CHAPTER 1

INTRODUCTION AND BACKGROUND

Reference and inquiry

1.1 The Research Involving Embryos and Prohibition of Human Cloning Bill 2002 (the Bill) was introduced into the House of Representatives on 27 June 2002. On 21 August 2002, the Senate, on the recommendation of the Selection of Bills Committee (Report No.6 of 2002), referred the provisions of the Bill to the Committee for report by 24 October 2002.

1.2 The Selection of Bills Committee, in recommending the reference of the Bill to the Committee, provided the following reason for referral:

> To consult widely with various stakeholders in the community to inform the Senate in its deliberations on the Bill. The Senate last considered embryo and cloning issues in 1986.

1.3 The inquiry was advertised in *The Australian* on 28 August and 11 September 2002 and through the Internet. Submissions were also invited from a large range of groups and individuals, including representatives from the medical science research community (domestic and international, private and public); consumer and other health care groups; ethics groups and other community organisations. Due to the tight timeframe for the inquiry, the closing date for submissions was 13 September 2002, although the Committee continued to receive submissions throughout the course of the inquiry.

1.4 The Committee received 1851 public submissions, together with a large amount of additional material from witnesses at hearings and in response to questions on notice. The list of submissions and other written material received by the Committee and for which publication was authorised is at Appendix 1. The Committee held public hearings in Canberra on 29 August and 17, 19, 24 and 26 September 2002 involving some 52 witnesses. A list of witnesses who appeared at the public hearings is included at Appendix 2. Submissions that were received electronically and the *Hansard* record of the public hearings may be accessed through the Committee's website at www.aph.gov.au/senate_ca

1.5 This inquiry has been undertaken in circumstances where the political parties have given their Senators a 'free vote' on the Bill when it is considered in the Senate. Thus, in conducting the inquiry and in the preparation of the report, the Committee has been mindful that the purpose of the inquiry was primarily to gather information to assist Senators make an informed decision on the Bill. The report aims to balance the major issues and arguments relating to the subject of the Bill without attempting to formulate conclusions or recommendations that the Committee considers should be the prerogative of individual Senators in a 'free vote'.

1.6 The report has been structured in the following fashion. This background chapter refers to the inquiries, reports and debate that has taken place over nearly two decades leading to the introduction of the Bill. Chapters 2 and 3 discuss the scientific and ethical issues that underpin the Bill, chapter 4 considers the provisions of the Bill in detail and finally chapter 5 provides international comparisons, legislative or otherwise, on the subject.

House of Representatives consideration of the Bill

1.7 As noted above, the Bill was introduced into the House of Representatives on 27 June 2002. The Bill was debated in the House on 27 June and on 20, 21, 22 August and in the Main Committee of the House on 26, 27 and 28 August 2002 with 105 members participating in the debate.

1.8 On 29 August 2002 the House agreed after a lengthy debate to a procedural motion that divided the provisions of the Bill into two Bills, as indicated below:

- Prohibition of Human Cloning Bill 2002 consisting of, with associated amendments, the title, enacting formula and Parts 1 and 2 and clauses 56, 61 and 62 and the schedule of the Bill as introduced, and an activating clause.
- Research Involving Embryos Bill 2002 consisting of, with associated amendments, Parts 3, 4, 5 and 6 of the Bill, and also including with amendments the provisions of clauses 56, 61 and 62 of the Bill as introduced, and a new clause 55A.

1.9 The Prohibition of Human Cloning Bill 2002 was passed by the House of Representatives on 29 August 2002 and introduced into the Senate on 18 September. The Research Involving Embryos Bill 2002 was considered in detail on 16, 24 and 25 September and was finally passed by the House without amendment on 25 September.

1.10 With the two Bills created by the splitting of the original Bill passing in the House of Representatives without amendment, the provisions of the original Bill as referred to the Committee remain unaltered. For ease of reference, the Committee has referred in the report to the provisions by the clause number from the original Bill.

Inquiries, reports and debate on human cloning and embryo research

1.11 There have been a number of reports and inquiries since the 1980s in relation to human cloning and research involving excess ART embryos. The following is a brief summary of the major inquiries and reports and their outcomes.[1]

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1 The following section is largely based on information from *Submission* 23, pp.5-8 (NHMRC); Parliamentary Library Bills Digest No.17 2002-03, *Research Involving Embryos and Prohibition of Human Cloning Bill 2002*, pp.16-18; and House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*, August 2001.

Senate Select Committee on the Human Embryo Experimentation Bill 1985

1.12 The Senate established a Select Committee in October 1985 to consider the Human Embryo Experimentation Bill 1985, a private Senator's bill introduced by Senator Brian Harradine. The Committee's primary task was to consider for the purposes of the IVF program whether it was necessary or desirable to carry out research on relevant human embryos by manipulation, dissection or administration of drugs, and, if so, whether any guidelines could be formulated to govern such research. The Committee reported in October 1986.[2]

1.13 The Select Committee adopted the usage 'embryo' to refer to 'genetically new human life organised as a distinct entity oriented towards further development'. The Committee observed the distinction between experimentation of diagnostic and/or curative value and experimentation with no such value but undertaken to advance medical/scientific knowledge. The former it termed 'therapeutic experimentation', the latter 'non-therapeutic experimentation' with a further distinction 'destructive non-therapeutic experimentation' indicating that such experiments were, based on the state of knowledge at the time, so invasive as to inevitably cause the destruction of the subject of the experiment.

1.14 The Committee concluded that 'the respect due to the embryo from the process of fertilisation onwards requires its protection from destructive non-therapeutic experimentation'. The Committee also found that 'any supposed distinction between so called "spare" embryos and those created specifically for experimental purposes to be ethically unsound' and recommended that 'the concept of guardianship be adopted as the most appropriate model to indicate the respect due to the embryo in this context'.[3]

Development of the NHMRC/AHEC[4] Ethical Guidelines on ART

1.15 In October 1982 the NHMRC issued guidelines on the ethical aspects of research related to the use of assisted reproductive technology (ART) - *In vitro fertilisation and embryo transfer* as a supplementary note to the *NHMRC Statement on Human Experimentation*. In 1993 the Australian Health Ethics Committee (AHEC)

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2 *Human Embryo Experimentation in Australia*, Report of the Senate Select Committee on the Human Embryo Experimentation Bill 1985, September 1986, Parliamentary Paper No. 437 of 1986.

3 *Human Embryo Experimentation in Australia* (1986), pp.xiii-xiv. See also *Committee Hansard* 26.9.02, pp.226-7 and *Submission* 899 (Rev Prof Michael Tate AO) – Former Senator Tate was Chairman of the 1985 Select Committee.

4 The Australian Health Ethics Committee is a principal committee of the National Health and Medical Research Council. AHEC's primary functions are to advise the NHMRC on ethical issues relating to health and developing guidelines for the conduct of medical research involving humans. Other functions include the promotion of community debate on health ethics issues, monitoring the work of human research ethics committees and monitoring and advising on international developments in health ethics.

commenced a review of these guidelines, leading to the release in June 1996 of *Ethical Guidelines on Assisted Reproductive Technology*.[5] The Guidelines are still operative, although as discussed in chapter 4 they are presently being reviewed, and describe a range of prohibited or unacceptable practices. On the issue of research involving excess ART embryos the Guidelines allow the use of excess ART embryos for research that may damage or destroy the embryo, under exceptional circumstances.

1.16 In releasing these guidelines, AHEC identified the need for all States and Territories to introduce comprehensive ART legislation and recommended to the Commonwealth Minister for Health that ART legislation be enacted in those States and Territories which had not introduced such legislation.

1998 AHEC Report to the Minister for Health and Aged Care

1.17 In 1998, the Minister for Health and Aged Care, Dr Michael Wooldridge, requested AHEC to report to him on the scientific, ethical and regulatory considerations relevant to cloning of human beings. The report entitled *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings* was provided to the Minister on 16 December 1998.

1.18 AHEC recommended that the Government should reaffirm support for the UNESCO *Declaration on the Human Genome and Human Rights*, especially the article recommending the prohibition of the reproductive cloning of human beings; all States should legislate to limit research on human embryos according to the principles set out in the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*; all States should establish statutory authorities to regulate research on human embryos according to the principles set out in the NHMRC *Ethical Guidelines*; and the Minister should encourage informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques.

House of Representatives Standing Committee on Legal and Constitutional Affairs – 2001 Report on Human Cloning

1.19 In August 1999, Minister Wooldridge asked the House of Representatives Standing Committee on Legal and Constitutional Affairs to review the 1998 AHEC report *Scientific, Ethical and Regulatory Considerations relevant to Cloning of Human Beings*. The Committee undertook extensive consultations over a period of two years. Mr Kevin Andrews, the Committee Chair, has commented that 'at the core of the Committee's deliberations was the question: is there any benefit in conducting stem cell research or in the application of cloning technologies to human beings? If there is, what use of these technologies is permissible to achieve these benefits?'[6] The

5 www.health.gov.au/nhmrc/publications/pdf/e28.pdf

6 *House of Representatives Hansard,* 28.8.02, p.5747 (Mr Kevin Andrews).

Committee's report *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research* was released in August 2001.[7]

1.20 The majority of the Committee recommended:

- the enactment of legislation to regulate human cloning and stem cell research;
- that such legislation should include a ban on cloning for reproductive purposes combined with criminal penalties and loss of an individual's research licence; and
- the establishment of a national licensing body empowered to issue licences for research involving the isolation, creation and use of embryonic stem cells.

1.21 A minority of Committee members opposed any research which involved the destruction of human embryos and expressed concerns about the continued use of embryonic stem cells derived from embryos, whether in Australia or overseas.

1.22 The NHMRC indicated that the Bill introduced into Parliament is consistent with the majority report of the House of Representatives Committee – which is also consistent with the NHMRC/AHEC *Ethical Guidelines on ART* issued in 1996.

Gene Technology Act 2000

1.23 In December 2000, community concern regarding a lack of legislation in some States and Territories to regulate the cloning of human beings led to the amendment of the Gene Technology Bill 2000 in the Senate. Clauses were inserted in the Bill that ban human cloning, certain experiments involving animal eggs and certain experiments involving putting human and animal cells into a human uterus. These were intended as interim provisions while the Commonwealth, States, Territories and the NHMRC identified the most effective and comprehensive wording for a prohibition on human cloning and the creation of hybrid embryos.

1.24 The current Bill provides for such prohibitions and therefore repeals the sections that were inserted in the *Gene Technology Act 2000*.

Australian Health Ministers' Conference consideration of the issues

1.25 Australian Health Ministers have considered the issue of human cloning and research involving excess ART embryos from 1999, when the recommendations of the AHEC report prompted the Minister for Health and Aged Care to write to State and Territory Health Ministers urging them to consider the development of complementary legislation and regulation in the area of human cloning and ART.

1.26 Following that correspondence, the Australian Health Ministers' Advisory Council (AHMAC) and then the Australian Health Ministers' Conference (AHMC) considered the issues. In July 2000, AHMC decided that each jurisdiction would

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7 www.aph.gov.au/house/committee/laca/humancloning/report.pdf

independently legislate to regulate ART clinical practice, but agreed to work towards a nationally consistent approach for the prohibition of human cloning. Following AHMC's decision, Commonwealth, State and Territory officials worked together to prepare a detailed report outlining regulatory options for prohibiting human cloning, for consideration by Health Ministers. However, at the same time the issue was also placed on the COAG agenda.

COAG consideration and the 5 April 2002 communique

1.27 On 8 June 2001, the Council of Australian Governments (COAG) discussed assisted reproductive technology including human cloning and in a communique stated that the Council committed itself to achieving nationally consistent provisions in legislation to prohibit human cloning. It also agreed that jurisdictions work towards nationally consistent approaches to regulate assisted reproductive technology and related emerging human technologies. However, on this latter issue, Heads of Government were acutely aware of the need to engage the community on the matter and to ensure that all sectors of the community benefit fully from advances in medical science while prohibiting unacceptable practices.

1.28 COAG sought a report from Health Ministers by the end of 2001 on technical issues, with the aim of a nationally consistent approach being in place by all jurisdictions by June 2002. Health Ministers endorsed this approach at a meeting on 1 August 2001.

1.29 A technical report, *Human Cloning, Assisted Reproductive Technology (ART) and Related Matters*, was subsequently prepared by the Commonwealth in close consultation with officials from all jurisdictions and following consultation with experts in a range of fields including medical research, ART, ethics and law. Consultation was also undertaken with community and religious leaders as well as community groups. Both Health Ministers and COAG considered the report at concurrent meetings on 5 April 2002, although the Australian Health Ministers' Conference deferred any further consideration of the subject until after the outcome of the COAG meeting was known.

1.30 At the COAG meeting on 5 April 2002, the Prime Minister and all Premiers and Chief Ministers agreed that the Commonwealth, States and Territories would introduce nationally consistent legislation to ban human cloning and other unacceptable practices. A communique setting out the agreed outcomes of the discussions issued after the meeting stated:

> The Council agreed that research involving the use of excess assisted reproductive technology (ART) embryos that would otherwise have been destroyed is a difficult area of public policy, involving complex and sensitive ethical and scientific issues. Having noted the range of views across the community, including concerns that such research could lead to embryos being created specifically for research purposes, the Council agreed that research be allowed only on existing excess ART embryos, that would otherwise have been destroyed, under a strict regulatory regime, including requirements for the consent of donors and that the embryos were

> in existence at 5 April 2002. Donors will be able to specify restrictions, if they wish, on the research uses of such embryos.
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> …
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> The Council agreed that research involving the destruction of existing excess ART embryos be permitted under a strict regulatory regime to enable Australia to remain at the forefront of research which may lead to medical breakthroughs in the treatment of disease. It was further agreed that the regulatory regime governing the use of excess ART embryos that would otherwise have been destroyed will be reviewed within three years. Research would need to have approval from an ethics committee and be in accordance with NHMRC and Australian Health Ethics Committee guidelines.

The relevant sections of the communique dealing with human cloning, ART and related matters are reproduced in full at Appendix 3. The Committee requested access to the documentation that was presented to the Health Ministers and used as the basis of the report to COAG that informed COAG's decision on these issues. The NHMRC provided advice from AHMAC that while the decisions and resolutions made at AHMC meetings may be made publicly available, the agenda papers submitted to Ministers, which are often subject to Cabinet consideration, are not available for public information.[8]

1.31 The COAG Communique is not legally binding on the Commonwealth, the States and the Territories, but is an agreement which depends on the goodwill of each of the governments concerned. However, the NSW and Queensland Governments emphasised the importance of the fact that all States and Territories have worked cooperatively towards the development of nationally consistent legislation to fulfil the requirements of the COAG communique. Indeed, the State and Territory Governments pointed to the achievement of national consistency as a key principle in their acceptance of the Bill.[9]

1.32 The NSW and Queensland Governments' submissions expressed concern that the division of the provisions into two Bills was moving away from the COAG Agreement. However, the Prime Minister said in the House:

> What is in the COAG agreement is a series of principles, and this bill – or these bills, if you split it – gives effect to the COAG principles…I have advice that, by splitting the bill, you are not endangering the establishment of the regime agreed to at COAG, providing both bills are passed.[10]

This concern was not expressed to the Committee by any other States or Territories.

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8 *Committee Hansard* 26.9.02, p.254 (Senator Harradine). *Submission* 23, Additional information 16.10.02, p.4 (NHMRC).

9 *Submissions* 891 (NSW Government) and 1500 (Queensland Government).

10 *House of Representatives Hansard* 29.8.02, p.5809 (Mr Howard). The Minister's second reading speech for the Prohibition of Human Cloning Bill 2002 confirmed the Prime Minister's comments (see *Senate Hansard* 18.9.02, p.4324).

Development of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002

1.33 Between 5 April 2002 and the introduction of the Bill in June 2002, staff of the NHMRC worked with the Principal Committees of the Council, relevant Commonwealth agencies and all States and Territories to develop the legislation. The NHMRC emphasised to the Committee that it was the task of the Council to implement the policy position taken at COAG. The parameters for the legislation were provided by the decisions of COAG as set out in the COAG communique.[11]

1.34 An exposure draft of both the Bill and an explanatory memorandum was developed which became part of consultations undertaken by the NHMRC in each State and Territory. These consultations included discussions with experts in science, medical research, law and ethics and representatives from human research ethics committees as well as religious and community leaders.[12] The NSW Government submission refers not only to the Commonwealth consultations held in NSW, but also to in depth consultations with key stakeholders conducted by the Premier of NSW.[13] The NHMRC also took account of submissions made to the House of Representatives Standing Committee on Legal and Constitutional Affairs during its two year inquiry into human cloning and stem cell research, and written submissions received by the NHMRC on the draft Bill.[14]

11 *Committee Hansard* 29.8.02, pp.4-6, 9 and 26.9.02, p.246 (NHMRC).

12 The list of invitees for the consultations and actual attendees is included in the NHMRC *Submission* 23, Attachments B and C.

13 *Submission* 891, pp.4-5 (NSW Government).

14 *Committee Hansard* 29.8.02, p.9 (NHMRC).