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Human Cloning and Stem Cell Research

by

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EXECUTIVE SUMMARY

The issues of human cloning and related research such as stem cell technologies have generated considerable media and public attention over the last six months. Advances in biotechnology have created difficult ethical and moral questions that cannot be avoided.

There are many definitions of cloning in use for both the plant and animal world, which often leads to confusion about what is being referred to. Cloning in the animal and plant kingdom is a natural process, and in humans the formation of identical twins is a result of natural cloning. It is important to acknowledge that cloning does not necessarily mean the replication of an entire individual. A working definition of cloning is:

- Cloning is the production of a cell or organism with the same nuclear genome as another cell or organism;
- Reproductive cloning is the production of a human fetus from a single cell by nuclear replacement; and
- Therapeutic cloning is to produce human stem cells, tissues and organs, ie, the application of cloning technology which does not result in the production of genetically identical fetuses or babies.

There have been two major scientific breakthroughs that have shaped the recent development of cloning technologies. The first is somatic cell nuclear transfer, and the second is the isolation of human embryonic stem cells. Stems cells have the ability to divide for indefinite periods of time in culture and to give rise to specialised cells (pages 3 – 5). Stem cells may be isolated from both embryos and adults. Embryonic stem cell research is thought to offer several advantages over adult stem cells. However, the isolation of embryonic stem cells results in the destruction of the embryo, and this is the main criticism of this work. Stem cell research aims to find cures for many degenerative diseases, and has the potential to revolutionise medicine (page 6). The ethics of cloning and stem cell research are discussed (pages 7 – 11).

There continue to be great differences in the way countries around the world regulate human cloning and related technologies. For instance, it appears to be well accepted that a distinction must be made between the application of cloning techniques to the replication of a person, and the application of cloning techniques to the creation of tissues and cell lines with the aim of developing therapies for use in the treatment of disease. The use of cloning techniques for reproductive purposes has brought international condemnation and there appears to be a consensus against reproductive cloning (pages 11 – 13) .

In Australia, at the April 2002 Council of Australian Governments meeting, it was agreed to introduce nationally consistent legislation to ban human cloning. The Council also agreed to permit research involving the destruction of pre-existing surplus assisted reproductive technology embryos, with the aim to ensure that Australia remains at the forefront of research which may lead to medical breakthroughs in the treatment of disease (page 18).

1.0 INTRODUCTION

The issues of human cloning and related research such as stem cell technologies have generated considerable media and public attention over the last six months. Advances in biotechnology have created difficult ethical and moral questions that cannot be avoided. Governments around the world are grappling with the most appropriate means by which to regulate technologies such as human cloning. However, advances in science tend to be much faster than the advances in the understanding and comprehension of the issues of the general public and governments alike.

This paper explains what cloning and stem cell research are, canvasses the ethical issues associated with such work, and outlines the regulatory framework in which it operates. The issues of human cloning and stem cell research introduce terms which are not necessarily in every day use. It is important to understand that the human body has two fundamentally different cell types: germ cells and somatic cells. Germ cells are located in the ovaries and testes, and are the cells from which eggs and sperm arise. In contrast, somatic cells are all other cell types in the body.

2.0 CLONING

There are many definitions of cloning in use for both the plant and animal world, which often leads to confusion about what is being referred to. Cloning in the animal and plant kingdom is a natural process, and occurs for example in the asexual reproduction of plants or the budding of yeast in beer. In humans the formation of identical twins is a result of natural cloning. Cloning can also be achieved through artificial technologies, and it is now possible to clone DNA, cells, tissues, organs and whole individuals. The House of Representatives Standing Committee on Legal and Constitutional Affairs (referred to as the Andrews Committee after the Committee Chair), in its report on Human Cloning, notes that it is important to acknowledge that cloning does not necessarily mean the replication of an entire individual. However, this is often the public perception.[1]

A working definition of cloning published by the Australian Academy of Science is as follows:[2]

- Cloning is the production of a cell or organism with the same nuclear genome[3] as another cell or organism;
- Reproductive cloning is the production of a human fetus from a single cell by nuclear replacement; and

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1 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 18.

2 Australian Academy of Science, *Human Stem Cell Research*, 18 April 2001.

3 The genome is the complete genetic make up of a cell or organism.

- Therapeutic cloning is to produce human stem cells, tissues and organs, ie, the application of cloning technology which does not result in the production of genetically identical fetuses or babies.

These definitions distinguish between the cloning of a whole human individual and cloning of cells and tissues. However, there is still overlap between the definitions for reproductive cloning and for therapeutic cloning, since in both an embryo may be formed or used for research. It is evident that any legislation that deals with the issue of cloning must carefully define what is meant by the term. There have been two major scientific breakthroughs that have shaped the recent development of cloning technologies. The first is somatic cell nuclear transfer, and the second is the isolation of human embryonic stem cells.[4]

2.1 Somatic Cell Nuclear Transfer[5]

Scientists have experimented with animal cloning, but have never been able to stimulate a specialised (differentiated) cell to produce a new whole organism directly. Instead, they have relied on transplanting the genetic information from a specialised cell into an unfertilised egg cell whose genetic information has been destroyed or physically removed. In the 1970s, scientist John Gurdon successfully cloned tadpoles. He transplanted the nucleus from a specialised cell (skin or intestinal cell) of one frog (A) into an unfertilised egg of another frog (B) in which the nucleus was destroyed by ultraviolet light. The egg with the transplanted nucleus developed into a tadpole that was genetically identical to frog A. However, the tadpoles did not survive to grow into adult frogs. His experiment showed that the process of specialisation (differentiation) in animal cells was reversible and his technique of nuclear transfer paved the way for later cloning successes. The term commonly used to describe this process is somatic cell nuclear transfer.

In 1997, cloning was revolutionised when Ian Wilmut and his colleagues at the Roslin Institute in Edinburgh, Scotland, successfully cloned a sheep named Dolly. The scientists transplanted a nucleus from a mammary gland cell of a Finn Dorsett sheep into the enucleated (nucleus removed) egg of a Scottish blackface ewe. The nucleus-egg combination was stimulated with electricity to fuse the two and to stimulate cell division. The new cell divided and was placed in the uterus of a blackface ewe to develop and Dolly was born months later. Dolly was shown to be genetically identical to the Finn Dorsett mammary cells and not to the blackface ewe, which clearly demonstrated that she was a successful clone (it took 276 attempts before the experiment was successful). Dolly has since grown and reproduced several offspring of her own through normal sexual means. Therefore, Dolly is a viable, healthy clone. Since Dolly, several university laboratories and companies have used various modifications of the somatic cell nuclear transfer technique to produce cloned mammals, including cows, pigs, monkeys, and mice.

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4 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 19.

5 Adapted from: http://www.howstuffworks.com/cloning.htm

2.2 Stem Cells[6]

Stems cells have the ability to divide for indefinite periods of time in culture and to give rise to specialised cells. An overview of human development aids the understanding of what stem cells are. Human development begins when a sperm fertilises an egg and creates a single cell that has the potential to form an entire person. This fertilised egg cell is called totipotent, meaning that its potential is total. In the first hours after fertilisation, this single cell divides into identical totipotent cells. This means that either one of these cells, if placed in a woman's uterus, has the potential to develop into a fetus. Identical twins develop when two totipotent cells separate and develop into two individual, genetically identical people. Approximately four days after fertilisation, and after several cycles of cell division, these totipotent cells begin to specialise, forming a hollow sphere of cells, called a blastocyst. The blastocyst has an outer layer of cells and inside the hollow sphere there is a cluster of cells called the inner cell mass.

The outer layer of cells will develop into the placenta and other tissues needed for fetal development in the uterus. The inner cell mass will develop into virtually all of the tissues of the human body. However, although the inner cell mass can form virtually every type of cell found in the human body, they cannot form an organism because they are unable to give rise to the placenta and other tissues necessary for development in the human uterus. The cells in the inner cell mass are called pluripotent – they can give rise to many types of cells but not all types of cells necessary for fetal development. Because their potential is not total, they are not totipotent and they are not considered embryos. If an inner cell mass was placed into a woman's uterus, it would not develop into a fetus.

The pluripotent inner mass cells undergo further specialisation into stem cells that give rise to cells that have a particular function. For example, blood stem cells give rise to red blood cells, white blood cells and platelets, whilst skin stem cells give rise to the various types of skin cells. These more specialised stem cells are called multipotent.

Stem cells are therefore extraordinarily important in early human development. The isolation of pluripotent stem cells means that they can be grown to produce cell lines and tissues with the aim of treating disease, an application known as therapeutic cloning. The problem is that in the process of isolating the pluripotent stem cells the embryo is destroyed.

Multipotent stem cells are also found in children and adults. 'Adult' stem cells remain present in the body throughout life and are responsible for normal repair and replacement of the different tissues and organs of the body. Using the example of blood stem cells as above, they are found in the bone marrow of every adult and child, and a person could not survive without them.

Pluripotent stem cells, often referred to as pluripotent cell lines, have been developed from two sources. These are:

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6 Adapted from: Office of the Director, National Institute of Health (US) *Stem Cells: A Primer,* May 2000. See URL: http://www.nih.gov/new/stemcell/primer.htm

- Isolated directly from the inner cell mass of human embryos at the blastocyst stage. These embryos have been received from In Vitro Fertilisation (IVF) clinics where the embryos were in excess of clinical need for fertility treatment;
- Isolated from fetal tissue obtained from terminated pregnancies.

The use of somatic cell nuclear transfer may be another way in which pluripotent stem cells could be isolated. In studies in animals using this technology, the nucleus (the cell structure which contains the chromosomes) of a normal animal egg cell is removed. The material left behind in the egg cell contains nutrients and other material essential for embryo development. Then a somatic cell (any cell other than a sperm or egg cell) is placed next to the egg from which the nucleus has been removed, and the two are fused. The resulting fused cell, and its immediate decendants, are believed to have the full potential to develop into an entire animal, and hence are totipotent. These totipotent cells will soon form a blatocyst, and cells from the inner cell mass of this blastocyst could, in theory, be used to develop pluripotent stem cell lines.

The first embryonic stem cells from mammals were isolated from mice in 1981. It took another 14 years before embryonic stem cells were isolated from non-human primates, with the breakthrough resulting from experimenting on the rhesus monkey in 1995, followed by the marmoset monkey in 1996. Using the same techniques with 14 human blastocysts produced by IVF programs resulted in the isolation of five human embryonic stem cell lines in 1998.[7] The study of human stem cells has barely begun and the vast majority of experimental data is the result of experiments on mice.

2.3 Adult Stem Cells Versus Embryonic Stem Cells

There has been and continues to be a fierce debate in the community about the pros and cons of research using embryonic stem cells compared to using adult stem cells only. One of the main criticisms against embryonic stem cell research is that the embryo is destroyed in the process of accessing the stem cells.

It is an intriguing anomaly that the human body repairs and replaces the cells and tissues of some organs, but not others. For example, heart attack and burn victims cannot regenerate their own damaged tissues. In attempting to work out why, scientists are now focussing their attention on adult stem cells. There is increasing evidence that stem cells are present in far more tissues and organs than once thought, and that they are capable of developing into more kinds of cells than previously imagined. In summary, the following is known about adult stem cells:[8]

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[7] House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 21.

[8] National Institutes of Health (United States), *Stem Cells: Scientific Progress and Future Research Directions*. June 2001, at 23.

- Some adult stem cells have the capability to differentiate into tissues other than the ones from which they originated (referred to as plasticity). However, rarely have experiments that claim plasticity demonstrated that the adult stem cells have generated mature, fully functional cells or that the cells have restored lost function *in vivo*;
- Adult stem cells are rare, often difficult to identify and their origins are not known;
- To date, adult stem cells have been derived from brain; bone marrow; peripheral blood, dental pulp; spinal cord; blood vessels; skeletal muscle; epithelia of the skin and digestive system; cornea; retina; liver and pancreas.

Adult stem cells have the great advantage that an embryo does not need to be destroyed to access them. They also have great potential use for the development of cell therapies. For example, there would be many advantages to using adult stem cells for transplantation. If the adult stem cells from a patient could be isolated, coaxed to divide and direct their specialisation, and transplanted back into the patient, it is unlikely that they would be rejected by the patient's immune system.[9]

However, many scientists claim that adult stem cell therapies will complement, but cannot replace, therapies that may be eventually obtained from embryo stem cells. This is because many cells of medical interest cannot yet be obtained from adult stem cells, and that production of large numbers of these is much more difficult than is the case with embryo stem cells.[10] Because of these limitations, many scientists argue that research on both adult and embryo stem cells should continue. For instance, the American Academy for the Advancement of Science, in a letter to President Bush, said:

> One of the misconceptions held by some is that study of adult stem cells will be sufficient to realize the medical promise of this line of research. But the prevailing view of expert scientific opinion is that it is far too early to know if adult stem cells have the same potential as embryonic stem cells. It is important to convey to the public the limitations and preliminary nature of much of the research on adult stem cells. It is likely to take years to discover whether adult stem cells will be effective in treating many diseases that may be treatable sooner with embryonic or fetal stem cells.[11]

In a review of stem cell research the Australian Academy of Science noted:

> Alternative approaches to tissue repair that do not involve human embryos, but make use of scattered stem cells in the adult, may one day be a reality. The understanding gained by study of growth factors and their receptors in embryo stem cells may speed the demise of embryo stem cell use in tissue repair.[12]

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9 Office of the Director, National Institute of Health (US) *Stem Cells: A Primer,* May 2000. See URL: http://www.nih.gov/new/stemcell/primer.htm

10 American Association for the Advancement of Science and the Institute of Civil Society, *Stem Cell Research and Applications. Monitoring the Frontiers of Biomedical Research*, November 1999 at 4.

11 See URL: http://www.aaas.org/spp/dspp/sfrl/projects/stem/bushletter.htm, accessed 22 May 2002.

12 Australian Academy of Science, *Human Stem Cell Research*, 18 April 2001, at 14.

3.0 THE CLINICAL POTENTIALS FOR STEM CELL PRODUCTS

Advances in stem cell technologies have the potential to revolutionise medicine. Chronic, degenerative and acute diseases affect many people, who often have no hope of improvement in their condition. Some examples of treatments for major diseases from stem cell technologies are outlined below:

- Type 1 Diabetes in Children: Type 1 diabetes is an autoimmune disease characterised by destruction of insulin producing cells in the pancreas. Current efforts treat patients with pancreas transplants, which is limited by the small number of donated pancreas and the toxicity of immuno-suppressive drug treatments required to prevent organ rejection. It is hoped that pluripotent stem cells, instructed to differentiate into a particular pancreatic cell called a beta cell, could overcome the shortage of material to transplant.
- Nervous System Diseases: Many of these diseases result from the loss of nerve cells, as mature nerve cells cannot divide to replace those that are lost. In Parkinson's disease, nerve cells that make the chemical dopamine die. In Alzheimer's disease, cells that are responsible for the production of certain neurotransmitters die. In multiple sclerosis, the cells that protect nerve fibres are lost, and in spinal cord injury, brain trauma and even stroke, many different types of cells are lost or die. It is thought that perhaps the only hope for treating such individuals comes from the potential to create new nerve tissue restoring function from pluripotent stem cells.
- Primary Immunodeficiency Diseases: There are more than 70 different forms of congenital and inherited deficiencies of the immune system that have been recognised, and are some of the most complicated diseases to treat. These diseases are characterised by an unusual susceptibility to infection. However, the transplantation of stem cells reconstituted with the normal gene could result in restoration of immune function and normalisation of life span and quality of life for these people.
- Diseases of Bone and Cartilage: Differentiated stem cells could correct many diseases and degenerative conditions in which bone or cartilage cells are deficient in numbers or defective in function.
- Cancer: Presently bone marrow stem cells are used to help patients following high doses of chemotherapy. Unfortunately the recovered cells are limited in their capacity to restore immune function completely. It is hoped that injection of properly differentiated stem cells would return the complete array of immune response to patients undergoing bone marrow transplants.[13]

Embryonic stem cells are also potentially very useful in research in the following capacities:

- A window on human developmental biology: many unexplained events in early human development can result in congenital birth defects – it may be possible to identify the genetic, molecular and cellular events that lead to these problems and identify methods for preventing them;

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13 American Association for the Advancement of Science and the Institute of Civil Society, *Stem Cell Research and Applications. Monitoring the Frontiers of Biomedical Research*, November 1999 at 5.

- Human embryonic stem cells could be used to test therapeutic drugs;
- Human embryonic stem cells could be employed to screen potential toxins;
- Human embryonic stem cells could be used to develop new methods of genetic engineering.[14]

4.0 THE ETHICS OF HUMAN CLONING FOR REPRODUCTIVE PURPOSES

The UNESCO Declaration on the Human Genome and Human Rights was adopted unanimously by its 186 member nation states (including Australia) in November 1997, and provides a framework for consideration of the ethical issues of human cloning for reproductive purposes. Article 11 of the Declaration states that: "practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted." It is evident that Article 11 covers the use of cloning technology to produce whole human beings. There are differing views internationally as to the further operation of the Article, and the issues arising are a matter of domestic policy to be settled by individual countries.[15]

The following reasons have been put forward in support of prohibiting reproductive cloning:[16]

- The lack of any medical need for cloning for reproductive purposes;
- Cloning for reproductive purposes would constitute an infringement of human dignity;
- Cloning for reproductive purposes would have a negative effect on the family and personal relationships;
- Cloning for reproductive purposes would undermine individuality and identity;
- It would be unsafe;
- Cloning for reproductive purposes would potentially pose a threat to human diversity and run the risk of reintroducing notions of eugenics; and
- It would raise the potential for coercion of women.

In contrast, some of the more commonly suggested reasons why human cloning should be permitted include:[17]

- To reproduce a dying child;

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14 National Institutes of Health (United States), *Stem Cells: Scientific Progress and Future Research Directions*. June 2001, at 17.

15 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 176.

16 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 77.

17 Thomson, J "Legal and Ethical Problems of Human Cloning" in *Journal of Law and Medicine*, Volume 8, August 2000 at 36.

- To enable infertile couples (including gay and lesbian couples) to have children genetically related to at least one of them;
- To provide a source of compatible organs for persons requiring transplants;
- To provide subjects for fetal experiments; and
- To enable efficient production of a genetically engineered / enhanced clone.

The Andrews Committee noted that overwhelmingly evidence and submissions opposed human cloning, and unanimously concluded that human cloning for reproductive purposes was unacceptable.[18]

4.1 The Ethics of Research and Therapy

It is apparent that there are wider issues than just the cloning of humans for reproductive purposes. Related practices such as the use of embryonic stem cells, the prospect of the creation of embryos by somatic cell nuclear transfer for research or therapy, and the use of surplus embryos from assisted reproductive technologies for research purposes have also created much concern and interest.

The Andrews Committee noted that before any ethical issues are examined, the preliminary question of what, if any, benefit will flow from conducting the above types of research needs to be answered. The Committee emphasised that the scientific evidence before it indicated that discussion of some of the potential benefits may be premature, and that many of the mooted benefits have long time frames and in some cases may be unobtainable.

It is also widely argued that because of the great potential of cloning and related research to improve health, it would be unethical to prohibit or restrict the research. For example, Professor Williamson of the Murdoch Institute for Research into Birth Defects in a submission to the Committee stated:

> …there are very great potential benefits in continuing research into ways in which somatic cells from living individuals can become totipotent. These benefits are most clear in the field of transplantation medicine…if it were possible to take a cell from an individual…and dedifferentiate / redifferentiate this cell into a bone marrow cell with normal properties, these problems would be solved. This is such a stunning prospect that it would be highly unethical NOT to pursue it.[19]

The Andrews Committee also received a considerable amount of evidence from members of the public who are suffering from illness, or who care for family members who do, who strongly urged the Committee to support the continuation of research work in the hope of finding cures.

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18 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 80.

19 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 100. Submission from Professor Williamson, *Submissions* pS347.

The use of embryos surplus to assisted reproductive technology programs is also a contentious issue. In these programs (such as IVF) more embryos are created than will be required to achieve children for those undergoing treatment. Under legislation or guidelines applicable, such embryos are usually stored for a certain period of time and may then be discarded if unused. There are currently more than 65,000 embryos in storage in Australia. It has therefore been suggested that instead of discarding these surplus embryos, they be used for research. For example, the Humanist Society of Victoria argued to the Andrews Committee:

> Frozen embryos no longer required for IVF should be used (with owner's consent) for research rather than discarded. This should proceed to day 14 of embryonic development. [the Society does] not believe the early embryo is a sentient being (before day 14 of development) nor a person or a moral agent.
>
> The research carried out on a cluster of cells that may, or may not develop into a human being, offers major clinical and therapeutic benefits for the present and future generations…
>
> We believe there is a moral and societal obligation to promote such research.[20]

However, there are many people and organisations that specifically oppose the use of embryos that are surplus to assisted reproductive technology requirements for research use. For instance, the Caroline Chisholm Centre for Health Ethics submitted to the Andrews Committee:

> Non-therapeutic, destructive or harmful research on human embryos, be they naturally conceived, IVF embryos or cloned embryos, is absolutely unethical and should be legally banned. The same applies to a cell or group of cells which is probably an embryo.[21]

The reasons for opposing embryonic research have also been expressed as follows:

> The human embryo is a distinct, living human being, and as such is entitled to all the rights and protections as any other human being. That human life begins at conception (or fertilisation) is not opinion but scientific fact. Therefore, the human embryo (regardless by what means by which it is created) should not be treated as a means to an end. It is entitled to life, liberty and respect. The truth is, the human embryo contains the exact same amount of genetic information as adults do. The embryo differs from an adult not in kind but only in degree. Once embryonic development commences, a separate and distinct human being exists. As such, the embryo should not be used in a purely instrumental fashion. It is never ethical to sacrifice one human being for the real or perceived benefits of another human being. Such utilitarian considerations cannot be

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20 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 107. Submission from Humanist Society of Victoria, *Submissions* p S151.

21 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 107. Submission from Caroline Chisholm Centre for Health Ethics, *Submissions* p S778.

> justified. Therefore any technology or proposed therapeutic procedure which involves the destruction of a human embryo should be banned altogether….and those who argue that the frozen embryo would be destroyed anyway miss the point. The couples who had the embryos created did so for the purpose of implantation, of bringing about life. They did not do it so they could be destroyed and / or experimented on…The fact that frozen embryos will eventually die is no reason to prematurely kill them. After all, all of us will eventually die, but that does not justify our being killed. Letting die is not the same as deliberate killing.[22]

The Andrews Committee also canvassed the arguments concerning the use of embryos deliberately created by asexual reproduction. This process would use the somatic cell nuclear transfer technique for the therapeutic benefit of particular individuals suffering from diseases which require transplantation of tissues or cells. Whilst this scenario is presently speculative, it would involve the use of the somatic cell of an ill person to create an embryo by means of somatic cell nuclear transfer. Such a procedure would also involve a donated egg. Embryonic stem cells would then be harvested from the resulting embryo (leading to its destruction) with a view to then directing the stem cells down the pathway required by the somatic cell donor's illness. The greatest benefit of this technique may be expected in transplantation medicine where the risks of tissue rejection may be avoided by supplying a person with new cells or tissue of exactly their own genetic type.[23]

It was noted by the Committee that some people object to the use of somatic cell nuclear transfer for extracting embryonic stem cells because the procedure is identical to that involved in cloning for reproductive purposes. The difference is that the resulting embryo is destroyed whilst the stem cells are extracted, rather than implanted in a woman's uterus. Those who objected to the use of somatic cell nuclear transfer techniques did so on the basis that any potential benefits did not justify the creation and destruction of embryos.

In concluding its discussion on the ethical issues of research and therapy, the Andrews Committee noted the following:[24]

- The evidence indicates there is potentially significant benefit in the form of treatments of serious disease and illness;
- The specific issue becomes whether it is permissible to use and/or destroy human embryos in order to conduct research and gain the benefits.
- All members of the Committee oppose cloning for reproductive purposes;
- All members of the Committee endorse the use of adult stem cells in research – this should be encouraged and pursued;
- The majority of the Committee accepted non-reproductive cloning research involving embryonic stem cells because of its potential for the treatment of serious disease. They

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22 Muehlenberg,B "Adult stem cells: the better option." In *News Weekly*, March 23 2002, at 13.

23 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 110.

24 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 117.

believed that the use of existing embryonic stem cell lines to conduct research or to develop banks of cell lines for future therapeutic use should be permitted, and that it is permissible to derive additional embryonic stem cell lines from embryos that are surplus to assisted reproductive technology requirements, but only within clear and stringent guidelines.

- However, other members, including the Committee Chair Mr Andrews, believed that the research and therapy involving the destruction of human embryos should be prohibited. These members considered that: existing stem cell lines are sufficient for research and the development of stem cell banks; with developments in adult stem cell therapies it does not appear necessary to use embryos; and the potential benefits of the research must be balanced against the actual harm.
- It was unanimously agreed that there should be a three year moratorium on the creation and use of embryos created by somatic cell nuclear transfer, after which the issue can be re-examined by the Australian Health Ethics Committee.

Ultimately, the Committee proposed a regulatory framework in which any use of embryos or their destruction in order to obtain embryonic stem cells for research purposes could be performed. This proposed framework is outlined later in this paper.

5.0 INTERNATIONAL DEVELOPMENTS

In reviewing international developments in regard to the regulation of human cloning and related research, the Andrews Committee noted that there are clearly great differences in approach in various countries. These differing approaches made it difficult to discern a clear international consensus especially on issues as sensitive as the use of embryos in research. For instance, the response of President Bush to the vexed issue of embryonic stem cell research is discussed below.

5.1 The Decision of President George W Bush

On August 9 2001, President Bush in an address to the Nation announced his administration's position on Federal funding for embryonic stem cell research. In his address he canvassed some of the ethical issues involved in embryonic stem cell research, and also noted the potential that stem cells may have to help improve the lives of those who suffer from diseases from Alzheimer's to diabetes. President Bush identified two fundamental questions: "First are these embryos (that are to be destroyed in the stem cell research) human life and therefore something precious to be protected? And second, if they're going to be destroyed anyway, shouldn't they be used for a greater good, for research that has potential to save and improve other lives?" President Bush noted that in the answer to these questions, he came across widespread disagreement. In shaping his conclusions, the President noted: "I'm a strong supporter of science and technology, and believe they have the potential for incredible good…I also believe human life is a sacred gift from our creator. I worry about a culture that devalues human life…As a result of private research, more than 60 genetically diverse stem cell lines already exist. They were created from embryos that have already been destroyed, and they have the ability to regenerate themselves indefinitely, creating ongoing opportunities for research. I have concluded that

we should allow Federal funds to be used for research on these existing stem cell lines, where the life and death decision has already been made….This allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life." [25]

President Bush also announced the creation of a President's Council on Bioethics to monitor stem cell research, to recommend appropriate guidelines and regulations, and to consider all of the medical and ethical ramifications of biomedical innovation.

5.2 The United Kingdom Response

In 1990 the *Human Fertilisation and Embryology Act* was passed. It established the Human Fertilisation and Embryology Authority, which has comprehensive authority and jurisdiction over all clinics and laboratories dealing with gametes or embryos, both in the public and private sector. The Act states that the Authority cannot authorise a research project involving the use of human embryos unless it appears necessary or desirable according to five prescribed conditions, or as allowed in the regulations. After a process of several commissions and advisory groups reviewing the state of stem cell therapies, it was recommended to the Government that it include in the regulations permission for research using embryos (created by assisted reproductive technologies or cell nuclear replacement) in order to increase understanding about human disease and disorders and their cell based treatments. After a conscience vote of both Houses of the United Kingdom Parliament, the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 came into force on 31 January 2001. The Regulations legalise embryo research to extract stem cells and deliberate creation of embryos by somatic cell nuclear transfer for research purposes.[26]

It is evident that the approaches of the United Kingdom and United States governments in relation to embryo research are quite different. The Andrews Committee noted that there are elements of international consensus emerging on some issues. For instance, it appears to be well accepted (although not in all quarters) that a distinction must be made between the application of cloning techniques to the replication of a person or the creation of a child and the application of cloning techniques to the creation of tissues and cell lines with the aim of developing therapies for use in the treatment of disease and disability. The use of cloning techniques for reproductive purposes has brought international condemnation and there appears to be a consensus against reproductive cloning. The potential for significant developments and gains to be made from stem cell research is accepted in the United States and the United Kingdom, and regulatory developments in each of these countries have attempted to balance the harnessing of this potential with the protection of the embryo.[27]

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25 See the White House website: http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html

26 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 197.

27 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*.

6.0 THE CURRENT AUSTRALIAN REGULATORY FRAMEWORK GOVERNING HUMAN CLONING AND RELATED RESEARCH

6.1 Legislative Provisions Prohibiting Human Cloning and Associated Research

On 31 July 2000 Australian Health Ministers met and agreed to the development of a national framework to prevent human cloning. Each State and Territory was to work cooperatively to ensure consistency in banning the cloning of human beings.[28] However, reaching this ideal has proven somewhat of a challenge, and has only recently been achieved some two years later. As indicated earlier in this paper, the definitions used in legislation to describe cloning are critical to the success of any legislative provisions.

In the Commonwealth sphere the *Gene Technology Act 2000* prohibits the cloning of whole human beings.[29] It also prohibits placing human cells into animal eggs or placing a combination of animal and human cells into a human uterus. 'Cloning a whole human being' is defined in the Act to mean 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. The inclusion of this prohibition was not part of the original Bill, and was made because of an amendment in the Senate.

In Victoria, the *Infertility Treatment Act 1995* regulates both assisted reproductive technologies and experimentation on embryos. The Act specifically prohibits human cloning. The term clone is defined as: " 'clone' means to form, outside the human body, a human embryo that is genetically identical to another human embryo or person". The Act is administered by the Infertility Treatment Authority. Under the Act destructive research on an embryo is prohibited. Destructive research is that which may result in an embryo being unfit for implantation. Research involving tissue derived from human embryos such as embryonic stem cells would fall outside the operations of the Act – although not if an embryo was destroyed in Victoria in order to obtain them.

In Western Australia the *Human Reproductive Technology Act 1991* prohibits any procedure directed at human cloning. Cloning is defined as: "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." Embryo research is strictly regulated, and section 14(2) of the Act directs that such research must be intended to be therapeutic and not likely to harm the embryo.

In South Australia the *Reproductive Technology Act 1988* regulates both assisted

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August 2001 at 200.

28 *Media Release* "National Framework Agreed to Prevent the Exploitation of Human Cloning" Hon Dr Michael Wooldridge MP, Minister for Health and Aged Cared (Cth) 31 July 2000.

29 (Section 192B).

reproductive technologies and experimentation involving embryos. The Act prohibits carrying out research involving human embryos except with a licence. However, a licence can only be issued subject to a condition prohibiting research that may be detrimental to an embryo. Research that is prohibited under the associated regulations includes: culturing or maintaining embryos outside the human body; research on embryos more than 14 days old; mixing human and animal reproductive material; altering the genetic structure of a cell where that cell forms part of an embryo or an ovum in the process of fertilisation; replacing the nucleus of a cell of an embryo or of an ovum in the process of fertilisation with any other nucleus or placing any cells extracted from an embryo into the body of any person. Whilst the legislative framework is restrictive, research involving embryonic stem cells would not be precluded by the Act nor would research involving adult stem cells.

Neither New South Wales, Queensland[30], Tasmania or the Territories have legislation regulating cloning or associated research. In September 2001 the Minister for Health Hon Craig Knowles MP introduced into the Legislative Assembly the *Gene Technology (New South Wales) Bill*. This Bill, which is currently before the Legislative Council, provides the NSW component of the national regulatory scheme as applied in the *Gene Technology Act 2000* (Cth). However, whilst the Commonwealth Act as noted above prohibits human reproductive cloning, the NSW Bill excludes this component from State operation. In relation to these exclusions, Minister Knowles explained to the House: "The Commonwealth Government has clarified that these prohibitions were included as an interim measure until all States and Territories have nationally consistent legislation in place to comprehensively ban the cloning of human beings. The provisions relating to human cloning and human animal cell experimentation … are not adopted in this Bill as the New South Wales Government will be introducing separate legislation on these issues immediately after the cessation of this second reading speech."[31] The legislation introduced is discussed further below.

The Andrews Committee Report noted that the definitions of cloning in the different pieces of legislation as noted above are not consistent and that each prohibits slightly different conduct. The Committee was concerned about the narrowness and technicality of the legislative definitions of cloning and urged that they be replaced by a definition that is broader, more effective and not focused on the requirement of genetic identicality. This is because a cloned 'individual' may not be completely genetically identical to the original.[32] Whilst these differences may be small, the product of cloning is likely to be less identical than monozygotic (ie 'identical') twins. In the Committee's view the prohibition on human cloning in the *Gene Technology Act 2000* is insufficient and inappropriate.

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30 The Cloning of Humans (Prohibition) Bill was introduced into the Queensland Parliament on 27 November 2001.

31 *NSWPD*, *Gene Technology (New South Wales) Bill*, 21 September 2001 at p 17 041.

32 The process of cloning involves the replacement of the nucleus of a donated egg with the nucleus of a donated somatic donor cell. Surrounding the nucleus in the egg is cytoplasm that contains DNA – known as mitochondrial DNA. This DNA will also form part of the genetic inheritance of any offspring and may lead to slight changes from the original donor of the somatic cell.

The Committee noted that the focus of effective criminal prohibitions on reproductive cloning should be on the intention to produce a whole human being other than by means of existing assisted reproductive technologies. If in any definition of cloning the retention of some concept of genetic similarity is sought, the Committee recommended that the inclusion of the words '… or substantially identical to…' would appear to be a worthwhile safeguard. However, the Committee noted that it may also be necessary to guard against the possibility of substantial alteration of some DNA in the course of the creation of a human embryo by somatic cell nuclear transfer.

On 21 September 2001 the Minister for Health Hon Craig Knowles MP introduced the *Human Reproductive Cloning and Trans-Species Fertilisation Bill*. The objects of the Bill were:

- To prohibit the creation of living human clones and to prohibit the gestation of human embryo clones; and
- To prohibit by creation, fertilisation or a similar process, of an embryo that is a hybrid of a human and an animal and to prohibit the gestation of such a hybrid embryo.

Clause 4 of the Bill states: A person (a) who creates, or attempts to create, a human clone by means of a technological or other artificial process, and (b) who intends to create a living human clone, is guilty of an offence.

Human clone is defined in the bill to mean a human that is a genetic copy of another living or dead human. Recognising the definition limitations as discussed above, the Government inserted into the Bill the following: "For the purposes of establishing proceedings under this Act that a human or human embryo is a genetic copy: (a) it is sufficient to establish that the set of genes in the nucleus of the human cell has been copied; and (b) it is not necessary to establish that the copy is an identical copy."

The Bill then goes on to prohibit the gestation of a human embryo clone; the creation and gestation of a trans-species embryo. The Bill does not prohibit embryonic stem cell research or therapeutic cloning, as these techniques do not involve the creation of a whole human being

However, the *Human Reproductive Cloning and Trans-Species Fertilisation Bill 2001* lapsed on prorogation at second reading stage in the Legislative Assembly. On 12 March 2002 the Hon Rev Fred Nile MLC gave a notice of motion to introduce a private Member's Bill *Human Cloning and Embryo Experimentation Bill 2002*. As explained later in this Paper, the Council of Australian Governments has recently agreed on a national regulatory framework for human cloning and related research, and it could be expected that the NSW Government will re-introduce legislation shortly.

In terms of less specific legislation governing cloning at the State level, the most relevant legislation is that regulating the donation and use of human tissue. This is because research involving cloning technologies requires embryos (to extract embryonic stem cells); ova (if embryos are to be created specifically for research using somatic cell transfer techniques);

and / or human tissue (to gain adult stem cells or somatic cells for cloning purposes). All States and Territories have enacted legislation regulating the donation and transplantation of human tissue. In NSW the *Human Tissue Act 1983* covers the removal and donation of tissue for transplant, scientific research or therapeutic use and post mortem examination. The legislation provides that living adults may consent to donate regenerative tissue for transplantation or for therapeutic, medical or scientific purposes.

However, in regards to cloning and related research, the ownership of human tissue is a complex matter and the law is uncertain. For instance, it is not clear who, if anyone, 'owns' stored or other genetic material or human tissue, hence it is unclear who has the right to 'possess' and 'use it'. Advances in cloning technologies have created a new series of issues regarding the donation and use of human tissue. For instance, human tissue removed as part of medical procedures could be a source of stem cells or somatic cells for research purposes. The Andrews Committee noted that the current framework of human tissue legislation does not easily accommodate these possibilities, and that legislation is premised on a once-only 'donation' of organs or tissues. The Committee suggested that this is an area that needs review.[33]

6.2 Non-Legislative Regulation of Cloning and Research Involving Embryos

In States and Territories where there is no specific legislation regulating cloning and related research, non-legislative guidelines regulate this work. This primarily involves compliance with National Health and Medical Research Council (NHMRC) guidelines. The NHMRC has issued two sets of guidelines that guide research in this area. These are: the *National Statement on Ethical Conduct in Research Involving Humans 1999*; and the *Ethical Guidelines on Assisted Reproductive Technology 1996*. The NHMRC requires all institutions or organisations who receive NHMRC funding to establish an Institutional Ethics Committee, and to subject all research involving humans, whether funded by the NHMRC or not, to ethical review by that Ethics Committee using the above National Statement on Ethical Conduct as the standard for that review.

The infringement of a provision of any NHMRC guidelines is not an offence, and sanctions for any breach may involve the loss of access to research funds. The Andrews Committee noted the following: "The growth and spread of cloning research and the substantial involvement of the private sector in it renders it very difficult for a body such as the NHMRC or the Australian Health Ethics Committee [a committee of the NHMRC] to monitor this area of risk. The leverage of the NHMRC is very much tied to its capacity to grant or withhold funding, and hence its real capacity to influence the private sector must be problematic…In such an environment sanctions such as the loss of research funding may have minimal influence."[34] The Committee concluded that the current regulatory framework

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33 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 153.

34 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 157.

could not be allowed to continue.

7.0 THE REGULATORY FRAMEWORK FAVOURED BY THE ANDREWS COMMITTEE

The Andrews Committee noted that if Australian Governments decide to allow stem cell research using embryos derived from the surplus from assisted reproductive technology programs, it should be regulated in the following manner:[35]

- A national uniform legislative approach;
- A ban on cloning for reproductive purposes;
- One system of regulation for privately and publicly funded research;
- Legislation regulating human cloning and stem cell research to be separate from that governing artificial reproductive technologies;
- Any attempt to undertake cloning for reproductive purposes to be subject to criminal penalty and the withdrawal of a licence to undertake research in this area;
- Research using cloning techniques be subject to clear legislative parameters, including a complete ban on the deliberate creation of embryos for research purposes (subject to a three year moratorium as previously discussed);
- A national licensing body be established to regulate human cloning and research using cloning techniques;
- Individual researchers be licensed for each research project that involves the use of an embryo;
- The import and export of embryonic stem cells should be permitted with the framework of principles outlined in this report, ie, it should be permissible to import and export embryonic stem cell lines that are already in existence or have been created using embryos that are surplus to the requirements of assisted reproductive technology programs;
- The regulatory framework must be transparent, accountable and responsive.

The Andrews Committee's clear preference was for the Commonwealth to enact legislation to regulate cloning and related research. It was the Committee's view that the Commonwealth had the constitutional power to legislate in this area. In their view any legislation could be enacted relying on the Commonwealth's constitutional powers over areas such as corporations, trade and commerce, quarantine, patents, external affairs and its power to attach conditions to its funding of projects and institutions. However, this view was open to some debate. For instance, the Commonwealth Attorney-General's Department submitted to the Committee:

> …it may be possible to legislate in a piecemeal fashion using a number of Commonwealth heads of power such as the trade and commerce power and the

35 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 218.

> corporations power, ultimately it is probably the case that the Commonwealth Parliament does not have the power to enact legislation that would provide a comprehensive basis for prohibiting scientific research aimed at achieving reproductive human cloning or cloning research that involves the use of embryonic tissue.…Commonwealth powers to legislate is one part of the issue, but, even assuming the Commonwealth Parliament does have power to legislate, it would be doing so because there was a perceived gap in State and Territory legislation, or in order to override State and Territory legislation…even if the Commonwealth Parliament were to legislate on these issues, … it would…be necessary to consult quite heavily with the States and Territories an ideally to have agreement…So…there are some other political dimensions as well.[36]

In any event, as the following section discusses, all Governments of Australia have agreed on a framework for regulating cloning and related technologies.

8.0 THE COUNCIL OF AUSTRALIAN GOVERNMENTS DECISION

On 5 April 2002 the Council of Australian Governments (COAG) discussed the issue of human cloning, assisted reproductive technologies and related issues such as stem cell research. Before the meeting both Prime Minister Howard and Premier Bob Carr extensively (and publicly) canvassed the issue with scientists and community leaders. At one stage it was reported that the Federal Cabinet was considering a ban on embryonic stem cell research.[37] Premier Carr was very vocal in his support for embryonic stem cell research, and announced that the NSW Government would set up its own regime for this research if the federal government banned it. The Premier was reported as saying: "If Prime Minister Howard moves to smother such research we will set up rules in NSW and it will proceed in NSW…Then the federal government would have to look at options for overriding us."[38]

At the meeting the Council agreed that the Commonwealth and States/Territories would introduce nationally consistent legislation to ban human cloning and other 'unacceptable practices'. It was noted that the Commonwealth intends to introduce legislation by June 2002. The Council noted the following:

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

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36 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*. August 2001 at 212.

37 "Howard to study stem cell research before ban" in The Sydney Morning Herald, 27 February 2002.

38 "State may continue stem cell research if fed gov't bans it" *AAP*, 14 March 2002.

> consent of donors and that the embryos were in existence at 5 April 2002. Donors will be able to specify restrictions, if they wish, on the research uses of such embryos.
>
> The regulation restricting the use of embryos created after 5 April 2002 will cease to have effect in three years, unless an earlier time is agreed by the Council. The Council also agreed to establish an Ethics Committee with membership jointly agreed by the Council to report to the Council within 12 months on protocols to preclude the creation of embryos specifically for research purposes, with a view to reviewing the necessity for retaining the restriction on embryos created after 5 April 2002. The Council also agreed to request the National Health and Medical Research Council to report within 12 months on the adequacy of supply and distribution for research of excess ART embryos which would otherwise have been destroyed.
>
> The Council agreed that research involving the destruction of existing excess ART embryos be permitted under a strict regulatory regime to enable Australia to remain at the forefront of research which may lead to medical breakthroughs in the treatment of disease.[39]

The arrangements agreed by the Council are outlined in Appendix One.

The Prime Minister noted the following: "The central ethical issue here is that I have been personally unable to find a huge moral distinction between allowing the human embryo to succumb as a result of its exposure to room temperature, and ending it through research."[40] COAG's decision was welcomed by the National Health and Medical Research Council. The CEO of the Council stated: "Medical researchers working in this field are keen to make rapid progress in a responsible way to achieve the best possible outcomes. That is why today's decision by COAG in relation to embryonic stem cells is so important."[41] However, others condemned the COAG decision, with the president of the Right to Life group stating: "What the Prime Minister has done is to sanction a gross abuse of human rights…These hapless embryos are members of the human family…they have been treated like frozen peas and now they are to be sacrificed on the altar of scientific and political expediency."[42]

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39 Council of Australian Governments, *Communique*, 5 April 2002.

40 "PM gives green light to embryo research" in *The Sydney Morning Herald*, 4 April 2002.

41 "NHMRC welcomes responsibility of administering arrangements on the use of embryos for stem cell research" Media Release, NHMRC, 5 April 2002.

42 "Right to life condemns decision" in *The Sydney Morning Herald*, 4 April 2002.

9.0 CONCLUSIONS

The issues of cloning and stem cell technology are both complex and confronting. A Morgan poll conducted during November 2001 found that 70 percent of Australians aged 14 and over approved of extracting stem cells from human embryos to treat disease and injury. Seventy percent also believed that couples with excess embryos after infertility treatment should be able to donate them to research rather than discard them. However, when it came to using a patient's own genetic material to create a cloned embryo to be used as a source of stem cells (ie therapeutic cloning), just over half (55 percent) of the respondents approved, with 32 percent disapproving and 13 percent undecided.[43]

Research on cloning and related technologies is progressing worldwide, and Australian scientists are playing a leading part in this. Clearly governments have to weigh up the respective merits of promoting research and development in medical technologies that may improve the quality of life for many people on the one hand, and respecting early human life on the other.

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43 "Australian's endorse using human embryos for treating disease" *Morgan Poll, Finding No 3481*, December 13, 2001.

APPENDIX 1

Council of Australian Government's Decision on Cloning and Related Research

Council of Australian Government's Decision on Cloning and Related Research

A nationally-consistent ban on the cloning of a human being

1. The following wording is to be used as the basis for a nationally-consistent ban on the cloning of a human being:

1.1 A person must not:

a) create, or attempt to create, a human clone by means of a technological or other artificial process; or

b) cause a human embryo clone to be placed in the body of a human or animal for any period of gestation.

1.2 For the purposes of establishing that a human clone or human embryo clone is a genetic copy:

a) it is sufficient to establish that the set of genes in the nucleus of the human cell has been copied; and

b) it is not necessary to establish that the copy is an identical genetic copy.

1.3 It is not a defence that the human clone or human embryo clone did not or could not survive.

"Human clone" means a human that is a genetic copy of another living or dead human.

"Human embryo clone" means a human embryo that is a genetic copy of a living or dead human.

"Embryo" is a developing organism from the completion of fertilisation, or initiation of development by any other means, until eight weeks when the organism becomes known as a foetus.

Nationally-consistent regulation of certain unacceptable practices

2. The following practices are unacceptable and should be prohibited in Australia.

2.1 A person must not create or develop an embryo outside the body of a woman:

a) for purposes other than assisted reproduction; or

b) by a process other than the fertilisation of a human ovum by human sperm.

2.2 A person must not create or develop an embryo for assisted reproduction that contains genetic material from more than two people.

2.3 A person must not create or develop an embryo for assisted reproduction that uses any precursor cells of eggs or sperm from an embryo or foetus.

2.4 A person must not maintain an embryo outside the body of a woman after the 14^{th} day of its development excluding any time in which its development has been suspended.

2.5 A person must not alter the genome of a cell of a human being or in vitro embryo such that the alteration is inheritable.

2.6 A person must not conduct embryo flushing.

3. A person must not:

a) create or develop a hybrid embryo; or

b) place a hybrid embryo in the body of a human or animal for any period of gestation.

"Hybrid embryo" means a single living organism which has a mixed genetic origin as a consequence of combining cells derived from humans and other species.

3.2 A person must not:

a) place a human embryo in an animal or in any human body cavity other than the female human reproductive tract; or

b) place an animal embryo in a human for any period of gestation.

3.3 A person must not give or offer valuable consideration to any person for donation of

gametes or embryos of that person or of any other person.
"Valuable consideration" includes a discount or priority in the provision of a service but does not include the disbursement of any reasonable expense incurred by a person in connection with a donation of his or her reproductive material.
4. The prohibited practices will be comprehensively reviewed within three years of nationally consistent legislation taking effect, taking into account changes in technology, the potential therapeutic uses for such technology and any changes in community standards.

A nationally-consistent approach to research involving human embryos
5. Research involving human embryos should be regulated through nationally-consistent legislation.
6. The following principles should underpin nationally-consistent legislation:
6.1 legislation should ensure appropriate ethical oversight of research involving embryos based on nationally-consistent standards;
6.2 the nationally-consistent standards should be clear, detailed and describe the ethical issues to be taken into account, research which may be permitted and the conditions upon which it may be permitted (that is, the "rules" to be observed by researchers undertaking work with embryos) and should be based on National Health and Medical Research Council (NHMRC) guidelines as devised by the Australian Health Ethics Committee (AHEC);
6.3 these national standards should be applied consistently throughout Australia, recognising that jurisdictions may use different mechanisms to establish that proposals comply with the national standards;
6.4 the system should provide for public reporting of research involving embryos so as to improve transparency and accountability to the public; and
6.5 the system should enable appropriate monitoring of compliance with the national standards and provide legislated penalties for non-compliance.
7. There is a range of legislative options that could meet these principles including systems of accreditation, licensing or mandating of compliance with the revised AHEC guidelines.

A nationally-consistent approach to the development and/or use of embryos for the derivation of stem cells
8. Research with existing stem cell lines will be permitted to continue in Australia subject to observance of conditions set by NHMRC/AHEC.
9. Research and possible therapeutic applications which involve the destruction of existing excess ART embryos (or which may otherwise not leave the embryo in an implantable condition) will be permitted in accordance with the regulatory regime at appendix 1.
10. The ban on the development of embryos for purposes other than for assisted reproduction will be maintained and reviewed within three years taking into account the implications for therapeutic use of embryonic stem cells (as detailed in the Health Ministers' report, Chapter 4).

A nationally-consistent approach to ART
11. Accreditation by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia should provide the basis for a nationally-consistent approach to the oversight of ART clinical practice in Australia, noting that compliance with the NHMRC/AHEC Ethical Guidelines on ART is a key requirement of RTAC accreditation.
12. Individual jurisdictions may choose to mandate RTAC accreditation in legislation or supplement requirements for RTAC accreditation with an additional layer of oversight (for

example, through a system of licensing or accreditation of ART service providers).
13. Non-legislative measures should be implemented to improve clarity regarding the role of Human Research Ethics Committees in relation to innovative practice and to increase public reporting of research and innovative practice (as detailed in the Health Ministers' report, Chapter 5).

REGULATORY REGIME CRITERIA FOR RESEARCH USES OF EXCESS ASSISTED REPRODUCTIVE TECHNOLOGY (ART) EMBRYOS

Governments agree to put in place a strict regulatory regime under nationally-consistent legislation and administered by the National Health and Medical Research Council (NHMRC) as the national regulatory and licensing body. The NHMRC would issue a licence for a person to use an excess embryo from an ART programme for research or therapy that damages or destroys the embryo. A licence would only be issued where that project has the approval of an ethics committee established, composed and conducted in accordance with NHMRC guidelines, and that the approval is given on a case by case basis that:

- there is a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed procedure;
- the significant advance in knowledge or improvement in technologies could not reasonably be achieved by other means;
- the procedure involves a restricted number of embryos and a separate account of the use of each embryo is provided to the ethics committee and the national licensing body;
- all tissue and gamete providers involved and their spouses or domestic partners, if any, have consented to research for each embryo used, including by specifying restrictions, if they wish, on the research uses of such embryos; and
- the embryo had been created prior 5 April 2002.

These regulations will be reviewed within three years.