The Cloning of Humans (Prohibition) Bill 2001 (Qld)

On 27 November 2001, the Minister for Health, the Hon Wendy Edmond MP, introduced the Cloning of Humans (Prohibition) Bill 2001 (Qld) into the Queensland Parliament.

The objective of the Bill is to prohibit:

- the creation or attempted creation of cloned humans; and
- the gestation of human embryo clones.

The Bill is not directed at medical and scientific applications of cloning technologies that do not result in human reproductive cloning.

This Research Brief discusses: the scientific concepts surrounding cloning; recent developments in related human cloning technologies (somatic cell nuclear transfer and stem cell research); and possible applications of human cloning and ethical considerations. The Brief outlines the recommendations of a number of key Australian and international reports on cloning technologies, in particular, human reproductive cloning. The Brief also compares the Queensland Bill with existing and proposed legislative prohibitions on human cloning in Australia and overseas.

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1 INTRODUCTION

The birth of “Dolly” the cloned sheep in 1996 raised the real possibility of human cloning and precipitated a worldwide debate about the benefits and scientific and ethical implications of the scientific advances related to cloning technologies.

Consistent with earlier agreements of Australian Health Ministers and the Council of Australian Governments, the Minister for Health, the Hon Wendy Edmond MP, on 27 November 2001, introduced the Cloning of Humans (Prohibition) Bill 2001 (Qld) into the Queensland Parliament.

The objective of the Bill is to prohibit:

- the creation or attempted creation of cloned humans; and
- the gestation of human embryo clones.

The Bill is not directed at medical and scientific applications of cloning technologies that do not result in human reproductive cloning. Neither does it purport to apply to naturally occurring cloning processes.

This Research Brief discusses: the scientific concepts surrounding cloning; recent developments in related human cloning technologies (somatic cell nuclear transfer and stem cell research); and possible applications of human cloning and ethical considerations. The Brief outlines the recommendations of a number of key Australian and international reports on cloning technologies, in particular, human reproductive cloning. The Brief also compares the Queensland Bill with existing and proposed legislative prohibitions on human cloning in Australia and overseas.

2 WHAT IS CLONING?

This section discusses cloning as a scientific concept and describes terms that relate to “cloning” and cloning-related techniques in that context. However, readers should be aware that as legislative definitions of cloning and related terms vary, when a piece of legislation about cloning is being considered, it is important to refer to the relevant definition used in that legislation.

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A clone is a genetically identical cell or individual descended from one original cell or individual by non-sexual reproduction. The term “cloning” does not just encapsulate the replication of an entire individual, although often this is the public perception. Cloning can occur naturally in the asexual reproduction of plants, the formation of identical twins and the multiplication of cells in the natural process of repair. The cloning of DNA, cells, tissues, organs and whole individuals is also achievable with artificial technologies.

The cloning of cell or an individual may be achieved through a number of techniques, including:

- Molecular cloning: the process of copying genes and other pieces of chromosomes to generate identical material.
- Blastomere separation (sometimes called "twinning" after the naturally occurring process that creates identical twins): splitting a developing embryo soon after fertilisation of the egg by a sperm (sexual reproduction) to give rise to two or more embryos. The resulting organisms are identical twins (clones) containing DNA from both the mother and the father.
- Somatic cell nuclear transfer: the transfer of the nucleus of a somatic cell into an unfertilised egg whose nucleus, and thus its genetic material, has been removed. (All cells that are not egg or sperm cells are somatic cells). This cloning procedure produces an animal carrying the DNA of only one parent. This type of cloning process was used in 1996 to produce the first mammal cloned from a fully differentiated adult somatic cell, a sheep named “Dolly”.

A number of scientific review bodies have noted that the term “cloning” is applicable in various contexts, as a result of the development of a range of cloning techniques with varying applications. Two applications of cloning technologies that relate to humans are human reproductive cloning and therapeutic cloning. These terms acknowledge the

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2 An “embryo” may be defined as: the developing organism from the time of fertilisation until significant cellular differentiation has occurred, when the organism becomes known as a ‘fetus’.

Note that there are a number of definitions of “embryo”. The definition given above, however, is the one adopted in recent reports by both the Australian Health Ethics Committee of the National Health and Medical Research Council and the House of Representatives Standing Committee on Legal and Constitutional Affairs: Australian Health Ethics Committee (AHEC), Report, Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings, December 1998; Australia, Parliament, Standing Committee on Legal and Constitutional Affairs, Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research, Report, August 2001.

aim of the cloning and differentiate between the cloning of a whole human individual and the cloning of the component parts (cells and tissues) of a human.

As a result, there is some fluidity in the concept of what is human reproductive cloning. The concept of human reproductive cloning contemplated in the new Bill is “the creation of another human being who is the copy of another human, whether or not that person is living”.

Similarly, the concept of therapeutic cloning may describe a number of approaches with the aim of producing human stem cells, tissues and organs.

Inherent in each of these cloning applications is the possibility that an embryo may be created or used for research.

### 3 DEVELOPMENTS RELATED TO CLONING TECHNIQUES

Two scientific breakthroughs have influenced the recent development of cloning technologies. The first of these is somatic cell nuclear transfer (discussed in section 3.1).

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4 For example, “reproductive cloning” might describe:
- the use of somatic cell nuclear transfer with the intent of producing a whole human being; or
- the use of somatic cell nuclear transfer with the intent of producing an embryo with no intention of implanting that embryo into a woman’s uterus or seeking the production of a whole human being; or
- both of the above: SCLCA report, para 6.7.


6 For example, “therapeutic cloning” might describe:
- somatic cell nuclear transfer with stem cells being derived from the blastocyst formed by this procedure;
- embryonic stem cell therapies, resulting from cells derived from an embryo, for example a surplus embryo from IVF procedures; and
- adult stem cell therapies where an embryo stage is not involved: SCLCA, para 3.21.

The second is the isolation and characterisation of human embryonic stem cells, first reported in 1998 (discussed in section 3.2).

3.1 SOMATIC CELL NUCLEAR TRANSFER

The application of the cloning technique of somatic cell nuclear transfer in a laboratory setting dates back to 1938 when a German scientist cloned a salamander embryo. In 1996, scientists at the Roslin Institute in Scotland cloned a sheep, named “Dolly”, from a frozen mammary (udder) cell from an adult ewe. Dolly was born after a normal pregnancy, subsequently living an apparently normal life and producing lambs. Dolly was the only survivor of 277 cell fusions. A number of these procedures resulted in abnormal placentas and foetuses and other complications in pregnancy or at birth. Similar failure rates and abnormalities are apparent in attempts at cloning other animals.

The Dolly experiment proved that an adult cell could, under certain circumstances, become capable of producing all cell types, form an embryo and develop into a whole individual. It also raised the possibility that human reproductive cloning was achievable.

In late November 2001, scientists at Advanced Cell Technology, a privately owned biotechnology company in the United States of America, reported cloning a human embryo that developed to the six cell stage. The stated aim of the experiment was to yield a special class of cells - embryonic stem cells - from inner cell mass of the cloned embryos. Although none of the cloned embryos progressed to the requisite stage, the


9 I Wilmut, AE Schnieke, J Mcwhir, AJ Kind and KHS Campbell, ‘Viable offspring derived from fetal and adult mammalian cells’, Nature, Vol 385, 27 February 1997, pp 810-813. In the Dolly experiment, a cell from the mammary gland of an adult sheep was fused by means of an electric pulse with an unfertilised enucleated (nucleus removed) egg from a second sheep. The resulting fused cells developed into an embryo that after transfer into the uterus of a third sheep developed into a whole individual (“Dolly”).

10 AHEC, p 2.

11 JB Cibelli, RP Lanza, MD West and C Ezzell, e-biomed: The Journal of Reproductive Medicine, 2(25) November 2001, pp 25-31. The scientists also reported producing a human embryo by the process of parthogenesis in which an egg is induced to divide into an embryo without being fertilised by a sperm.

12 An embryonic stem cell is derived from a group of cells called the inner cell mass, which is part of the early (4-5 day) embryo called the blastocyst. A blastocyst is formed at about the 100 cell
scientists claim the results represent an important step towards the goal of therapeutic cloning. Some members of the scientific community, however, have questioned the likely significance of these experimental results because the failure to develop an embryo of sufficient maturity to yield stem cells might indicate that human therapeutic cloning could be much harder to achieve than is suggested by studies on animal models. A diagrammatic representation of how the human embryo was cloned, in addition to an article “The First Human Cloned Embryo” authored by the scientists who produced the clone, are attached as Appendix A.

3.2 STEM CELLS

The second major scientific advance to influence the development of cloning technologies is the isolation and development of human embryonic stem (ES) cells.

A stem cell is a special type of cell that has the capacity to renew itself and to give rise to specialised cell types. Although most cells of the body, such as heart cells or skin cells, are committed to conduct a specific function, a stem cell is uncommitted and remains uncommitted, until it receives a signal to develop into a specialised cell.

Embryonic stem cells, which come from the inner cell mass of an early stage human embryo, have the potential to develop into all or nearly all of the tissues in the body. The scientific term for this characteristic is “pluripotentiality”. These cells can be used to produce cell lines and tissues with the aim of treating disease or perhaps growing organs for transplantation.

An adult stem cell is an undifferentiated (unspecialised) stem cell that occurs in differentiated (specialised) tissue, renews itself and becomes specialised to yield all of the specialised cell types of the tissue from which it originated. Sources of adult stem cells

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14 Embryonic stem cells derive from the inner cell mass of a blastocyst, an early developmental stage of an embryo.


16 A large number of cells grown in a laboratory from a single cell or cells of the same type.
include bone marrow, blood, the cornea and the retina of the eye, brain, skeletal muscle, liver, skin, gastrointestinal tract lining and pancreas. Adult stem cells remain present in the body throughout life and are responsible for normal repair and replacement of tissues and organs.

Although adult stem cells are thought to have less flexibility than embryonic stem cells, evidence suggests that some adult stem cells are capable of being reprogrammed to generate specialised cells that are characteristic of different tissue. Adult stem cell research is at an early stage but is progressing rapidly. The successful identification and multiplication of adult stem cells could allow the development of stem cells therapies that do not use embryos as a stem cell source.\(^\text{17}\)

Appendix B provides a diagrammatic comparison of embryonic and adult stem cells and the process of somatic cell nuclear transfer, in addition to their relevant applications.

4 POSSIBLE APPLICATIONS OF HUMAN CLONING AND ETHICAL CONSIDERATIONS

In 1998, the Australian Health Ethics Committee of the National Health and Medical Research Council\(^\text{18}\) listed possible objectives of cloning technologies that are based on production of human embryos:

- To investigate and understand human biology and pathology;
- To assist in reproductive technology programs by:
  - enabling a couple to have a child genetically related to one or both of them;
  - enabling a couple to avoid passing on a disease arising from mitochondrial genes;
  - increasing the number of embryos available for implantation; or
  - enabling the individual or couple to avoid the ‘infertility’ imposed by normal biology (for example, in the case of single people or same sex couples);
- To produce transplantable organs and tissues (produced from embryonal stem cell lines). The possible applications of cloning in this context could be the provision of donor organs for the use of transplant recipients and the elimination of donor organ

\(^{17}\) NIH, Executive Summary, p 2.

\(^{18}\) The Australian Health Ethics Committee (AHEC) is a principal committee of the National Health and Medical Research Council (NHMRC), 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.
rejection with the use of donor organs genetically identical to the transplant recipient;
- To produce valuable proteins and pharmaceuticals; and
- To produce an identical copy of an existing or deceased human being.\(^{19}\)

The potential application of cloning techniques for reproductive or therapeutic purposes has generated vigorous worldwide religious and ethical debate amongst scientists, ethicists, theologians, government entities and the community.

Human cloning raises profound religious concerns.\(^{20}\) The fundamental question comes down to, in the words of US President George W Bush, *'are these frozen embryos human life, and therefore, something precious to be protected?’*\(^{21}\)

There is also great diversity of opinion over the ethical considerations posed by the possibility of human cloning. (While ethical considerations may be seen as secular arguments, many of them parallel religious viewpoints.) The following ethical concerns have been raised:\(^{22}\)
- possible physical harm to the embryo;
- possible psychological harm to the child—through a diminished sense of individuality and personal autonomy;
- possible degradation of parenting and family life—for example, cloning might encourage parents to value their children according to how well they meet expectations, instead of loving them for their own sake;

\(^{19}\) AHEC, pp 24-27.

\(^{20}\) However, even within particular religious traditions—Roman Catholic, Protestant, Jewish, Islamic—there is no consensus on the morality of human cloning: see the University of Virginia’s webpage, *Human Cloning: The Religious and Ethical Debate*, at [http://www.cs.virginia.edu](http://www.cs.virginia.edu) pp 1-10, downloaded 1 December 2001.

\(^{21}\) US. White House. *‘Radio address by the President to the nation’ [on embryonic stem cell research]*, *Media Release*, 11 August 2001, available at [http://www.whitehouse.gov/news/releases](http://www.whitehouse.gov/news/releases). The US President’s address is a good summary of the ethical issues surrounding embryonic stem cell research.

The House of Commons Library 2000 Research Paper on stem cell research succinctly states the range of ethical issues involved in the use of embryos in research:

*The use of embryos in research is controversial. There is a wide spectrum of opinion on this issue. Those who believe that the use of human embryos is unethical on the grounds that a fertilised egg from the moment of conception is entitled to full human status, argue that the early embryo has a right to life and a right not to be used as a means to an end. At the other end are those who believe that an early embryo is a collection of cells with no greater rights than any other collection of human cells. There are also those who consider that although the status and dignity of early embryos should be respected, it is reasonable to weigh this against the benefits of allowing research on such early embryos to proceed.*

5 **KEY REPORTS ON HUMAN CLONING**

The birth of Dolly and other scientific advances in cloning technologies precipitated a number of inquiries in Australia and around the world about the benefits of such scientific advances and also the ethical and regulatory implications they raised.

5.1 **AUSTRALIA**

5.1.1 **The 1998 Australian Health Ethics Committee (AHEC) report**

In early 1998, the then Commonwealth Minister for Health and Aged Care, the Hon Dr Michael Wooldridge, MP, sought advice from the Australian Health Ethics Committee (AHEC) on the “potential and need for further pronouncement or possible

In its report, the AHEC found 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). The AHEC noted the “consensus is that it is unacceptable to undertake any procedure with the aim of cloning a human being”.25 The AHEC also noted that legislation in three Australian states, as well as ethical guidelines across Australia, prohibited the cloning of individual humans.

The AHEC made 4 recommendations to the Minister:

- The Commonwealth Government should reaffirm its support for the UNESCO Declaration on the Human Genome and Human Rights, particularly Article 11 which states: “practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted ...” (Recommendation 1);26
- 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’s Ethical Guidelines on Assisted Reproductive Technology (Recommendation 2) (see section 6.1.1);
- 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). The AHEC was critical of the states that had not introduced regulation, despite earlier urging;

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25 AHEC, p 1.

• 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).

5.1.2 The 2001 House of Representatives Standing Committee on Legal and Constitutional Affairs (SCLCA) report

In August 1999, the then Minister for Health and Aged Care, the Hon Dr Michael Wooldridge, MP, asked the Australian House of Representatives Standing Committee on Legal and Constitutional Affairs (“the Committee” or “the SCLCA”) to review the report of the AHEC on human cloning. The Committee published its report entitled Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research in August 2001.

The Committee noted that almost all people and organisations that submitted to it opposed the use of cloning techniques for the reproductive purposes.

While Committee members acknowledged the potential benefits of human cloning, they differed in their views about using stem cells, depending on the source of the material. The majority of the Committee believed that it should be permissible for surplus embryos from assisted reproductive technology programs to be used in clearly defined, limited circumstances. However, other members believed that procedures that involve the destruction of embryos are unethical and should be rejected.

The Committee unanimously supported the use of adult stem cells in research. The Committee considered that using adult stem cells was advantageous because of their potential to provide the key to future advances in medicine without the ethical problems associated with embryonic stem cells.

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27 AHEC, p 43.


29 SCLCA report, para 7.103.

30 SCLCA report, para 12.2.

31 SCLCA report, para 7.104.
The Committee concluded that there should be a national legislative ban on cloning for reproductive purposes but endorsed continued research involving adult and placental stem cells.\textsuperscript{32}

The Committee made a series of 16 recommendations about the proposed regulation of human cloning in Australia. These recommendations are listed in Appendix C. The prime recommendation of the Committee was that the Commonwealth should enact legislation regulating all human cloning and stem cell research. Specifically, the Committee recommended that the legislation should ban cloning for reproductive purposes and contain attendant criminal and licence sanctions. The Committee also recommended the establishment of a national licensing body to regulate any research involving the isolation, creation and use of embryonic stem cells and that AHEC should monitor scientific developments in this area.

5.2 **INTERNATIONAL REPORTS**

The report of the Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*, provides a summary of the background of inquiries conducted by Parliamentary Select Committees and expert advisory groups in the United Kingdom and the National Bioethics Advisory Commission in the United States of America. The summary is reproduced as Appendix D.

6 **KEY POSITION STATEMENTS AND ETHICAL GUIDELINES RELATING TO THE USE OF CLONING TECHNOLOGIES RELEVANT TO HUMANS**

A number of eminent Australian and international bodies have produced policies and guidelines that represent human reproductive cloning as an “unacceptable” practice. Some of the key policies and guidelines published about the use of human reproductive cloning are summarised in this section.

\textsuperscript{32} SCLCA report, para 7.103.
6.1 AUSTRALIA

6.1.1 The National Health and Medical Research Council

The NHMRC is authorised under the *National Health and Medical Research Council Act 1992* (Cth) to issue guidelines for the conduct of health research and other purposes related to health. These guidelines are regarded as national standards of acceptable practice – although they are enforceable only in respect of institutions funded by the NHMRC (see also section 10 of this paper). In 1996, the NHMRC published a set of guidelines on assisted reproductive technology, *Ethical Guidelines on Assisted Reproductive Technology*. Guidelines 6 and 11 relate to research and experimentation on human embryos. Under the guidelines, a number of practices are characterised as unacceptable and are prohibited. Specifically, Guideline 11.3 prohibits experimentation with the intent to produce two or more genetically identical individuals, including the development of human embryonic cell lines with the aim of producing a clone of individuals.

6.1.2 The Australian Academy of Science

The Council of the Australian Academy of Science issued a *Position Statement on Human Cloning* in February 1999. The Council recommended that reproductive cloning, which it considered unethical and unsafe, should be prohibited. The Council, however, maintained that the use of human cells should not be precluded from use in approved medical and scientific research activities. The Council stated that:

*If Australia is to capitalise on its undoubted strength in medical research, it is important that research on human therapeutic cloning is not inhibited by withholding federal research funds or prevented by unduly restrictive legislation ....*


6.1.3 The Australian Medical Association

The Australian Medical Association (AMA) is the peak representative body for medical doctors in Australia. The AMA formulates relevant policies and ethical guidelines relating to issues of concern to the medical profession.

Clause 6 of the *Position Statement on Human Genetic Issues – 1998* of the AMA states:

6. Cloning

6.1 The cloning of human beings should be prohibited.

6.2 With approval by an institutional ethics committee, human genetic tissue can be used for processes involving cloning techniques.

In November 1999, the AMA reiterated its prohibitive position on human cloning in its submission to the House of Representatives Standing Committee on Legal and Constitutional Affairs in response to its inquiry on human cloning. The AMA supported the general principles of the Recommendations and Resolutions of the AHEC, in its report, *Scientific, Ethical and Regulatory Considerations Relevant to the Cloning of Human Beings*. The AMA also recommended that there should be a nationally consistent system of legislation or regulation in relation to cloning with a mechanism for periodic review.35

6.1.4 The Fertility Society of Australia

The Fertility Society of Australia (FSA) is the peak body representing scientists, doctors, researchers, nurses, consumer groups, patients and counsellors in reproductive medicine in Australia and New Zealand. The FSA promotes guidelines that apply to accredited member clinics that treat patients with ovulation induction, artificial insemination, IVF and related techniques such as gamete intrafallopian transfer (GIFT) and all procedures involving donated gametes or embryos (assisted reproductive technology centres).

FSA Guideline 7.4 provides, in part, that it is unacceptable to:

- clone a human embryo in an attempt to produce babies, and

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• keep or use an embryo after a specified developmental stage.36

6.1.5 The Code of Ethics for Biotechnology in Queensland

In June 2001, the Queensland Government released the *Code of Ethical Practice for Biotechnology*37 to complement its legislative initiatives in the biotechnology area. The Code, which became effective on 1 September 2001, sets out a number of ethical principles to guide biotechnology research and development in all major sectors of the biotechnology industry in Queensland. It contributes to the framework of non-legislative regulation of human cloning in Queensland (see section 10) and applies as an adjunct to any relevant Queensland or Commonwealth legislation.

The Code specifically prohibits the cloning of or attempted cloning of whole human beings - human reproductive cloning – but allows the “therapeutic” cloning of genes and cells for tissue regeneration.

6.2 INTERNATIONAL

6.2.1 United Nations Educational, Scientific and Cultural Organisation (UNESCO)

Article 11 of the UNESCO *Declaration on the Human Genome and Human Rights* states:38

> Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to cooperate in identifying such practices and in taking, at national or international level, the measures to ensure that the principles set out in this Declaration are respected.


6.2.2 World Health Organisation (WHO)

In May 1997, the Fiftieth World Health Assembly adopted a resolution affirming that the use of cloning for the replication of human beings is ethically unacceptable and contrary to human integrity and morality.\(^{39}\)

7 DEVELOPMENTS LEADING TO AN AGREED LEGISLATIVE BAN IN AUSTRALIA OF HUMAN REPRODUCTIVE CLONING

In July 2000,\(^{40}\) Australian Health Ministers, at a meeting in Wellington, New Zealand, agreed to develop complementary legislation across the states and territories to ban human cloning for reproductive purposes, while effectively leaving open “broader issues relating to human and therapeutic cloning”.\(^{41}\) The health ministers agreed to ongoing consultation between the jurisdictions, facilitated by the NHMRC, to establish state and territory regulatory frameworks.\(^{42}\) At the time, Associate Professor Loane Skene of the University of Melbourne Faculty of Law was reported as commenting that it was “significant that ministers had made a distinction between reproductive and therapeutic cloning, and recognised the medical potential of the latter approach”.\(^{43}\)

In June 2001, the Council of Australian Governments (COAG) agreed to a proposal by the Prime Minister to put in place nationally consistent legislation to prohibit human cloning. The Communique of the 8 June 2001 meeting clarified that:\(^{44}\)

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40 The Federal Health Minister had earlier given an assurance (in January 1998) that the Commonwealth Government “would pursue ways of trying to ensure human cloning did not take place in Australia” and that “no public funds would be used for any type of research involving the cloning of human beings”: Dr Michael Wooldridge, Minister for Health, ‘Federal Government against human cloning’, Media Release, 14 January 1998.


42 Ibid.


44 COAG, Communique, COAG meeting, 8 June 2001, Canberra, p 6.
The definition of human cloning will take account of the Australian Health Ethics Committee’s advice that a distinction must be drawn between the cloning of human beings, which is ethically unacceptable (and legally prohibited in three States), and the cloning of such parts as DNA or cells which has brought benefits to both science and medicine.

COAG stated that it had 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 in all jurisdictions by June 2002”.

In August 2001, the House of Representatives Standing Committee on Legal and Constitutional Affairs released its human cloning report (referred to above). The SCLCA expressed concern at the delay that had occurred in implementing the June 2000 agreement of Australian Health Ministers, and urged the Commonwealth to take the lead in relation to the issue. The committee continued in its report to make the recommendations concerning Commonwealth legislation regulating human cloning and stem cell research that are set out in Appendix C of this report.

8 THE CURRENT BILL

The Explanatory Notes to the Cloning of Humans (Prohibition) Bill 2001 (Qld) state that the Bill “implements” the Australian Health Ministers and COAG agreements to pursue a (nationally consistent) ban on human reproductive cloning.

During the Minister’s Second Reading Speech to the Bill, the Minister said:

The Bill does not prohibit stem cell research or so-called therapeutic cloning, … which may result in new treatments for serious diseases. These issues are complex, and need further, careful consideration. In June, COAG agreed to work toward consistent approaches to emerging human technologies in each State and Territory.

The current Queensland Bill prohibits human reproductive cloning and the gestation of human embryo clones by creating two primary offences:

- A prohibition on the creation or attempted creation of a human clone with the use of a technological or other artificial process (cl 3), and

45 Ibid.
47 Explanatory Notes to the Bill, p 2.
48 Second Reading Speech, p 1.
• A prohibition on the placement of a human embryo clone anywhere in a human or animal for any period of gestation (cl 4).

The **Schedule** provides a dictionary of words used in the Bill. A *human clone* is a human that is a genetic copy of another living or dead human. A *human* does not include a human embryo.\(^49\) A *human embryo clone* is a human embryo that is a genetic copy of a living or dead human.

As the definition of “human” is defined to preclude a human embryo, it would appear that cl 3 only restricts the creation of a genetically copied human being. However, because cl 3 also makes it an offence to *attempt* to create a human clone, the offence might be applicable to the creation of an embryo in circumstances where there was evidence of an intention for the process to result in human reproductive cloning.

A maximum penalty of 4000 penalty units ($300 000 or $1.5 million in the case of a corporation) or 10 years imprisonment applies in the case of each offence.

**Clauses 5 and 6** of the Bill are evidentiary provisions that relate to some of the technological aspects of cloning technologies.

**Clause 5** provides that, to prove in a proceeding for an offence against the proposed Act that a human or human embryo is a genetic copy, it is enough to prove that the set of genes in the human cell nucleus have been copied. It is not necessary to prove that the copy is an identical copy. **Clause 5** takes into account the possibility that a cloning technique, such as somatic cell nuclear transfer, may produce a human clone or human embryo clone which contains genetic material that is not exactly identical to the original from which it was copied. It is therefore sufficient that the genes found in the nucleus of the original person's cells have been copied to create the offspring.\(^50\)

**Clause 6** provides that for a proceeding brought under the Act, it is immaterial whether the human clone or human embryo clone did not or could not survive.

The commission of an offence against the proposed Act is a crime for which an offender may be arrested on a warrant (cl 7). An individual or a corporation may be responsible for the acts or omissions of a representative if the representative acted within the scope of his or her authority and had the requisite state of mind. It is a defence for the individual or corporation to show that they could not by the exercise of reasonable diligence have prevented the act or omission (cl 8, Schedule, definitions of “representative”, “state of mind”). **Clause 9** places an obligation on the executive officers of a corporation to

\(^{49}\) The term “embryo” is not defined in the Bill.

\(^{50}\) Explanatory Notes, Cloning of Humans (Prohibition) Bill 2001 (Qld), p 2.
ensure that the corporation complies with the legislation and creates an offence on the part of each executive officer where the corporation has committed an offence against the proposed Act. It is a defence for the executive officer to show he or she exercised reasonable diligence to ensure compliance or was not in a position to influence the relevant conduct of the corporation.

The provisions of the Queensland Bill are discussed further in the next section, where it is compared with a similar recent NSW Bill, and in section 9.3, where various Australian and overseas legislative bans on “cloning” are compared.

8.1 COMPARISON WITH THE NSW BILL

The current Queensland Bill is very similar to a recently introduced NSW Bill, the Human Reproductive Cloning and Trans-Species Fertilisation Bill 2001 (NSW). The bans in cls 3 and 4 of the Queensland Bill are worded in similar terms as the NSW Bill, and the two Bills define “human clone” and “human embryo clone” in a similar manner.

Clauses 5 (Proving that a human embryo is a genetic copy) and 6 (Survival of clone or embryo immaterial) of the Queensland Bill also have equivalents in the NSW Bill.

However, the NSW Bill (cls 6 & 7) goes further in what it purports to ban, by creating offences of:

- creating, or attempting to create, by a fertilisation process, a hybrid embryo (defined as an embryo that is a hybrid of the human species and another animal species); and
- placing a hybrid embryo created by a fertilisation process in the body of a human or animal for any period of gestation.

9 AUSTRALIAN LEGISLATIVE CLONING PROHIBITIONS

Victoria, Western Australia and South Australia have legislative bans on human cloning (pre-dating the COAG 8 June 2001 call for nationally consistent legislation). Most

51 The Human Reproductive Cloning and Trans-Species Fertilisation Bill 2001 (NSW) was introduced into the NSW Legislative Assembly on 21 September 2001. As at 3 December 2001, it has not been passed by the NSW Parliament. That Bill followed the introduction of a Private Member’s Bill, the Human Cloning and Embryo Reproduction Experimentation Bill 2000, introduced into the NSW Legislative Council by Revd Mr Fred Nile a year earlier, on 29 August 2000.
recently, the Commonwealth—to the extent of its constitutional powers—enacted a prohibition on (reproductive) human cloning.

To assist comparison with the wording of the proposed Queensland prohibition, section 9.1 reproduces the human cloning bans contained in other Australian legislation and section 9.2 reproduces the human cloning bans in proposed UK and US legislation. Section 9.3 compares the various legislative definitions of cloning, in terms of whether the associated prohibitions are directed towards “therapeutic” or “reproductive” human cloning.

9.1 EXISTING AUSTRALIAN LEGISLATIVE BANS OF HUMAN CLONING

The existing Australian legislative prohibitions of human cloning are as follows.

Victoria (Infertility Treatment Act 1995 (Vic), ss 3, 47):

47. Ban on cloning

A person must not carry out or attempt to carry out cloning.

3. Definitions

…

“clone” means to form, outside the human body, a human embryo that is genetically identical to another human embryo or person;

Western Australia (Human Reproductive Technology Act 1991 (WA), ss 3,7(1)(d)(i)):

7. Offences relating to reproductive technology

(1) A person, whether or not a licensee, who causes or permits:

…

(d) any procedure to be carried out directed at:

(i) human cloning

… commits an offence.

3. Interpretation and application

…

"cloning" means the use of reproductive technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical, live born and viable;\(^{52}\)

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\(^{52}\) It is also an offence under the Human Reproductive Technology Act 1991 (WA) to cause or permit a nucleus of a cell of an egg in the process of fertilisation or any embryo to be replaced (s
South Australia (Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 (SA), regs 2, 6): 53

6. Prohibition on cloning

A licensee must not carry out, or cause, suffer or permit to be carried out, the procedure of cloning.

2. Interpretation

"cloning" means any procedure directed at producing two or more genetically identical embryos from the division of one embryo;

(The South Australian Council on Reproductive Technology established a cloning working party to revisit the South Australian definition of cloning in light of scientific advances. While the South Australian legislative definition remains as above, the working party’s definition is: 54

“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.”)

Commonwealth (Gene Technology Act 2000 (Cth), s 192B):

192B Cloning of human beings is prohibited

(1) A person is guilty of an offence if:

(a) the person engages in conduct; and

(b) the person knows that, or is reckless as to whether, the conduct will result in the cloning of a whole human being.

(2) In this section:

Cloning of a whole human being means the use of technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical to the original. 55

7(1)(e)) or to cause or permit the genetic structure of any cell to be altered while the cell forms part of an egg in the process of fertilisation or any embryo (s 7(1)(f)).

53 Made under the Reproductive Technology Act 1988 (SA).

54 South Australian Council on Reproductive Technology, submission 273 to the SCLCA, February 2000, p 2.

55 It is also an offence under the Gene Technology Act 2000 (Cth) to put human cells into animal eggs (s 192C) or put a combination of human cells and animal cells into a human uterus (s 192D).
The s 192B ban on human cloning was inserted into the Commonwealth Gene Technology Bill by the Commonwealth Government late during the passage of the Bill in the Senate. When the amendments were made the Commonwealth Government clarified that:56

- the prohibition on human cloning is included as a “stop-gap” measure until all States and Territories have nationally consistent legislation in place to comprehensively ban the cloning of human beings. On 8 June 2001, the Council of Australian Governments agreed to aim to have this legislation in place by June 2002;

- the National Health and Medical Research Council (NHMRC) will work with States and Territories to develop such legislation;

- such legislation will embrace the recommendations of the NHMRC's Ethical Guidelines on Assisted Reproductive Technology, which state as unacceptable any “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”; and

- once States and Territories have legislation in place banning human cloning, the prohibition in the GT Act will be repealed.

Otherwise, the general regulatory scheme in the Gene Technology Act 2000 (Cth) does not cover the cloning of humans, animals or plants, since cloning does not involve the modification of genes or other genetic material but instead involves the replication or duplication of genetic material.57

In terms of positioning, the House of Representatives Standing Committee on Legal and Constitutional Affairs said it considered it “both inappropriate and inadequate” to include provisions concerning human cloning in the then recently introduced Commonwealth Gene Technology Act 2000.58 The Senate Community Affairs References Committee, during its Inquiry into the Gene Technology Bill 2000, had similarly commented (before the human cloning bans were inserted into the Bill in the Senate) that it agreed with the views of the Queensland Government, which had


58 SCLCA report, para 12.34.
submitted to it that “human cloning raises complex and sensitive issues which are probably best dealt with in separate legislation”.  

The s 192B ban on human cloning in the Commonwealth Act will only apply to the extent of the specific constitutional powers relied on to introduce the Act. The Act applies to corporations, to things done in the course of trade and commerce, to things done that may cause the spread of disease or pests, for statistical purposes and actions by Commonwealth or Constitutional authorities (s 13 of the Commonwealth Act).

There are also issues in relation to the effect of the Commonwealth provision on state legislation. Section 109 of the Commonwealth Constitution states that a Commonwealth law on a particular subject will prevail over a state law on the same subject to the extent of the inconsistency. This is an issue despite the fact that the Commonwealth Act does not purport to apply in all areas and does explicitly permit the concurrent operation of some state laws.

9.1.1 Other Australian jurisdictions

Tasmania, the Northern Territory and the Australian Capital Territory have not yet introduced Bills seeking to ban human cloning.

New South Wales recently introduced the Human Reproductive Cloning and Trans-Species Fertilisation Bill 2001 (NSW)—described in section 8.1 of this paper—which would ban the creation or attempted creation of a “human clone” (in terms similar to the Queensland Bill).

The non-legislative regulatory framework that applies to those jurisdictions (and to Queensland) is described below in section 10.


60 Indeed, when the Federal Health Minister had initially contemplated a national ban of human cloning, the Minister said: “The Commonwealth does not have complete power to legislate on human cloning – it’s a matter for the States and Territories”: Dr Michael Wooldridge, Minister for Health, ‘Federal Government against human cloning’, Media Release, 14 January 1998. The House of Representatives Standing Committee on Legal and Constitutional Affairs later considered that the Commonwealth does have legislative power to regulate most aspects of research involving the use of cloning technologies”: SCLCA report, para 11.46.

9.2 **INTERNATIONAL BANS**

Almost every Western nation has introduced or is in the process of introducing legislation against the possibility of human reproductive cloning.\(^62\) This section will outline proposed UK and US legislation.

Very recently, on 26 November 2001, the Human Reproductive Cloning Bill was introduced into the House of Commons, having been initially introduced in the House of Lords.\(^63\) Clause 1(1) of the UK Bill provides that:

*A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence.*

None of those words or phrases is further defined in the Bill.

On 31 July 2001, the US House of Representatives passed the Human Cloning Prohibition Act 2001 (Bill HR 2505; sponsored by Reps Dave Weldon, Republican-Florida, and Bart Stupak, Democrat-Michigan). HR 2505 seeks to prohibit human cloning by somatic cell nuclear transfer for any purpose, reproductive or therapeutic. On the same day, the House rejected an amendment introduced by Rep James Greenwood, Republican-Pennsylvania, that would have allowed therapeutic cloning. The US Administration put its support behind HR 2505, stating that the Administration was “unequivocally opposed to the cloning of human beings either for reproduction or for research”\(^64\). HR 2505 has now been referred to the US Senate, which has not yet considered it.

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\(^63\) The Explanatory Notes to the Bill describe the background to the Bill in the following manner: “This Bill fulfils the Government’s commitment to bring in legislation to put the ban on human reproductive cloning onto a statutory footing. It is brought forward following the judgement of the High Court on 15th November 2001. This held that embryos created by cell nuclear replacement were not governed by the Human Fertilisation and Embryology Act 1990. As a consequence the Human Fertilisation and Embryology Authority could not implement a ban on reproductive cloning by refusing to licence any application for this purpose.”

HR 2505 seeks to make it an offence to perform, attempt to perform or participate in an attempt to perform human cloning, or to transport or import an embryo produced by human cloning. The Bill provides the following definitions:

The term “human cloning” means human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism (at any stage of development) that is genetically virtually identical to an existing or previously existing human organism.

The term “asexual reproduction” means reproduction not initiated by the union of oocyte and sperm.

The term “somatic cell” means a diploid cell (having a complete set of chromosomes) obtained or derived from a living or deceased human body at any stage of development.

9.3 THE LEGISLATIVE BANS OF “CLONING” COMPARED

In its report, the AHEC noted that: “The importance of clearly defining this term [“cloning”] will be of great importance in ensuring adequate regulation of this area of science”.66 There is no clear, consistent definition of “cloning” in the Australian or overseas legislation outlined above.

The Victorian prohibition would apply to the cloning of (genetically identical) embryos regardless of proposed use, that is, whether the use was “therapeutic” or “reproductive”.67 The existing South Australian legislation also focuses on the formation of (genetically identical) embryos rather than the attempt to replicate a person.

The Western Australian definition focuses on the use of technology for the purpose of producing duplicates or descendants that are “genetically identical, live born and viable”; it is directed toward “reproductive” cloning.68 The Commonwealth definition of

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65 While the Bill seeks to ban human reproductive and therapeutic cloning, it also states that it does not affect “research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than embryos, tissues, organs, plants, or animals other than humans”.

66 AHEC report, para 4.3.

67 SCLCA report, para 8.25.

68 SCLCA report, para 8.26. However, the Western Australian legislation does include provisions that further regulate the creation of embryos.
human cloning is similar to that of Western Australia in focusing on the use of technology for the purpose of producing (genetically identical) duplicates or descendants; it also appears directed toward “reproductive” cloning. 69

The prohibitions in the current Queensland Bill (like the similarly worded NSW Bill) are directed toward the production of a genetically copied human (cl 3) or gestation (cl 4). However as noted earlier, because cl 3 also covers attempts at the production of a genetically copied human, it might in certain circumstances cover the production of a genetically copied embryo, where there is evidence that the embryo was created with the intention of reproductive cloning.

(The Queensland prohibition bypasses the concept—present in other Australian legislation—of the product being genetically “identical”, which has been identified as problematic: the science of cloning does not necessarily mean the cloned entity is entirely “identical”. 70)

The recently introduced UK prohibition is directed toward reproductive cloning: it focuses on the placing of a human embryo (that has been created otherwise than by fertilisation) in a woman. The US Bill, if passed in the US Senate, would ban both therapeutic and reproductive human cloning.

10 NON-LEGISLATIVE REGULATION OF HUMAN CLONING

Queensland, NSW, Tasmania, the ACT and the Northern Territory do not currently have legislation specifically regulating human cloning or embryo research. In Queensland 71 and those other states and territories, human cloning and embryo research is regulated by non-legislative means, primarily by:

- National Health and Medical Research Council (NHMRC) guidelines—the Ethical Guidelines on Assisted Reproductive Technology 1996 and the National Statement on Ethical Conduct In Research Involving Humans 1999 (“the National Statement”);
- approval of research by Human Research Ethics Committees, also known as “institutional ethics committees”, under NHMRC guidelines; and

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69 SCLCA report, para 8.32.

70 See SCLCA report, paras 8.33-8.36.

71 In Queensland the Code of Ethical Practice for Biotechnology also applies. That code commits government biotechnology organisations and organisations that subscribe to the code to not undertake human reproductive cloning. See section 6.1.5 of this paper.
• self-regulation, administered by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia under the standards contained in its Code of Practice for Units using Assisted Reproductive Technology.

The human cloning report of the House of Representatives Standing Committee on Legal and Constitutional Affairs (SCLCA) describes the interaction of these various sets of guidelines as “complex” and sets out in detail the current Australian non-legislative regulatory framework. The SCLCA report notes:\(^2^2\)

- the NHMRC requires all institutions or organisations that receive funding from it to establish an institutional ethics committee (IEC) and to subject all research involving humans, whether funded by the NHMRC or not, to IEC review using National Statement guidelines;

- the National Statement covers research involving human tissue samples and human genetic research, and would cover human cloning and related technologies. The National Statement affects the general design of research projects involving humans and the approval process for such research. Each applicable institution and organisation is responsible for developing criteria to classify which of its activities are reviewable by its IEC;

- more specifically, the NHMRC’s Ethical Guidelines on Assisted Reproductive Technology (“the Ethical Guidelines”) covers assisted reproductive technology services and research involving the use of embryos. Guideline 6 (Research on embryos) states:\(^2^3\)

  Research involving early human embryos raises profound moral and ethical concerns. There are differences of opinion amongst Australians regarding the moral status of the human embryo, particularly in its early stages of development. … At the present time these differences cannot be resolved.

- the Ethical Guidelines differentiate between “therapeutic” and “non-therapeutic” research involving embryos. “Therapeutic” in this context means therapeutic in relation to the embryo itself; doing something to it with an intended therapeutic outcome for the embryo. Guideline 6.4 states that “non-therapeutic” research, which involves the destruction of the embryo or leaves the embryo unable to be implanted, should only be approved by an IEC “in exceptional circumstances”.

\(^2^2\) SCLCA report, chapter 9 (paras 9.1-9.50).

The SCLCA report summarises that the Ethical Guidelines prohibit the intentional creation of embryos for research;\(^74\)

- a breach of a standard contained in either the NHMRC’s National Statement or Ethical Guidelines is not an offence; sanctions for infringement may involve loss of NHMRC funding or publication of the infringers’ names in Parliament (or peer pressure in the form of journals refusing to publish associated findings, etc);
- self-regulation in the area of assisted reproductive technology (and embryo research) is administered by the RTAC through its *Code of Practice for Units using Assisted Reproductive Technology*. The code of practice lists as unacceptable activities such as cloning of human embryos in attempts to produce babies and replacing the nucleus of a cell of an embryo with a nucleus taken from the cell of another person, another embryo or foetus.

The SCLCA in its report outlined disadvantages of the current non-legislative regulatory system—guidelines have no legal authority, legal sanctions are absent, compliance is largely voluntary and the courts cannot enforce guidelines. The committee also outlined potential advantages—flexibility in specific circumstances, responsiveness to rapidly changing technology, indirect enforcement and accurate reflection of community and professional values. The SCLCA concluded that the disadvantages outweighed the advantages.\(^75\)

The SCLCA described the system as “*deeply unsatisfactory*” and “*confused, inconsistent and ad hoc. It is hard for the public to understand and it lacks openness and transparency*”.\(^76\) The SCLCA’s recommendations about a new regulatory framework and new legislation, outlined in Appendix C of this report, are designed to overcome those shortcomings.

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\(^74\) SCLCA report, paras 9.16. As the SCLCA notes, this is despite the facts that the guidelines were formulated before somatic cell nuclear transfer cloning was developed and that the guidelines do not refer to artificial embryos. The guidelines contemplate “*embryos*” as embryos created in the course of assisted reproductive technology.

\(^75\) SCLCA report, paras 9.40-9.41.

\(^76\) SCLCA report, paras 9.42 & 9.46.
APPENDIX A

The Australian, 27 November 2001

Embryos in the making

THE EGG DONORS
Twelve women aged between 24 and 32 who had had at least one child. They took hormone injections so that they would ovulate about 10 eggs, rather than one or two. Closing attempts were timed based on their menstrual cycles.

THE CELL DONORS
Cells collect fibroblasts were collected from people of varying ages. The donors were generally healthy or had a disorder such as diabetes or a spinal cord injury (two groups that may benefit from therapeutic cloning). After some unsuccessful attempts with fibroblasts, tiny ovarian cells called cumulus cells were used instead.

THE IMPLANTATION
Fine needles are used to suck the genetic material from a mature egg through a plug in the zona pellucida, the protective layer around the egg.

1. Removed from egg

2. After unsuccessful attempts using fibroblasts, a cumulus cell was taken from the exterior of a donor cell and implanted into the egg

3. The egg with the donor material inside is incubated to prompt it to divide and grow

THE RESULTS
None of the 63 eggs injected with fibroblasts divided in two. Of the eight injected with cumulus cells, two divided to form early embryos of four cells and one reached the six-cell stage.

WHERE TO NEXT
The aim is to coax the embryos to divide into spheres of 100 or so cells, called blastocysts. These spheres contain stem cells, which could be used as the starter stock for growing replacement nerve, muscle and other tissues to treat patients with a variety of diseases.

4. Stem cells

The diseases that may be treated
Sooner
- Diseases of the nervous and cardiovascular systems
- Diabetes
- Autoimmune disorders
- Diseases involving the blood and bone marrow

Later
- Damaged spinal cords
- Brain disorders such as
  - Alzheimer’s disease
  - Strokes
  - Epilepsy
  - Congestive heart failure
- Arrhythmias
- Cardiac tissue scarred by heart attacks

The scientists

Breakthrough: The authors of the report, Michael West, left, Robert Lanza, centre, and Joe Cellici
THE FIRST HUMAN CLONED EMBRYO

Jose B. Ciblli, Robert P. Lanza, Michael D. West, Carol Ezzell

Cloned early-stage human embryos—and human embryos generated only from eggs, in a process called parthenogenesis—now put therapeutic cloning within reach.

They were such tiny dots, yet they held such immense promise. After months of trying, on October 13, 2001, we came into our laboratory at Advanced Cell Technology to see under the microscope what we'd been striving for—little balls of dividing cells not even visible to the naked eye. Insignificant as they appeared, the specks were precious because they were, to our knowledge, the first human embryos produced using the technique of nuclear transplantation, otherwise known as cloning.

With a little luck, we hoped to coax the early embryos to divide into hollow spheres of 100 or so cells called blastocysts. We intended to isolate human stem cells from the blastocysts to serve as the starter stock for growing replacement nerve, muscle and other tissues that might one day be used to treat patients with a variety of diseases. Unfortunately, only one of the embryos progressed to the six-cell stage, at which point it stopped dividing. In a similar experiment, however, we succeeded in prompting human eggs—on their own, with no sperm to fertilize them—to develop parthenogenetically into blastocysts. We believe that together these achievements, the details of which we reported November 25 in the online journal *e-biomed: The Journal of Regenerative Medicine*, represent the dawn of a new age in medicine by demonstrating that the goal of therapeutic cloning is within reach.

Therapeutic cloning—which seeks, for example, to use the genetic material from patients’ own cells to generate pancreatic islets to treat diabetes or nerve cells to repair damaged spinal cords—is distinct from reproductive cloning, which aims to implant a cloned embryo into a woman’s uterus leading to the birth of a cloned baby. We believe that reproductive cloning has potential risks to both mother and fetus that make it unwarranted at this time, and we support a restriction on cloning for reproductive purposes until the safety and ethical issues surrounding it are resolved.

Disturbingly, the proponents of reproductive cloning [see Reproductive Cloning: They Want to Make a Baby] are trying to co-opt the term "therapeutic cloning" by claiming that employing cloning techniques to create a child for a couple who cannot conceive through any other means treats the disorder of infertility. We object to this usage and feel that calling such a procedure "therapeutic" yields only confusion.

What We Did

We launched our attempt to create a cloned human embryo in early 2001. We began by consulting our ethics advisory board, a panel of independent ethicists,
lawyers, fertility specialists and counselors that we had assembled in 1999 to guide the company’s research efforts on an ongoing basis. Under the chairmanship of Ronald M. Green, director of the Ethics Institute at Dartmouth College, the board considered five key issues [see The Ethical Considerations] before recommending that we go ahead.

The next step was to recruit women willing to contribute eggs to be used in the cloning procedure and also collect cells from individuals to be cloned (the donors). The cloning process appears simple, but success depends on many small factors, some of which we do not yet understand. In the basic nuclear transfer technique, scientists use an extremely fine needle to suck the genetic material from a mature egg. They then inject the nucleus of the donor cell (or sometimes a whole cell) into the enucleated egg and incubate it under special conditions that prompt it to divide and grow [see Therapeutic Cloning: How It’s Done].

We found women willing to contribute eggs on an anonymous basis for use in our research by placing advertisements in publications in the Boston area. We accepted women only between the ages of 24 and 32 who had at least one child. Interestingly, our proposal appealed to a different subset of women than those who might otherwise contribute eggs to infertile couples for use in in vitro fertilization. The women who responded to our ads were motivated to give their eggs for research, but many would not have been interested in having their eggs used to generate a child they would never see. (The donors were recruited and the eggs were collected by a team led by Ann A. Kiessling-Cooper of Duncan Holly Biomedical in Somerville, Mass. Kiessling was also part of the deliberations concerning ethical issues related to the egg contributors.)

We asked potential egg contributors to submit to psychological and physical tests, including screening for infectious diseases, to ensure that the women were healthy and that contributing eggs would not adversely affect them. We ended up with 12 women who were good candidates to contribute eggs. In the meantime, we took skin biopsies from several other anonymous individuals to isolate cells called fibroblasts for use in the cloning procedure. Our group of fibroblast donors includes people of varying ages who are generally healthy or who have a disorder such as diabetes or spinal cord injury—the kinds of people likely to benefit from therapeutic cloning.

Our first cloning attempt occurred last July. The timing of each attempt depended on the menstrual cycles of the women who contributed eggs; the donors had to take hormone injections for several days so that they would ovulate 10 or so eggs at once instead of the normal one or two.

We had a glimmer of success in the third cycle of attempts when the nucleus of an injected fibroblast appeared to divide, but it never cleaved to form two distinct cells. So in the next cycle we decided to take the tack used by Teruhiko Wakayama and his colleagues, the scientists who created the first cloned mice in 1998. (Wakayama was then at the University of Hawaii and is
now at Advanced Cell Technology.) Although we injected some of the eggs with nuclei from skin fibroblasts as usual, we injected others with ovarian cells called cumulus cells that usually nurture developing eggs in the ovary and that can be found still clinging to eggs after ovulation. Cumulus cells are so small they can be injected whole. In the end, it took a total of 71 eggs from seven volunteers before we could generate our first cloned early embryo. Of the eight eggs we injected with cumulus cells, two divided to form early embryos of four cells—and one progressed to at least six cells—before growth stopped.

Parthenogenesis

We also sought to determine whether we could induce human eggs to divide into early embryos without being fertilized by a sperm or being enucleated and injected with a donor cell. Although mature eggs and sperm normally have only half the genetic material of a typical body cell, to prevent an embryo from having a double set of genes following conception, eggs halve their genetic complement relatively late in their maturation cycle. If activated before that stage, they still retain a full set of genes.

Stem cells derived from such parthenogenetically activated cells would be unlikely to be rejected after transplantation because they would be very similar to a patient’s own cells and would not produce many molecules that would be unfamiliar to the person’s immune system. (They would not be identical to the individual’s cells because of the gene shuffling that always occurs during the formation of eggs and sperm.) Such cells might also raise fewer moral dilemmas for some people than would stem cells derived from cloned early embryos.

Under one scenario, a woman with heart disease might have her own eggs collected and activated in the laboratory to yield blastocysts. Scientists could then use combinations of growth factors to coax stem cells isolated from the blastocysts to become cardiac muscle cells growing in laboratory dishes that could be implanted back into the woman to patch a diseased area of the heart. Using a similar technique, called androgenesis, to create stem cells to treat a man would be trickier. But it might involve transferring two nuclei from the man’s sperm into a contributed egg that had been stripped of its nucleus.

Researchers have previously reported prompting eggs from mice and rabbits to divide into embryos by exposing them to different chemicals or physical stimuli such as an electrical shock. As early as 1983, Elizabeth J. Robertson, who is now at Harvard University, demonstrated that stem cells isolated from parthenogenetic mouse embryos could form a variety of tissues, including nerve and muscle.

In our parthenogenesis experiments, we exposed 22 eggs to chemicals that changed the concentration of charged atoms called ions inside the cells. After five days of growing in culture dishes, six eggs had developed into what appeared to be blastocysts, but none clearly contained the so-called inner cell mass that yields stem cells.
Why We Did It

We are eager for the day when we will be able to offer therapeutic cloning or cell therapy arising from parthenogenesis to sick patients. Currently our efforts are focused on diseases of the nervous and cardiovascular systems and on diabetes, autoimmune disorders, and diseases involving the blood and bone marrow.

Once we are able to derive nerve cells from cloned embryos, we hope not only to heal damaged spinal cords but to treat brain disorders such as Parkinson’s disease, in which the death of brain cells that make a substance called dopamine leads to uncontrollable tremors and paralysis. Alzheimer’s disease, stroke and epilepsy might also yield to such an approach.

Besides insulin-producing pancreatic islet cells for treating diabetes, stem cells from cloned embryos could also be nudged to become heart muscle cells as therapies for congestive heart failure, arrhythmias and cardiac tissue scarred by heart attacks.

A potentially even more interesting application could involve prompting cloned stem cells to differentiate into cells of the blood and bone marrow. Autoimmune disorders such as multiple sclerosis and rheumatoid arthritis arise when white blood cells of the immune system, which arise from the bone marrow, attack the body’s own tissues. Preliminary studies have shown that cancer patients who also had autoimmune diseases gained relief from autoimmune symptoms after they received bone marrow transplants to replace their own marrow that had been killed by high-dose chemotherapy to treat the cancer. Infusions of blood-forming, or hematopoietic, cloned stem cells might “reboot” the immune systems of people with autoimmune diseases.

But are cloned cells—or those generated through parthenogenesis—normal? Only clinical tests of the cells will show ultimately whether such cells are safe enough for routine use in patients, but our studies of cloned animals have shown that clones are healthy. In the November 30, 2001, issue of Science, we reported on our success to date with cloning cattle. Of 30 cloned cattle, six died shortly after birth, but the rest have had normal results on physical exams, and tests of their immune systems show they do not differ from regular cattle. Two of the cows have even given birth to healthy calves.

The cloning process also appears to reset the “aging clock” in cloned cells, so that the cells appear younger in some ways than the cells from which they were cloned. In 2000 we reported that telomeres—the caps at the ends of chromosomes—from cloned calves are just as long as those from control calves. Telomeres normally shorten or are damaged as an organism ages. Therapeutic cloning may provide “young” cells for an aging population.

A report last July by Rudolf Jaenisch of the Whitehead Institute for Biomedical Research in Cambridge, Mass., and his colleagues gained much attention because it found so-called imprinting defects in cloned mice. Imprinting is a type of stamp placed on many genes in mammals that changes how the genes
are turned on or off depending on whether the genes are inherited from the mother or the father. The imprinting program is generally "reset" during embryonic development.

Although imprinting appears to play an important role in mice, no one yet knows how significant the phenomenon is for humans. In addition, Jaenisch and his co-workers did not study mice cloned from cells taken from the bodies of adults, such as fibroblasts or cumulus cells. Instead they examined mice cloned from embryonic cells, which might be expected to be more variable. Studies showing that imprinting is normal in mice cloned from adult cells are currently in press and should be published in the scientific literature within several months.

Meanwhile we are continuing our therapeutic cloning experiments to generate cloned or parthenogenetically produced human embryos that will yield stem cells. Scientists have only begun to tap this important resource.
APPENDIX B
SUMMARY OF PROCEDURES


Figure 9. Summary of procedures.

The three main lines of research are summarised in this diagram. On the left, embryonic stem cells are recovered from the inner cell mass of surplus embryos from IVF programs, for research including cell therapies. In the centre, embryos are cloned by the somatic cell nuclear transfer technique to provide ‘designer’ stem cells for research aimed at specific patients and diseases. On the right, adult stem cells may be isolated, programmed to grow into particular cell or tissue types, and used in cell therapies.
APPENDIX C


Recommendation 1

The Committee recommends the enactment of legislation by the Commonwealth to regulate human cloning and stem cell research.

Recommendation 2

The Committee recommends that legislation regulating human cloning and stem cell research cover all research in this area, both publicly and privately funded.

Recommendation 3

The Committee recommends that the regulation of research involving the use of cloning technologies should be separate from that governing assisted reproductive technologies.

Recommendation 4

The Committee recommends that the legislation regulating human cloning and stem cell research contain a ban on cloning for reproductive purposes. Any attempt to undertake cloning for reproductive purposes should result in a criminal penalty and the withdrawal of a licence to undertake research in this area for the individual concerned.

Recommendation 5

The Committee recommends that the Commonwealth regulate human cloning and stem cell research within the strict parameters outlined in paragraphs 12.41-12.43.

Recommendation 6

The Committee recommends that a national licensing body be established to regulate any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 7

The Committee recommends that a licence issued by the national licensing body should be required to undertake any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 8

The Committee recommends that the national licensing body have the responsibilities listed in paragraph 12.55.

Recommendation 9
The Committee recommends that the Australian Health Ethics Committee (AHEC) be responsible for monitoring scientific developments in this area, analysing their potential impact and providing advice to Commonwealth, State and Territory governments on these matters.

Recommendation 10

The Committee recommends that individuals and organisations be licensed for each research activity involving the isolation, creation and use of embryonic stem cells they intend to undertake.

Recommendation 11

The Committee recommends that the matters listed in paragraph 12.63 be prohibited. Such a prohibition would mean that the licensing body would not have the authority to issue a licence for research involving any of the items listed in paragraph 12.63.

Recommendation 12

The Committee recommends that research using cloning technologies and involving the use of embryos may only be undertaken pursuant to a licence.

Recommendation 13

The Committee recommends that a licence for research using cloning technologies and involving the use of embryos only be granted if the licensing body is satisfied of the matters listed in paragraph 12.43 and that informed consent has been granted by all relevant persons.

Recommendation 14

The Committee recommends that the licensing body develop detailed guidelines specifying the requirements for informed consent and take into account the matters discussed in paragraphs 12.69-12.77 in developing these guidelines.

Recommendation 15

The Committee recommends that the Government establish an independent review of the institutional ethics committee system in Australia.

Recommendation 16

The Committee recommends that all Commonwealth Departments refer to the licensing body for guidance where a matter arises that involves the use of human reproductive material, embryonic stem cell research or cloning research.
APPENDIX D

INTERNATIONAL DEVELOPMENTS

From a report of the Commonwealth Standing Committee on Legal and Constitutional Affairs on Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research, chapter 1, pp2-4.

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 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. 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.

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.

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.

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

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'. 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 stern 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.*
Like most people, Professor Roger Short has a gut reaction against human cloning. But at a meeting of the Australian Paediatric Society at Ayers Rock, the Melbourne reproductive biologist had an experience that shook him to the core. Short had just given a talk on cloning when he was approached by a woman, a professor from a prestigious American university.

"She said to me, 'May I speak to you for a moment? I have a severely physically handicapped son who is in an institution in the United States. The day after the announcement of the cloning of Dolly the sheep, my son phoned me and said, 'Mummy, please could you get me cloned because then you'd find what a lovely person there is inside this horrible body.' " Short said he was moved to tears.

Few issues raise such hopes and fears as cloning and the related question of stem cell research. As science opens up astonishing new fields of knowledge, the public watches, half-fascinated, half-alarmed, often completely bewildered.

On the one hand, there is the promise of cures for brain and spinal injuries, Alzheimer's and Parkinson's and other hitherto intractable diseases. On the other hand, there is the prospect of cloned human beings, formed by scientists meddling with the very stuff of life.

The issue has mythic proportions, said Meera Verma of BresaGen, an Adelaide-based biotechnology company. It speaks of Prometheus and "the ancient fears of pride and vanity".

But Professor Alan Trounson, the Monash University researcher who was among the first to isolate human stem cells from an embryo, thought that "if you can get someone who has had a serious spinal injury to stand up from a wheelchair or stop their Parkinson's shaking and eat dinner with you, all this will be worthwhile". He warned, however, that many of the new treatments are years away. Treatments that produce skin for burns victims and primitive blood cells for blood disorders should come more quickly but, again, they are not imminent.

But can the excitement of the new research be separated from the alarm it also provokes? Not easily. One difficulty is that an important way to obtain stem cells (the cells that can develop into other cells and be used to treat diseases) is by taking them from embryos. One way to do this is by therapeutic cloning, or the creation of embryos from which to harvest stem cells.
But therapeutic cloning brings its own ethical dilemmas, as we shall see. What's more, while therapeutic cloning has nothing to do with reproductive cloning - one procedure never leaves a petri dish, the other would implant a cloned embryo inside a woman's womb - the two cannot be neatly separated. Developments in therapeutic cloning help the advance of reproductive cloning, enabling rogue scientists such as the Italian, Severino Antinori, to claim they are on the brink of cloning a child.

Australia responds

The Age convened a roundtable forum, inviting a group of scientists, ethicists, academics and business people to discuss these issues. The forum included one politician - Kevin Andrews, the Victorian Liberal MP who since the forum took place has become Australia's Minister for Ageing. Andrews' presence was crucial because the questions The Age wanted to raise were precisely those considered by a House of Representatives bipartisan committee, chaired by Andrews, on human cloning and stem cell research.

The committee's report, which was two years in the writing, got less attention than it deserved (it was published on September 17, six days after the terrorist attacks in America). The committee interviewed 59 witnesses and took 375 submissions. It heard from an array of people: doctors, scientists, priests, UNESCO, Right to Lifers and the Cairns branch of the Women's Electoral Lobby. It heard moving testimony from relatives of people with Alzheimer's and other degenerative diseases, urging the government to do all it could to hasten medical research. It also received so many letters opposing human cloning it took two densely-typed pages at the end of the report to list all the letter writers' names.

Federal, state and territory governments have agreed to produce uniform national regulations on stem cell and cloning research by June next year. In doing so, they are likely to rely heavily on the recommendations of the Andrews report, Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research.

The committee made 16 recommendations that cover the establishment of a national regulatory system for cloning and stem cell research. Only one recommendation was not unanimous - the committee voted six to four in favour of allowing limited use of surplus IVF embryos for the production of stem cells. Andrews was part of the minority, favouring research only on stem cell lines that already existed rather than on new lines taken from embryos. But he acknowledged that "the majority of the committee believed that if you have 60,000 or 70,000 IVF embryos in storage then why shouldn't some of those be used?"

In line with most parliaments in Europe and America, the report recommended a total ban on human, or reproductive, cloning. Andrews said this was the committee's easiest decision. It was also the subject that provoked least dissent at The Age roundtable. The scientists raised the safety issue: the risk of deformities to a cloned child, especially while the technology was developing.
Scientist Peter Mountford added: "As to the expectation that people should have the right to reproduce themselves because they do not have a child, I say that medicine was not developed to provide an answer to all the unfortunate occurrences in life."

Biotechnologist Meera Verma did not necessarily see people's anxiety as being an instinctive unease. The history of agriculture, she observed, was based on manipulating animal genes and people seemed to accept that. And she didn't think it was a fear of debasing the notion of kinship. People are "extremely adaptable in encompassing adoption, extended families and other non-nuclear set-ups".

Rather, she thought people were worried about what might happen if the wrong people gained access to the technology. "We saw last century what totalitarian regimes can do. If you have somebody with the power to control the manufacture of cloning, you start to get the whole eugenics debate."

For Peter Coghlan, a moral philosopher at the Australian Catholic University, the unease is instinctive. What, he asked, would cloning mean for the idea that a child is a gift from God, or just a gift, to be loved unconditionally? "We should be loved into existence," he said. The IVF program, he argued, was popular with the community because it helped people who wanted to love a child into existence.

Cloning, on the other hand, could lead to the production of children "out of ego, out of whim, or just as an assertion of a reproductive right ... Michael Jackson might seek to clone himself simply because he wants to see whether he can have a child who can sing as well as him".

The sole dissenter in the group was Lynn Gillam, an ethicist at Melbourne University. She said that if the safety issues were overcome, she would not oppose human cloning. She wondered whether raising a cloned child would be so different from normal child-rearing.

"If I want a copy of myself, perhaps that is a bad motivation, but maybe I am already trying to do that with the children I have. Maybe I can do just as much damage to children who are only 50 per cent genetically related to me as I can to children who are 100 per cent genetically related to me. All the concerns about parental expectations and how the family will be affected and the parents' motivations for doing it apply to ordinary forms of reproduction as well."

Were the consequences of allowing a few people to clone themselves so bad, Gillam asked, that society should try to stop them? "You can see lots of potential problems, such as the way in which a child might be brought up, but you can also imagine scenarios in which none of that happens and you get a good outcome."

Ethical dilemmas

If the roundtable group mostly agreed that human cloning should be banned, they differed a great deal on the report's proposed three-year moratorium on cloning for therapeutic purposes - that is, where a cloned embryo is produced solely to provide a source of stem cells.
Trounson's evidence to the Andrews committee had helped to persuade it that, because of existing stem cell lines, such cloned embryos were not yet needed in Australia. Still, he supported therapeutic cloning in the longer term. He saw a day when scientists would create a cloned embryo of an ill patient and, when the clone was four to five days old, harvest the embryonic stem cells. Once scientists learnt how to direct embryonic stem cells to grow into the desired tissue type - and this was some time off, Trounson warned - the cells could be used to replace damaged nerve cells in conditions such as Alzheimer's, or replace spinal cells in paraplegics.

Mountford, on the other hand, was disappointed by the government's decision. His company, Stem Cell Sciences, wants to clone human embryos in order to produce stem cells. The scientist thought a ban could rob Australia of a vital competitive advantage in this field. He hinted that his own company could be forced to take its research overseas, perhaps to Britain, where scientists could apply for licences to do therapeutic cloning research.

Mountford gave this example of what therapeutic cloning might do. "Uncle Harry" is told he has early signs of Parkinson’s disease. He goes home to ask whether his wife or other female relatives or friends would donate their eggs (oocytes) through IVF procedures. After the nucleus of one of the eggs is removed, Harry’s DNA, easily extracted from a mouth swab or a drop of blood, is put into the egg to create a cloned embryo. When the embryo is four to five days old, embryonic stem cells are extracted that are a perfect match for the patient.

But then, of course, the embryo is destroyed. In theory that embryo, implanted in a woman’s womb, could become a child. So, again, we come to an old ethical dilemma: when does life begin? To Mountford, therapeutic cloning is merely the reprogramming of cells with the help of a donated egg. "If I had a disease like Alzheimer’s and could use one of my cells to create a stem cell line that would slow down the disease or even cure it in some way, I would have no problem with using that procedure."

But Coghlan would. He saw the creation of embryos to benefit an existing person as the commodifying of life. "The idea that we can turn to our clones to draw on replacement parts of ourselves when we see fit involves a domination of our fellow human beings." It worried him even more than reproductive cloning, which might at least stem from a desire to have and love a child.

Coghlan did not agree that the early embryo was "just a clump of cells". If we accepted that it was nascent human life, then it deserved our "wonder and awe" and profound respect. "But what kind of a respect are you according an embryo if you are deliberately creating it to destroy it?"

What’s more, the same technology - in which the inside of an egg is removed and replaced with DNA from an adult - underpins both therapeutic and reproductive cloning. So if you want to ensure that human cloning is banned, shouldn’t therapeutic cloning be banned too?
Verma acknowledged the dilemma. "The whole therapeutic cloning area is harder for people to deal with because it can be seen as enabling technology (for human cloning)," she said.

The answer, she believed, was a clear ban on human cloning. "If it helps the public confidence to say that we are not allowing humans to be cloned but that we can use some aspects of related technologies to help improve the quality of life for humans, then that is a valid thing to do."

Trounson believed that even if therapeutic cloning was enabling technology, that was not a reason to ban it. "(You) should not criticise research on the basis that one thing is going to result in another," he said.

What’s more, he thought that advances in general cloning technology were less likely to come from therapeutic cloning than from a totally different molecular technique. "The slippery-slope argument is one of the worst ones, in my view, because you cannot predict where research is going."

The Andrews committee had thought hard about the issue. Andrews said the potential benefits of such cloning had persuaded the committee to "leave the door ajar". "I think everybody honestly would say that there is a hell of a lot that can be learnt before we even think of creating embryos. (But) in three or five years' time, if there have been advances, we can have another national discussion about this if need be."

The abortion question

Lynn Gillam saw inconsistencies in the moratorium on therapeutic cloning. "We permit abortion, which causes the death of a foetus, not just an embryo. We have legislation that embryos produced by IVF that are not required have to be destroyed." And finally, Gillam asked how the committee could ban therapeutic cloning while allowing surplus IVF embryos to be made available for stem cell research. "If you think it is wrong to kill embryos, you can make a good philosophical argument to show that it is wrong to use the products of embryos that have been killed by somebody else."

Roger Short agreed. Lamenting the "disgrace" of Australia's high abortion rate, he said it was illogical to give greater moral status to the embryo than to the foetus. "How could you possibly dispose of a foetus on a whim and yet have this enormous protection around a ball of cells? Australia is making a ridiculous stand because we have this staggering abortion rate and yet we are now straining at a gnat."

Short also noted that Britain's Houses of Commons and Lords produced a huge two-thirds vote in favour of such cloning. "It would be a shame to keep scientists in this country running on the spot for three years while the rest of the world runs ahead of us. In three years time we might be saying, 'Whoops! We should've done that three years ago'."

What the public thinks

Whether we like the idea of cloning or not, it is likely to happen one day, said Rosemary Robins of the history and philosophy of science department at Melbourne University.
Robins, whose work looks at public attitudes to science, said she wanted debate on these issues to go beyond questions of risk and benefit. "The public is also concerned about the pace of change," she said. "One of the things that comes up time and again in research that has been done by Biotechnology Australia is that people worry about scientists - not just rogue scientists but also scientists who are steeped in their work, are focused on the issues that interest them, are wanting to move ahead with it, and that it is all going too fast for the regulators or maybe the ethicists to keep up with.

"People remember things. They remember thalidomide, the photos of deformed babies. People often talk about the way the cigarette companies did not tell us about the dangers of smoking. Institutional failure to manage the risks is another way in which people remember how technologies develop."

Robins pointed to the vital importance of language in the debate. "To say 'I'm re-programming one of my cells and I'm then going to use that to cure my Parkinson's disease' does not sound particularly nasty. Whereas, if I say 'I'm making an embryo of myself and then using stems from that embryo, which I'm going to have to kill in the process,' it sounds much more threatening.

"People also respond to the way language is used to describe them. If people are constantly portrayed as misunderstanding, fearful and ignorant of science, then that creates a backlash, in and of itself."

Trounson, however, was optimistic the public would support the new science. The former IVF pioneer cited a poll showing 72 per cent support for making embryonic stem cells from unused or spare embryos that would otherwise be discarded. A majority even backed therapeutic cloning, he said. "If I had started IVF with that sort of support I would have been very pleased." The reason for the support, said Trounson, was that Australia was openly debating the issues.

While different roundtable participants opposed different recommendations of the Andrews report, they all praised its quality. Trounson wanted to see the report's proposals adopted. Mountford described the review as "a benchmark for a whole series of as yet unforseen debates that will go on in Australia".

The discussion concluded with a heartening sense that the politicians had come to a balanced, intelligent view on hard questions. The public could well do the same.

Read the report online at www.aph.gov.au/house/committee/laca.
Additional reporting by Jo Chandler.
MURKY MORALS OF CLONING

Dr Amin Abboud
Australian Doctor
23 November 2001

In February 1997 the pin-up girl of the world’s newspapers was a sheep. It was an historic moment. Scientists at the Roslin Institute in Scotland had cloned a sheep named Dolly from a ewe’s udder. Dolly had no genetic father and was genetically identical to her mother.

Along with a profusion of jokes and cartoons, this major scientific development sparked a fierce debate about the possibility of cloning humans. Within days of the news, the then US President Bill Clinton announced a ban on human cloning and French President Jacques Chirac asked the Group of Seven nations to do the same.

A simple summary of key scientific concepts may aid discussion of the ethics of this difficult area.

The normal reproductive process involves germ cells that contain a haploid nucleus (half the normal nucleus), with either the maternal or paternal genes. At fertilisation a complete genetic code is achieved.

The process that resulted in Dolly is nuclear somatic transfer where the nucleus is removed from a haploid egg and replaced with the diploid nucleus sucked out of a somatic cell. Equipped with the complete genetic tool kit, the egg is now able to develop into a mature organism, even though it has a single genetic "parent". This nucleus can come from an embryo, fetus or adult (as in Dolly).

Another important term in this discussion is stem cells. A stem cell is an undifferentiated cell which is a precursor to several differentiated cell types (muscle, skin, etc). Stem cells may be totipotent, pluripotent, or committed to a particular cell lineage (eg, neural stem cell). The stem cells from embryos are known to be totipotential. Stem cells from adults are either committed or pluripotential. Recent studies have shown an ever greater potential for adult stem cells.

Since Dolly there has been universal condemnation of reproductive cloning and almost every Western nation has introduced or is in the process of introducing legislation against this possibility. In the struggle to find an acceptable compromise between the yuk factor most people have against reproductive cloning and a reluctance by some scientists and corporations to limit potential research, another distinction developed in the debate on this subject -reproductive cloning versus therapeutic cloning.

Reproductive cloning is the production of a human fetus by nuclear replacement, allowing it to develop to birth. Therapeutic cloning is the use of embryos produced by nuclear replacement for scientific and medical application resulting in the destruction of the embryo.
This step led to discussion among ethicists. Is the distinction real or is it just a word game to allow experimentation on embryos while avoiding the public repulsion that comes with any discussion about reproductive cloning?

The use of stem cells from embryos for experimentation has raised exciting possibilities for some scientists. Possible cures for Alzheimer’s and Parkinson’s diseases have been widely reported in the media. To date, little solid evidence has been presented to support these claims and may not be available for the next 10 years. (In the only study done on Parkinson’s patients with embryonic cells the patients got worse.)

While these benefits may be real the ethics of embryo destruction for stem cell harvesting has generated significant controversy.

In its recent report, an Australian House of Representatives Committee on Human Cloning advised that a ban be introduced on reproductive cloning, that a three-year moratorium be placed on therapeutic cloning and that research be allowed under strict guidelines on excess embryos from IVF of which an estimated 62,000 exist in Australia.

The committee’s recommendation (it was a majority decision of five members to four) of using the excess embryos was not based on any ethical consideration of the dignity of the embryo but more from the utilitarian perspective of benefit to be gained from such research on embryos that otherwise might be destroyed. To some ethicists this involved putting the cart before the horse.

The need for scientific research into areas of therapeutic potential needs to be supported, as advances in treatment possibilities are an ethical imperative. (What has been overshadowed in this debate is the remarkable advances in adult stem cell research that, appear to match embryonic stem cells as time goes by.)

The ethical imperative of scientific advancement needs to be weighed against any possible ethical conflicts that may arise. All research needs to be tempered by other ethical restrictions.

The notable ethical question in this debate is the moral status of the embryo. Reviewing the literature, which extends back to the start of the IVF debate, this has always been an issue fraught with controversy.

Economic factors that affect the ethical consideration, either implicitly or explicitly, also need to be taken into consideration. This can impact on governments, scientists and even ethicists.

The UK launched into this area legislat ing for therapeutic cloning well before any adequate discussion could be had. In an unusual move they passed the legislation and then ordered a senate review. British Prime Minister Tony Blair was worried that Germany’s biotechnology sector was growing faster than Britain’s but said, “I want to make it clear: we don’t intend to let our leadership fall behind and are prepared to back that commitment with investment.”

Following the UK’s move Germany’s Chancellor Gerhard Schroder indicated he would like to follow the UK in support of German industry. This led the Federal President of Germany, Johannes Rau, wading into the
debate stating that “where human dignity is at stake, economic arguments have no value”.

In the end it seems to come down to that word again - dignity. The dignity of the human embryo is a vexed question that society needs to address more comprehensively. It only seems to be addressed when we are faced with new dilemmas. Until a deeper approach is adopted in this regard, no lasting consensus can be achieved.

Dr Abboud is an assistant lecturer in medical ethics and health law at the University of NSW and a coordinator of Australasian Bioethics Information, a bioethical group for doctors and lawyers. He is also a practising GP

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RBR 2001/34  Protecting the Energy Consumer: The Electricity Legislation Amendment and Repeal Bill 2001 (Qld)  Dec 2001
RBR 2001/32  Casual Employment and the Industrial Relations Act Amendment Bill 2001 (Qld)  Nov 2001
RBR 2001/31  Pay Equity – The Industrial Relations Act Amendment Bill 2001 (Qld)  Nov 2001
RBR 2001/30  The Guardianship and Administration and Other Acts Amendment Bill 2001: Withholding or withdrawing life-sustaining measures for an adult with impaired capacity  Nov 2001
RBR 2001/29  The Prostitution Amendment Bill 2001 (Qld)  Oct 2001
RBR 2001/28  The Ombudsman Bill 2001 (Qld)  Oct 2001
RBR 2001/26  Environmental Protection Legislation Amendment Bill (No. 2) 2001: Encouraging Recycling and Waste Minimisation Practices to Extend the Life of Landfill Sites  Oct 2001
RBR 2001/24  ‘Paddock to the Plate’ (Part 2) - Amendment of the Food Act 1981 (Qld) by the Health Legislation Amendment Bill 2001 (Qld).  Oct 2001
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