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Introduction

BACKGROUND TO THE INQUIRY

1.1 In the past few years two developments in science have placed the issue of human cloning firmly on the public agenda. The first of these was the birth of Dolly the sheep in 1996 and the second was the isolation of human embryonic stem cells in 1998. Since then there have been other developments in the field. The scientific, ethical and legal aspects of these developments are the subject of this report.

1.2 The Committee finds the term 'clone' unhelpful because it means different things to different people. Several scientific processes are associated with 'cloning'; they involve different techniques and serve different purposes.[1] To 'clone' is understood popularly to mean to replicate a whole, living being, for example, Dolly the sheep.

1.3 Dolly was the first mammal to be cloned from a cell of an adult animal[2] and her initial media appearance generated huge public interest and concern because of the implications it raised for humans.[3] The Committee

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1 In Appendix E, the glossary produced by the Australian Health Ethics Committee (AHEC) in its report, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*, is included, together with some definitions produced by the Australian Academy of Science, and other definitions that the Committee has found useful

2 The means by which Dolly was produced, somatic cell nuclear transfer, is discussed further in Chapters 2 and 3

3 Dolly was born on 5 July 1996. Her birth was announced formally in a paper by Dr Ian Wilmut, leader of the team that produced her, in *Nature* on 27 February 1997, but the *Observer* newspaper broke the story on 23 February 1997. See the Roslin Institute website: http://www.ri.bbsrc.ac.uk/library/research/cloning

notes there is almost universal condemnation of the proposition that a whole human being might be replicated.[4]

1.4 The term 'cloning' also may be used to describe processes that involve the replication of cells (including the clonal replication of embryonic and adult stem cells) and tissues, and may be associated with research directed towards the treatment of disease. These other processes, including 'therapeutic cloning' will be discussed further, beginning in Chapter 2.

The Committee's Approach

1.5 Dolly's birth raised the real possibility that humans might be cloned, and it was followed by a number of inquiries and consultation exercises around the world. These inquiries addressed not only the benefits of scientific advances related to cloning, but also the ethical and regulatory implications they raised. Implicit in these inquiries was the issue of whether there are benefits to be obtained from applying cloning techniques to human beings. This has also been a significant issue in this inquiry.

1.6 The Committee is conscious that cloning techniques may offer astounding alternatives to the treatment of human diseases. However, this area of science is in its early stages of development. If there are benefits—and risks—attached to the techniques, they should be identified and weighed, so that informed decisions can be made as to the uses that may be made of them. So that regulation in this area is appropriate to these benefits and risks, the debate and consultation over the issues arising from the scientific advances in science should be as informed as possible. During its inquiry and in this report the Committee has aimed to contribute to the debate and its outcomes.

1.7 Throughout the report, as the Committee describes the various processes or techniques (beginning in Chapter 2) and their purposes, it specifies the meaning it attaches to the scientific terms. The Committee canvasses the opinions that have come to its notice, and then draws its own conclusions about the issues involved in the processes and the oversight that may be appropriate to their use. In the final chapter the Committee proposes a regulatory model for Australia.

International Background

1.8 In the United Kingdom in February 1997 the House of Commons Science and Technology Select Committee inquired into experiments at the Roslin

4 Later in this chapter the Committee notes AHEC's early acknowledgment of this view. Further detail is also provided in later chapters, particularly Chapter 6

Institute, where Dolly was produced. The inquiry was concerned with the benefits that might flow from the work, the scientific challenge it represented, and the adequacy of the law regarding cloning.[5] The government's response to that report affirmed that the cloning of human individuals is ethically unacceptable and would not be permitted in the United Kingdom.[6]

1.9 In 1998 the United Kingdom Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority undertook a joint public consultation exercise on human cloning. They presented their findings in a report *Cloning Issues in Reproduction, Science and Medicine*, together with comment on the current legal and administrative arrangements on treatment using human embryos. The report recommended that the regulatory regime then in place be recognised as adequate to forbid human reproductive cloning in the United Kingdom.[7]

1.10 In 2000 an Expert Group established by the government and chaired by the Chief Medical Officer undertook an assessment of the benefits and risks of new areas of research using human embryos and was asked to advise whether the new areas of research should be permitted. The report, *Stem Cell Research: Medical Progress with Responsibility*, was released in August 2000. The report concluded that research across a range of sources of stem cells was warranted. The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 were passed by both Houses of the United Kingdom Parliament and implemented the Group's major recommendation: that research using embryos (created by assisted reproductive technologies or cell nuclear replacement) be permitted so as to increase understanding about human disease and cell-based treatments.[8]

1.11 In March 2001 the House of Lords appointed a Select Committee to consider and report on issues connected with human cloning and stem cell research arising from the Human Fertilisation and Embryology (Research

5 *The Cloning of Animals from Adult Cells*, Fifth Report from the Science and Technology Committee, Session 1996-97, HC 373-I

6 *The Cloning of Animals from Adult Cells*, Government Response to the Fifth Report of the House of Commons Select Committee on Science and Technology, 1996-97, Cm 3815. Recent developments in the United Kingdom are discussed in detail in Chapter 10

7 Human Genetics Advisory Commission and Human Fertilisation and Embryology Authority, *Cloning Issues in Reproduction, Science and Medicine*, December 1998, section 9.2

8 16 August 2000. See Chapter 10 of this report for further detail; see also: http://www.doh.gov.uk/cegc/stemcellreport.pdf

Purposes) Regulations 2001. These issues include the ethical, legal, scientific, medical and commercial issues surrounding the Regulations.[9]

1.12 In February 1997, President Clinton asked the United States National Bioethics Advisory Commission to report on the ethical and legal issues surrounding the cloning of human beings. The Commission sought evidence from interested parties including scientists, scientific societies, ethicists, theologians and legal experts. It focused on the particular technique that produced Dolly and the ethical, religious, legal and regulatory implications of cloning human beings in this way. The Commission reported in June 1997 and concluded, among other things, that 'at this time it is morally unacceptable for anyone in the public or private sector … to attempt to create a child using somatic cell nuclear transfer cloning'.[10] President Bush's statement of 9 August 2001 in which he approved federal funding for research on certain stem cell lines that already had been taken from human embryos received world-wide attention. In that address the President confirmed his opposition to human/reproductive cloning. When he discussed the issue of embryonic stem cell research he articulated concerns that were raised by many of those who gave evidence to this inquiry:

> Research on embryonic stem cells raises profound ethical questions, because extracting the stem cell destroys the embryo, and thus destroys its potential for life. …
>
> At its core, this issue forces us to confront fundamental questions about the beginnings of life and the ends of science. It lives at a difficult moral intersection, juxtaposing the need to protect life in all its phases with the prospect of saving and improving life in all its stages.
>
> As the discoveries of modern science create tremendous hope, they also lay vast ethical mine fields.[11]

The Australian Health Ethics Committee Report

1.13 In Australia, after the birth of Dolly, the Minister for Health and Aged Care, the Hon Dr Michael Wooldridge, MP, (the Minister), sought advice

9 House of Lords, *Current Inquiries and Invitations to Submit Evidence*, Session 2000-01, http://www.publications.parliament.uk/pa/ld199697/ldselect/ldscenqs.htm The Committee has been asked to report by the end of 2001

10 See the Bioethics Advisory Commission's site: http://bioethics.gov/pubs/cloning1/executive.htm. Recent international developments are discussed in Chapter 4, in which this Committee provides an overview of developments in research and Chapter 10, which canvasses the international regulatory framework

11 ABCNews.com, http://abcnews.go.com/sections/politics/DailyN…/stemcells_Bush_transcript010809.htm

from the Australian Health Ethics Committee (AHEC) on the 'potential and need for further pronouncement or possible legislation regarding cloning of human beings'.[12] AHEC set up a Working Group to consider the issues; the Group conducted limited consultation and sought comment from a number of individuals and organisations on its draft report. The final report was approved by the full membership of AHEC.[13]

1.14 The report by AHEC, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings* (the AHEC report), was presented in December 1998, and contained four recommendations and two resolutions. The AHEC report and recommendations are discussed in detail throughout this report but it is useful to begin with an outline of the findings.[14]

1.15 An initial finding by AHEC was that there was 'an international consensus that a distinction should be drawn between two categories of cloning: cloning of a human being and copying (cloning) of human *parts* (such as DNA and cells)'.[15] AHEC also considered there was consensus that it is 'unacceptable to undertake any procedure with the aim of cloning a human being'.[16] Cloning of individual human beings is prohibited by State legislation in Victoria, South Australia and Western Australia, as well as by the NHMRC *Ethical guidelines on assisted reproductive technology* (NHMRC *Ethical guidelines*), AHEC noted.[17]

1.16 In summary, AHEC recommended:

- the government reaffirm support for the UNESCO *Declaration on the Human Genome and Human Rights*, particularly Article 11 that states:

12 Australian Health Ethics Committee of the National Health and Medical Research Council (NHMRC), *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*, 16 December 1998, (referred to throughout this report as the 'AHEC report'), p.iv. The terms of reference, executive summary, recommendations and resolutions are contained at Appendix D of this report. An overview of the role of the NHMRC (as set out in section 7 of the *National Health and Medical Research Council Act 1992*) is contained in Chapter 9. The NHMRC is a statutory authority charged, among other things, with inquiring into and advising government on matters relating to health, public health and medical research, ethical issues relating to health, and making recommendations to the Commonwealth on expenditure on public health research and training and medical research and training. AHEC is a principal committee of the NHMRC and among other things it develops guidelines for the conduct of medical research involving humans. See also the NHMRC site: http://www.nhmrc.health.gov.au/ethics/clone.pdf

13 AHEC report, pp.47-49. Appendix 2 of the AHEC report lists the individuals and organisations which commented on the draft report. These include academics, ethicists, religious, scientific and medical organisations

14 AHEC's terms of reference, executive summary and recommendations are at Appendix D

15 AHEC report, Chapter 1, paragraph 1.1

16 AHEC report, Chapter 1, paragraph 1.1

17 AHEC report, E3, p.iv. The Committee notes that there is some uncertainty regarding the interpretation of the statutory prohibitions: see Chapter 8 of this report

'Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted...' (Recommendation 1);

- as Victoria, South Australia and Western Australia already have legislation regulating embryo research and prohibiting the cloning of human beings, the Minister should urge the other States and Territories to legislate to limit research on human embryos according to the principles set out in the NHMRC *Ethical guidelines* (Recommendation 2);
- as Victoria, South Australia and Western Australia have statutory authorities that consider and may approve human embryo research under strict conditions, the Minister should urge the other States and Territories to establish similar statutory authorities to regulate research on human embryos according to the principles set out in the NHMRC *Ethical guidelines* (Recommendation 3). AHEC was critical of the States that had not introduced regulation despite earlier urging;
- the Minister should encourage and promote informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques (Recommendation 4).

1.17 The Resolutions stated that pending State and Territory legislation, AHEC should collect information from institutional ethics committees (IECs) (in the jurisdictions without legislation) on IEC research approvals involving the application of current cloning techniques to human embryos. Also the NHMRC should consider establishing an expert advisory committee to assist IECs that seek advice on scientific aspects of research projects involving the application of current cloning techniques to human embryos.[18]

THE COMMITTEE'S INQUIRY AND REPORT

Referral Of The Inquiry

1.18 In August 1999 the Minister for Health and Aged Care, the Hon Dr Michael Wooldridge, MP, asked the House of Representatives Standing Committee on Legal and Constitutional Affairs (the Committee) to review the AHEC report. The following report is the result of the Committee's investigations into the issues raised by the AHEC report.

18 AHEC report, Chapter 6, Resolutions 1 and 2, p.44

Conduct Of The Inquiry

1.19 An advertisement inviting submissions to the inquiry appeared in major metropolitan newspapers on 21 August 1999 and was posted on the Committee's website.[19] Letters seeking submissions were sent to Commonwealth Government agencies, State Premiers, Territory Chief Ministers, church leaders, medical organisations and scientific research institutions as well as community groups, ethicists and individuals who were known or likely to have an interest in the subject of the inquiry.

1.20 The Committee received a total of 347 written submissions and 50 exhibits.[20] In addition, many members of the public (approximately 316) wrote simply to urge a ban on human cloning.[21]

1.21 The Committee collected most of its oral evidence at two public forums. These were held in Melbourne on 1 March 2000 and in Canberra on 29 March 2000. The Committee was keen to hold public forums so as to bring together as many members of the scientific community, church and community groups, ethicists and legal professionals as possible to explain and contest the array of views that were presented. Members of the public were able to participate directly in the collection of oral evidence at the forums by way of comment and questions to the witnesses.[22] The Chairman also met with representatives from relevant authorities and scientists in the United States and the United Kingdom. A list of these people is at Appendix G.

1.22 The transcripts of evidence taken at the public forums and hearings and electronic copies of this report, as well as written submissions provided to the Committee in electronic form, can be found on the Committee's website.[23]

The Report

1.23 As this report is a review of the findings of the AHEC report, the broad structure relates to the main themes canvassed by AHEC: the scientific, ethical and regulatory aspects of human cloning.

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19 The advertisement indicated that form letters received by the Committee would not be treated as individual submissions

20 Appendix A comprises a list of submissions and Appendix B comprises a list of exhibits. Witnesses who appeared before the Committee are listed at Appendix C

21 Appendix H contains a list of people who wrote to the Committee to urge a ban on human cloning

22 At intervals during the forums members of the public were invited to put questions and comments—through the Committee Chairman

23 www.aph.gov.au/house/committee/laca

Scientific issues

1.24 Chapter 2 provides an introduction to the science, as well as the scientific terms and techniques relevant to discussion of cloning.

1.25 In Chapter 3 the Committee discusses the scientific conclusions from the AHEC report and presents an overview of the scientific evidence to the inquiry. In Chapter 4 the Committee outlines the status of international scientific research, current Australian research, and timeframes for results.

Ethical issues

1.26 Chapter 5 introduces the general ethical issues surrounding cloning of human beings. It discusses the approach of the AHEC report to these issues, the views expressed to this Committee about AHEC's discussion of the ethical issues, and the approach the Committee has taken in this regard.

1.27 In Chapter 6 the Committee examines cloning for reproductive purposes. The initial question raised is, what does 'cloning for reproductive purposes', also called 'reproductive cloning', mean? The Committee considers what reproductive cloning technology may be used for and canvasses the opinions expressed about it. It is worth noting that almost all who presented evidence to the inquiry expressed opposition to cloning for reproductive purposes.

1.28 The focus of Chapter 7 is on ethical issues associated with research that involves cloning techniques and the possible application of these techniques to treat illness. The ethical issues relate to the way the research is to be conducted and the source material necessary to conduct it. The Committee considered the issues relating to material from the following sources: adult stem cells, stem cells from embryos surplus to assisted reproductive technology; from embryos created for research; from embryos created by somatic cell nuclear transfer using a patient's own tissue for therapy for the individual patient; and cells such as embryonic stem cells imported from overseas.

Regulatory issues

1.29 Chapter 8 introduces the issues involved in regulation of cloning. It begins with the approach taken by AHEC in its report and then considers the regulatory framework that applies to human cloning and related research in the Australian States and Territories. Relevant Commonwealth legislation is also considered. Non-legislative regulation in Australia is discussed in Chapter 9.

1.30 International developments in regulating human cloning are canvassed in Chapter 10, together with the implications they present for Australia.

1.31 In Chapter 11 the Committee responds to the recommendations of the AHEC report and in Chapter 12 the Committee provides its own model for the regulation of human cloning and related research in Australia.