cloning in itself, as well as the public policy issues associated with permitting or prohibiting such cloning.
- E7 Chapter 4 [of the AHEC report] sets out the relevant Australian legislation and regulations which prohibit the cloning of human beings. The NHMRC *Ethical guidelines on assisted reproductive technology* also prohibit 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.
- E8 Chapter 5 [of the AHEC report] provides information on international regulatory frameworks. It should be noted that there is considerable international consensus that the intentional cloning of a human being is unacceptable.
- E9 Chapter 6 [of the AHEC report] sets out the following recommendations in respect of an appropriate regulatory framework:

RECOMMENDATIONS AND RESOLUTIONS BY AHEC

Recommendations to the Commonwealth Minister for Health and Aged Care³

Recommendation 1

The Commonwealth Government, through the Minister for Health and Aged Care, should reaffirm its support for the UNESCO *Declaration on the Human Genome and Human Rights*, in particular Article 11, which states that:

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 cooperate 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.

Recommendation 2

Noting that Victoria, South Australia and Western Australia have legislation regulating embryo research and prohibiting the cloning of human beings, the Minister for Health and Aged Care should urge the other States and Territories to introduce legislation to limit research on human embryos according to the principles set out in Sections 6 and 11 of the NHMRC *Ethical guidelines on assisted reproductive technology*.

Recommendation 3

Noting that there are statutory authorities established in Victoria, South Australia and Western Australia which consider and may approve human embryo research under strict conditions, the Minister for Health and Aged Care should urge the remaining States and Territories to establish similar statutory authorities with power to regulate research on human embryos according to the principles set out in Sections 6 and 11 of the NHMRC *Ethical guidelines on assisted reproductive technology*.

Recommendation 4

The Minister for Health and Aged Care should encourage and promote informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques.

Resolutions of the Australian Health Ethics Committee pending State and Territory Legislation⁴

Resolution 1

The AHEC proposes that, until legislation is introduced in the remaining States and Territories, the AHEC will collect information from institutional ethics committees (IECs) in these States and Territories on IEC research approvals of projects involving the application of current cloning techniques to human embryos. This information will be obtained in the course of the IEC annual compliance reporting system that is currently in place.

Resolution 2

The AHEC proposes that, until legislation is introduced in the remaining States and Territories, the NHMRC should consider the establishment of an expert advisory committee to assist IECs which seek advice on the scientific aspects of research projects involving the application of current cloning techniques to human embryos.