



Prohibition of Human Cloning for Reproduction and the Regulation of Human Research Amendment Bill 2006

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Law and Bills Digest Section

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Prohibition of Human Cloning for Reproduction and the Regulation of Human Research Amendment Bill 2006¹

Date introduced: 19 October 2006

House: Senate

Portfolio: Private Member's Bill (Senator Kay Patterson)

Commencement: The operative provisions commence on Royal Assent. The substantive provisions contained in Schedules 1 to 4 commence on the day after six months from Royal Assent.

Purpose

The Bill amends the *Prohibition of Human Cloning Act 2002*, the *Research Involving Human Embryos Act 2002* and the *Customs (Prohibited Exports) Regulations 1958* in order to implement *most* of the recommendations made by the Legislative Review Committee that had reviewed the operation of the two Acts in 2005.²

Structure of the Bills Digest

This Bills Digest is structured in the following way:

- | | |
|--|---------|
| • Background to the Bill, including: | |
| – Historical background | page 2 |
| – Scientific background | page 6 |
| – Policy background | page 11 |
| • International background | page 23 |
| • Ethical arguments regarding the human embryo | page 23 |
| • Main provisions | page 33 |

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Historical background

Human intervention in the creation and cessation of human life presents legislators with a vast array of scientific, moral and ethical concerns with which to grapple. Debates on issues such as IVF, abortion and human cloning have always been contentious because of the precious subject matter at its core, namely human life. Advances in scientific research in recent decades have meant that legislators both domestically and overseas have been asked to deal with very difficult issues associated with the development of human clones. The challenges presented by scientific research were well summarised in the following extract from the *Issues Paper* released in August 2005 by the Legislation Review Committee:

During the 1990s, research in assisted reproductive technology (ART) and human stem cells raised some new challenges. New techniques for creating a human embryo became possible, the creation of ‘Dolly’ the sheep in 1997 raised the possibility that cloning a human may become technically feasible, and research interest in cells taken from inside human embryos (so-called ‘embryonic stem cells’) increased. These developments raised significant ethical issues about how human embryos can be created, what forms of human reproduction are acceptable, and what research uses of human embryos should be permitted.³

In the 1990’s three States, Victoria, South Australia and Western Australia, enacted legislation purporting to ban human reproductive cloning and to regulate research on human embryos.⁴ This regulation evolved as part of the regulation of assisted reproductive technology (ART).⁵ Under the legislation, the definition of ‘cloning’ and ‘human embryo’ varied in each State and accordingly so did the research practices that were prohibited and permitted.⁶

All states and territories were also governed by the National Health and Medical Research Council’s (NHMRC) Ethical Guidelines,⁷ although it was argued that the NHMRC guidelines were only enforceable against institutions receiving NHMRC funding, and hence, a privately funded body would not need to comply with the guidelines.⁸ It was also noted that the prohibition on destructive research on embryos in each of the States that had legislation, conflicted with the NHMRC guidelines which permitted researchers to apply for a licence to conduct such research on ‘excess’ ART embryos.⁹

The legislation in Victoria, South Australia and Western Australia was enacted prior to the cloning of ‘Dolly’ the sheep by somatic cell nuclear transfer (SCNT) and it was uncertain whether the definitions and prohibitions specified in the legislation would effectively deal with the possibility of cloning.¹⁰

Therefore by 1999 there was no nationally consistent legislation and for those jurisdictions that did have legislation, it was unclear whether the legislation was adequate for the changes in the scientific environment.¹¹ In 1999 the House of Representatives Standing

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Committee on Legal and Constitutional Affairs, chaired by the Hon Kevin Andrews MP, established an inquiry to consider the issues.¹²

In 2000, the Commonwealth *Gene Technology Act 2000* was enacted which contained a prohibition on the cloning of whole human beings. The legislation contained yet another definition of cloning.¹³ It had limited coverage and applied. It applied to, amongst other areas, corporations, things done in the course of trade and commerce, things done that may spread the disease or pests, for purposes relating to statistics and actions by the Commonwealth or Commonwealth authorities.¹⁴

In August 2001, the House of Representatives Standing Committee on Legal and Constitutional Affairs Committee, released its report (the Andrews Report).¹⁵ The Andrews Report made a number of recommendations, including that the Commonwealth legislate to regulate human cloning and stem cell research.¹⁶ A useful summary of the stance taken by the Committee members is as follows.

The Andrews Report revealed that its Standing Committee members were divided on the issue of whether the creation of embryos via the SCNT process should be permitted in Australia. It noted that a majority of the Standing Committee supported this process being legalised, primarily on the basis of the potential for such research to develop stem cell therapies to treat various diseases. A minority of the Committee were opposed to such research due to concerns about the ethics of the destruction of human embryos for research, particularly as, at that time, the potential benefits of such research were highly speculative. ...

[T]he Standing Committee reached a consensus to recommend a three-year moratorium on the legislation of nuclear transfer, with the issue to be reviewed at the conclusion of that period.¹⁷

The council of Australian Governments (COAG) considered the Andrews Report's recommendations and in 2002 agreed that nationally consistent legislation should be introduced banning human cloning and some other related practices and regulating research involving excess ART embryos.¹⁸

In December 2002 the Federal Parliament enacted the *Prohibition of Human Cloning Act 2002* (PHC Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act). Together the Acts:

- prohibit human cloning and several other practices considered unacceptable¹⁹
- prohibit the creation of human embryos, by any means, for any purpose other than for attempting to achieve a pregnancy in a woman[, and]
- allow certain uses of excess human embryos created through ART under strict regulation and licence.²⁰

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After the enactment of the PHC Act and the RIHE Act, the States and Territories passed legislation which reflected these provisions to ensure that the legislation had national coverage.²¹

Background to the Lockhart Review

Both the PHC Act and the RIHE Act contain provisions specifying that an independent review of the operation of each Act needed to be undertaken two years after the Acts received Royal Assent.²² Both Acts also contain provisions requiring that the reviews be undertaken by persons agreed to by the Minister with the agreement of each State.²³

To meet these legislative obligations the Legislative Review Committee (LRC) was appointed in June 2005 to consider and report on the scope and operation of each of the Acts. The LRC was chaired by the Hon John S Lockhart AO QC. On 19 December 2005 the LRC gave its report, *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002*²⁴ (Lockhart Report), to the Federal Government.²⁵ The Lockhart Report contained 54 recommendations and suggested that the current legislative arrangements required significant change.

Federal Government Response to the Lockhart Review

In a press release dated 23 June 2006, the Prime Minister stated the following:

The Australian Government has considered the recommendations of the Lockhart Review. This is a difficult and complex issue on which many different views are held.

After careful reflection, the Government is not disposed to make any changes to the existing national legislative framework for research involving human embryos, agreed in 2002.

Recognising, however, the range of issues and views, there will be a detailed discussion on this issue within the Government parties when Parliament resumes for the Spring sitting.²⁶

Thereafter followed the meeting of COAG on 14 July 2006. The *Communique* describing COAG's views and course of action stated that:²⁷

COAG noted that agreement had not yet been reached across jurisdictions on all the 54 recommendations of the Lockhart Review Committee Report. However, COAG agreed that officials would continue to work on those Lockhart Review recommendations of an administrative nature on which there is agreement and report back to COAG by December 2006.

While COAG restated its preference for nationally consistent arrangements, in the absence of national agreement some States and Territories reserved the right to alter

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the legislation within their own jurisdictions to the extent that is within their power.
See: <http://www.coag.gov.au/meetings/140706/index.htm#Lockhart> .

After the 14 July COAG meeting general political debate about the issue continued. After lobbying by some Coalition backbenchers, Cabinet level and Coalition party room discussions occurred and the Prime Minister indicated that if the matter came before Parliament, Coalition parliamentarians could vote according to their conscience, as was the case in 2002.²⁸ The leader of the opposition indicated that Labor Party members would do the same.²⁹

The subsequent political debate has culminated in the generation of two Bills dealing with stem cell issues. The first, a joint Bill sponsored by Senator Stott Despoja (Australian Democrats) and Senator Webber (Australian Labor Party) Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006 was released as an exposure draft on 14 September 2006.³⁰ The second, a Bill sponsored by Senator Patterson (Liberal Party) Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 released an exposure draft on 26 September 2006 and was introduced to the chamber. This Bill was then subsequently introduced into the Senate on 19 October 2006.

The Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 includes amendments permitting therapeutic cloning or SCNT for research, training and clinical application, for both human embryo clones and animal-human hybrid embryo clones. This raises a number of new areas that requires further examination. These include:

Scientific background

This part of the Digest explains the basic scientific principles associated with creation of an embryo by natural means and by human cloning.

Creation of the human embryo

The basic steps for natural creation of a human embryo are as follows and are illustrated in diagrams 1 and 2.

Fertilisation

The sperm inseminates the oocyte. Between 12 - 20 hours after the sperm has inseminated the oocyte two pronuclei are formed in the cytoplasm of the egg around the maternal and paternal chromatids and two polar bodies are formed in the perivitelline space.

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Zygote stage

Approximately 20 hours after the sperm enters the oocyte, the pronuclear membranes dissolve and the maternal and paternal chromosomes combine. Almost immediately (and without reformation of the nuclear membrane), the chromosomes align for the first cell division (a process known as syngamy).

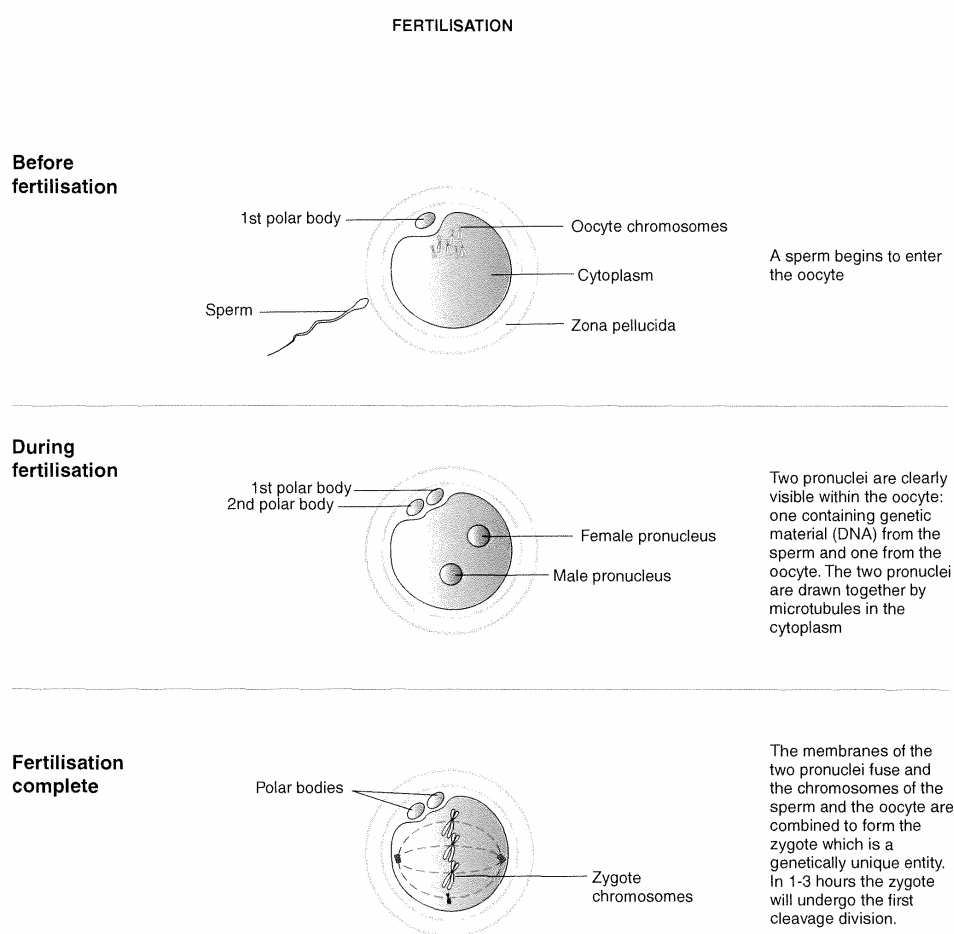


Diagram 1: Fertilisation.

Source: Discussion Paper: Human Embryo – A Biological Definition (NHMRC) 2005.

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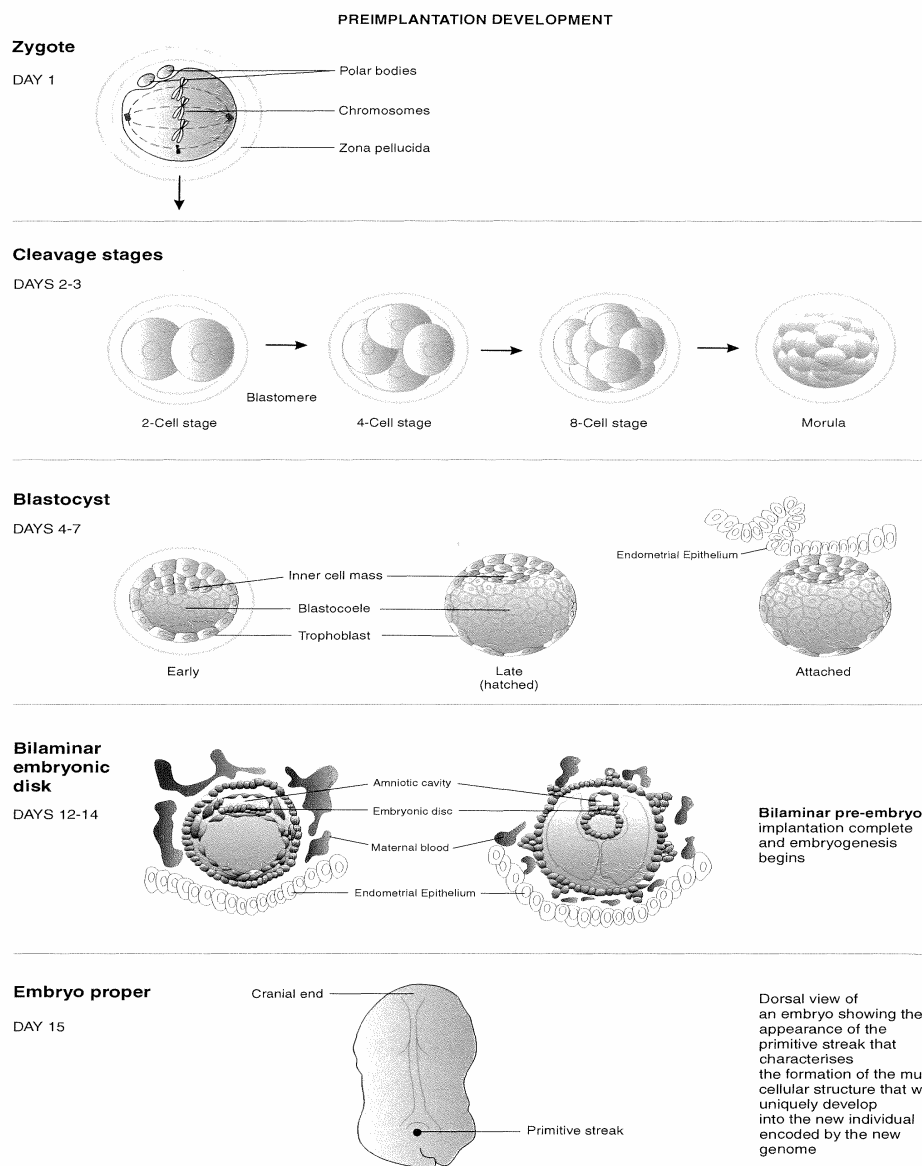


Diagram 2: Pre-implantation Development.

Source: Discussion Paper: Human Embryo – A Biological Definition (NHMRC) 2005.

The NHMRC working party on the definition of the human embryo concluded that syngamy is the most appropriate marker for the completion of fertilisation because this is when the genome of the new entity is created.³¹ However, as syngamy is difficult to visualise: the earliest point at which fertilisation can be visually confirmed is the first mitotic cell division (cleavage).

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Cleavage and Blastocyst stages

During days 2-3, the zygote goes through its first cell division and its progeny also divide several times thereafter to form a compact ball of cells called the morula. As the cells continue to divide, the morula enlarges to form a hollow sphere called a blastocyst. The cells in the outer layer of the blastocyst give rise to a placenta and other supporting tissues. The cells in the centre give rise to the developing body layers of the evolving embryo and foetus, and ultimately to all the organs and tissues of the body. The cells of the inner cell mass can be extracted from the blastocyst and cultured to derive embryonic stem cells.

Cloning

The following discussion sets out basic scientific information regarding cloning.

Cloning is a type of asexual reproduction that results in the production of an organism which is a genetic copy of another organism. Two types of cloning are important to keep in mind; 'reproductive cloning' and 'therapeutic cloning'. There seems to be general societal agreement that reproductive cloning is unacceptable and it is banned in Australia. There is a far greater divergence of views, however, in relation to therapeutic cloning. Although it is currently banned in Australia, a general consensus has not been reached as to whether it should be permitted in future.

Forms of cloning

Embryo clones may be created by a variety of methods including:

- Somatic cell nuclear transfer (SCNT) which is explained below
- Parthenogenesis; which has been performed on some mammals and occurs where egg cells have been stimulated to divide into embryos without fertilisation by sperm. Researchers have so far been unable to grow embryos to maturity
- Splitting an embryo at the early cell division stage, similar to the natural process by which monozygotic ('identical') twins are formed, and
- Inserting an embryonic cell nucleus into the oocyte cytoplasm after removal of the original oocyte nucleus.

Although embryonic cloning can occur naturally in humans, the scientific techniques of cloning usually differs from the basic steps that are gone through in the natural development of a human embryo and the following discussion deals with cloning by SCNT.

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Therapeutic cloning and somatic cell nuclear transfer

SCNT involves taking an egg cell (oocyte), removing the cell's nucleus (which contains almost all of the genetic material), and replacing it with another cell nucleus from another cell, usually a somatic cell (although other cells such as embryonic stem cells may be used). Scientists then use certain means (commonly an electric current), to induce the enucleated egg and its new nucleus to fuse and develop into an embryo.

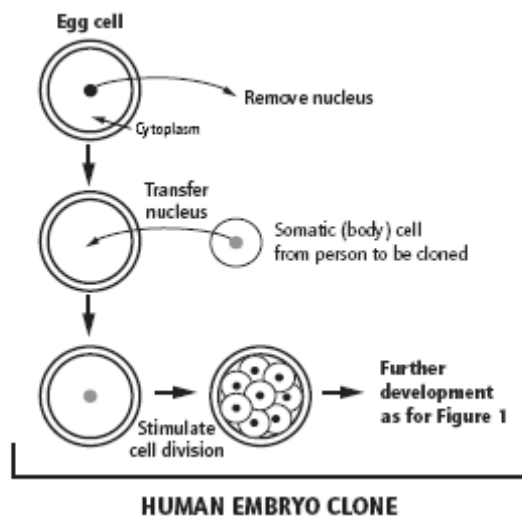


Diagram From Appendix 2 Issues Paper Lockhart Review

Because the nucleus contains most of the DNA of an organism, the embryo is genetically identical to the person from whom the somatic cell was taken (hence the term 'clone' is used). (nb except for the mitochondrial DNA which is in any embryo).

Reproductive cloning

If the embryo is transferred back to the uterus of the female and developed into a foetus, this is reproductive cloning.

Therapeutic cloning and production of embryonic stem cells

The embryo may, however, be cultured to the blastocyst stage at which point the embryonic stem cells are removed from the embryo. These embryonic stem cells can then be used for research or treatment (hence the term 'therapeutic cloning' is used). The removal of the embryonic stem cells destroys the capacity of the embryo to continue to grow and develop. However, recent advances suggest that it may soon be possible to remove one or two individual cells from the blastocyst or early morula without destruction

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of the embryo (in a technique similar to that used for pre-implantation genetic diagnosis). The cell or cells removed can be grown up into a pluripotent embryonic stem cell line. The embryo can continue its development. There is some speculation over whether the foetus and ultimately baby developed would be affected by the loss of an early embryonic cell.³²

Although the terms therapeutic cloning and SCNT are used interchangeably, SCNT is considered to be the more accurate of the two terms and is now in common scientific usage. Professor Alan Trounson, from the Australian Stem Cell Centre, argues that:

We're not cloning in the sense that people understand we're cloning...Nor, necessarily are we focused on a therapeutic. So somatic cell nuclear transfer is more descriptive of what we're trying to do.³³

Embryonic stem cells and adult stem cells

Stem cells come in two forms; embryonic stem cells and adult stem cells.

Embryonic stem cells

Human embryonic stem cells were first isolated in 1998.³⁴ Embryonic stem cells are *pluripotent cells*, which means that they have the capacity to turn into any cell type in the adult body. Technically, totipotent cells can differentiate into any cell type, including into cells of the placenta and other supporting tissues. Such cells are only present for the first few divisions after fertilisation. Cells thereafter are referred to as pluripotent, and can give rise to any cells of the body except placental and related tissues. Further differentiation results in multipotent stem cells. A multipotent cell can turn into a defined set of related cell types, for example different types of blood cell, but not into any cell type.]As noted above, they are extracted from the human embryo at the blastocyst stage of embryonic development. They can be extracted from an embryo created either through the sperm/egg fertilisation process or from an embryo created by artificial means such as SCNT.

Currently in Australia, researchers have access to some embryonic stem cells under the NHMRC licensing regime. Where embryos have been created for the purpose of assisted reproduction therapy (ART) such as in vitro fertilisation (IVF) but they are excess to the patients' needs, they may be donated to research. Researchers may apply to the NHMRC for a license to use these excess embryos for different purposes including the harvesting of embryonic stem cells. Currently the NHMRC had received four applications and four licences have been granted for research to derive ES cell lines.

Adult stem cells

Most tissues and organs in the adult human body have some adult stem cells (adult here means post-birth). Adult tissues in which stem cells that have been identified include skin, intestine, liver, brain and bone marrow.³⁵ Adult stem cells are *multipotent cells* as opposed

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to pluripotent cells and hence are limited in what they can become and in what they can be used for. They can only differentiate into a set of defined cell types but cannot become any type of cell.

Policy background

Policy arguments and Lockhart recommendations relating to embryonic stem cells

A range of policy issues have been canvassed during the debate on whether to permit SCNT/ cloning. The following is a brief discussion of these issues.

Therapeutic benefit of stem cells

The *Issues Paper* from the LRC provided the following explanation of why some scientists are interested in stem cells:

Stem cells are of great interest to researchers because of their potential to regenerate damaged or diseased tissues. The treatment of leukaemia patients with bone marrow containing blood stem cells from compatible donors has been a routine procedure since the 1970s. Since that time, scientists have hoped to develop other stem cell therapies. Stem cells also provide a good model for research on the development and function of different cell types and the features of certain cellular disease states. Embryonic stem cells have attracted particular interest because they are pluripotent.

Stem cells from human embryo clones have attracted additional interest because they provide an opportunity to obtain embryonic stem cells that are a precise match for the person of whom the human embryo clone is a copy. Treatment of this person with their own matched stem cells would prevent immune rejection problem and/or avoid having to wait for a suitable matched donor. The same would be true of adult stem cells if they were obtained from a person requiring stem cell treatment.³⁶

Therefore the main reasons for supporting stem cell research is the potential for therapeutic benefits including:

- treatment of serious and currently untreatable conditions³⁷
- studying disease states,³⁸ and
- screening new drugs.³⁹

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Embryonic stem cells from ART and embryonic stem cells derived from SCNT

Currently the use of excess ART embryos under licence has led to the development of a number of embryonic stem cell lines. Researchers in the area have however advocated for the creation of embryonic stem cell lines from embryos cloned through SCNT. The Lockhart Report stated that this would be beneficial because:

further development in this area of research requires the creation of human embryo clones to generate embryonic stem cells that are either patient matched for the development of specific cellular therapies or of known genotype for disease modelling and other research.⁴⁰

In essence, researchers argue that the development of individually DNA matched stem cells (which is made possible through SCNT) will overcome the problems of tissue rejection when treating patients. It is also argued that the development of SCNT stem cell carrying genetic disorders will be useful as scientists will be able to watch the cells grow and, hence, understand the development of complex diseases. Stem cells from SCNT could also lead to the identification of drugs and treatment for diseases.⁴¹ Therefore, there is specific interest in embryonic stem cells that are derived from SCNT (ie, cloning) because of the benefits of generating donor matched cells.

Currently the law does not permit SCNT and hence the generation of stem cell lines from SCNT.⁴² The Lockhart Report examined the issue of whether the law should be changed to permit SCNT. The following is a summary of some of the arguments considered in the Lockhart Report.

Embryonic stem cells versus adult stem cells

During the course of the stem cell debate one of the areas of contention that has arisen has been whether research using embryonic stem cells will produce outcomes that are different to research carried out on adult stem cells. If research on each type of stem cell produced the same result, this would weaken the argument in favour of using SCNT.

Whilst it is clear that embryonic and adult stem cells have different characteristics, in 2001 there was no agreement among scientists about whether research on adult or embryonic stem cells would produce different or more scientifically successful outcomes, particularly in relation to organ transplants.⁴³ The Lockhart Report noted that in 2001, many researchers considered that research involving both should continue until their efficacy became clearer.⁴⁴

The Lockhart Report documented arguments which suggested that embryonic stem cells could achieve different results to adult stem cells. It also noted evidence given that arguing that using adult stem cells would achieve similar outcomes.⁴⁵ The Lockhart Report also noted that there had been developments in the use of adult and embryonic stem cells since

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2001. It concluded that the potential for each of the type of stem cells was unclear however, that:

based especially on the evidence of experts who work directly in one or both fields of stem cell research (adult or embryonic), that further research involving both adult and embryonic stem cells is required to improve knowledge and to develop effective disease treatments⁴⁶

Scientific developments in human cloning and the use of embryonic stem cells

The Lockhart Report considered whether there had been any changes in the scientific landscape since 2001. If changes in the scientific state of play had occurred then it could be argued that the law should be revised so that it stays in step with scientific developments. Since the release of the Lockhart Report there have also been additional reports commissioned by Australian governments which have examined scientific developments, including:

- a report commissioned by the Department of Prime Minister and Cabinet titled *Analysis of advice on developments in assisted reproductive technology and related medical and scientific research* (mpconsulting report) and
- a report commissioned by the Victorian Department of Innovation, Industry and Regional Development titled, *Key Recent Advances in Human Embryonic Stem Cell Research, A Review of Scientific Literature*.

The Lockhart Report concluded that research into stem cells has been extremely active since 2002.⁴⁷ It also noted that there had been developments in research on somatic cell nuclear transfer.⁴⁸

The mpconsulting report focused on changes in the ‘state of play’ in relation to ART and related research since the passage of the PHC Act and the RIHE Act. The mpconsulting report classified ‘a change in the state of play’ as being the raising of new issues (be they scientific developments, unintended consequences of the legislation, or new ethical arguments) that were not considered in 2002 but had been raised and considered in the context of the LRC’s review of the legislation in 2005.⁴⁹ The report focused particularly on the definition of human embryo, the creation and use of embryos for ART research and the creation of embryos for stem cell research.⁵⁰

The report concluded that ‘on each of these issues it would appear, based on a consideration of relevant materials, that there has not been any significant change in the state of play since 2002’.⁵¹ Despite this conclusion, the report did, however, state in the section on stem cell research that ‘it is clear that there have been developments since the legislation was introduced in 2002’.⁵²

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On 8 September 2006, the Victorian Government released a report prepared by Dr. Nicholas Gough FTSE for the Victorian Department of Innovation, Industry and Regional Development', which set out a 'scientific summary of key recent advances in human embryonic stem cell research and key recent advances with respect to Somatic Cell Nuclear Transfer (SCNT).'⁵³ This report documented that there had been relevant scientific developments both in the fields of embryonic stem cells and SCNT since 2002.

Safety and other concerns

The Lockhart Report also noted other arguments put forward for opposing therapeutic cloning included:

- that there are safety concerns, such as whether stem cells derived from SCNT are 'sufficiently normal to allow their use as therapeutic agents in human medicine,⁵⁴ and
- that there are difficulties in monitoring the activities to determine whether the activities are reproductive cloning or therapeutic cloning.⁵⁵

Moral and ethical concerns

The issue of therapeutic cloning raises significant moral and ethical questions. The Lockhart Report noted that:

the main objection to ES cell research is because of ethical concerns about the destruction of human embryos.⁵⁶

Issues relating to the moral and ethical aspects of therapeutic cloning are discussed in more detail below.

Lockhart Report Recommendations relating to embryonic stem cells and SCNT

After weighing up the various arguments, the Lockhart Report recommended that human somatic cell nuclear transfer should be permitted (**recommendation 23**). The Bill implements this recommendation. This recommendation is limited by the current provisions in the PHC Act that prohibit:

- development of human embryos created by any means beyond 14 days gestation in any external culture or device, and
- implantation into the reproductive tract of a woman of a human embryo created by any means other than fertilisation of an egg by a sperm.

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Policy arguments and Lockhart recommendations relating to the definition of the human embryo

Many of the provisions in the PHC Act and RIHE Act rely on the term human embryo. Currently human embryo is defined in section 8 of the PHC Act and section 7 of the RIHE Act as:

A live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pronuclei or the initiation of its development by other means.

The NHMRC conducted investigations into the adequacy of the current definition of human embryo and considered that the current definitions contained some limitations which needed to be addressed. The NHMRC noted that problems with the current definition related to natural fertilisation, artificial fertilisation and individuals with DNA from more than one species.

Natural fertilisation

The current definition of human embryo refers to the appearance of the first two pronuclei. This has been regarded as being too restrictive for research purposes. The Lockhart Report, for example, stated the following:

The definition of a human embryo in the Acts (RIHE Act s7 and PHC Act s8) starts from the appearance of two pronuclei. This prevents any research requiring experimental fertilisation of an egg with sperm because, once the two pronuclei are visible (the earliest biological marker for such research), an embryo has been created and creation of a human embryo for research contravenes the PHC Act s14. These provisions prevent a range of research to improve IVF, including maturation of oocytes, testing of sperm quality and fertilisation research.⁵⁷

It went on to explain that:

Under the current definition of a human embryo, researchers are not able to undertake experimental fertilisation studies because the legislation requires the process to cease before the two pronuclei are formed – thereby preventing the researcher from confirming that fertilisation has occurred⁵⁸

As a result, the NHMRC recommended moving the point in time in which an embryo, formed through fertilisation of an oocyte with a sperms, is taken to be regarded as having been created, to the first mitotic cell division. The NHMRC argued that this should be the point in time where an embryo is regarded as being created because by that point in time the genome for the entity has been created and it is the earliest point after creation of the genome that scientists can actually visualise this milestone.⁵⁹

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Artificial fertilisation

The NHMRC also noted that there are a number of emerging technologies that produce embryos that do not involve the contribution of DNA from both sperm and egg such as SCNT. The NHMRC considered that the current definition of human embryo does not accommodate these new technologies and hence considered that it should be amended.⁶⁰

Moral/ethical considerations

Drafting a definition of a human embryo does raise a large number of moral and ethical considerations. These are explored in further detail below.

Lockhart recommendations

The NHMRC recommended that changes be made to the definition of human embryo. The Lockhart Report recommended that the legislation should be changed to address concerns (**recommendation 28**). The Bill implements these recommendations.

Policy arguments and Lockhart recommendations relating to the effect of the RIHE Act and the PHC Act on ART research

The Lockhart Report found that research to improve the success of ARTs (such as in vitro fertilisation - IVF) has been hampered as a result of the RIHE Act and the PHC Act. The Lockhart Report stated that:

The overwhelming response to the reviews from ART providers and researchers was that the legislation has impeded research to improve ART technologies that was active before the legislation was passed.⁶¹

Whilst it is beyond the scope of this Digest to explore all of these issues in depth, the following are examples of some of the areas identified in the Lockhart Report, that have been regarded as impeding ART research and clinical practice.⁶²

In vitro maturation of oocytes

The culture, and then maturation, of oocytes under laboratory conditions – in vitro maturation – (IVM) is regarded by researchers as being a process that could produce a variety of advantageous scientific outcomes.⁶³ The Lockhart Report noted that the development of technology to enable IVM is currently being impeded by the current legislative arrangements. The Lockhart Report explains that

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IVM is a complex procedure in which both the nucleus and the cytoplasm of the oocyte need to be brought to precisely the right point of maturity to allow fertilisation with a sperm.⁶⁴:

Determining the right point of maturity could happen by fertilising the oocytes. The Lockhart Report stated that following:

Dr John McBain, Director, Melbourne IVF, told the Committee that the biggest effect of the Act has been prevention of work on in vitro maturation of oocytes from frozen ovarian tissues. These oocytes cannot be fertilised under the current definition of embryo because the legislation requires the process to cease just before the two pronuclei are formed – thereby preventing the researcher from confirming fertilisation.⁶⁵

As noted above, the Lockhart Report proposed changes to the current definition of human embryo to address this problem.

One other way of determining the right point of maturity for IVM is through parthenogenesis. The Lockhart Report noted that currently IVM oocytes cannot be parthenogenetically activated to test their activation potential because parthenogenetic activation of oocytes is illegal under the PHC Act.⁶⁶ The Lockhart Report recommended that intentional parthenogenetically activation of oocytes should be permitted, under licence, for development for up to 14 days. The report also recommended that implantation of the oocyte into the women's reproductive tract should continue to be prohibited (**recommendation 16, 3 and 4**).

Human-animal hybrid embryos

The Lockhart Report noted that the prohibition of creation of human–animal hybrid embryos (PHC Act s20), combined with the current definition of an embryo, has also prevented research or testing requiring fertilisation.⁶⁷

The Lockhart Report explained that

For example, ART researchers and practitioners were previously able to undertake fertilisation studies using human sperm and animal oocytes (eg hamster) to test sperm quality.⁶⁸

The report noted that they are no longer able to do this as a result of section 20 of the PHC Act. The report went on to recommend that the legislation be changed to permit the creation of human-animal hybrids up to the point but not including the first cell division to allow testing of human gamete maturity or viability (**recommendation 17**).

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Non availability of fresh embryos for research

The Lockhart Report noted that the creation of a human embryo for any purpose other than to achieve a pregnancy in a woman prevents the creation and use of fresh embryos for research. The Lockhart Report noted that:

Some ART researchers indicated that a number of valuable studies could be done if it were possible to use embryos created from eggs and sperm specifically for research up to the stage of implantation. This is prohibited by current legislation.....⁶⁹

The Lockhart Report rejected the idea of permitting the creation of human embryos specifically for research purposes, apart from that permitted under **recommendation 15**.

Excess embryos

The Lockhart Report noted that provisions of the RIHE Act for declaring embryos to be excess ART embryos and giving proper consent for research has operated to prevent the immediate (fresh) availability of ART embryos for research.⁷⁰ The report stated that:

The current legislation also prohibits the use of fresh excess ART embryos through the consent process. The 14 day cooling-off period that is required after embryo donors give consent for a specific research project but before the embryo is used (see Sections 11.1 and 11.2) limits the use of fresh embryos.⁷¹

The Lockhart Report recommended that the NHMRC Australian Health Ethics committee should review its guidelines for consent (**recommendation 29**) with a view to easing this problem.

Embryos unsuitable for implantation

The Lockhart Report also noted that embryos that are not suitable for implantation for any reasons are allowed to die and are not available for research despite the fact that such embryos would be a useful source of fresh embryos for research, training and quality assurance activities.⁷²

The Lockhart Report recommended that embryos that are unsuitable for implantation should be permitted to be used for research, training and improvements in clinical practice. It also recommended that objective guidelines be drawn up for use in determining when an embryo is unsuitable for implantation (**recommendations 20-22**).

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Cytoplasmic transfer

Cytoplasmic transfer has been used as a fertility treatment overseas, particularly for older women. It has also been flagged as a possible treatment for the prevention of mitochondrial disease. Research on cytoplasmic transfer in Australia has been prohibited since 2002 because it would lead to the creation of a human embryo containing genetic material provided by more than two persons (currently section 15 and 18 of the PHC Act).

The Lockhart Report stated that:

It is the Committee's view that cytoplasmic transfer offers potential for the treatment of mitochondrial disease and to improve fertilisation for some women. Therefore consideration should be given to research, under licence, on this procedure.

Recommendation 19 of the Lockhart Report reflects this conclusion.

Other aspects of the licensing system

Licensing of researchers

The Lockhart Committee identified three areas of concern in relation to having prescriptive legislation in relation to these issues.⁷³ One of these was a lack of legal protection for researchers.⁷⁴ It noted that a researcher who had been granted a licence by the NHMRC Licensing Committee would have no defence if a court subsequently found that the actual licence contravened the legislation.⁷⁵ The other concerns identified by the Lockhart Committee were related to the difficulties associated with drafting legislation in relation to rapidly changing technology and in the interpretation of the legislation.⁷⁶

Accordingly, the Lockhart Committee made **recommendations 50–52**. The Revised Explanatory Memorandum explains:

Those recommendations suggest that the NHMRC Licensing Committee should be given the power to give legally binding rulings on the interpretation of the legislation and that a person who conducts research on the basis of a ruling should be protected from liability under the legislation.⁷⁷

However, the Revised Explanatory Memorandum goes on to explain that this latter recommendation (**recommendation 52**) 'raises significant constitutional issues relating to the impermissible exercise of judicial power by a non-judicial body.'⁷⁸

Monitoring powers

The Lockhart Committee reported that:

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The processes that have been put in place for monitoring compliance with the legislation and facilitating compliance are generally regarded as suitable, although suggestions for improvements to the system were also made. It is clear that there is a major deficiency in the legislation with regard to the limited powers of the inspectors appointed under the RIHE Act to monitor activities that are not covered by a licence. As a result of this deficiency, suspected breaches by non-licence holders cannot be adequately investigated.⁷⁹

Further, the Lockhart Committee reported that it had heard that in relation to licensed premises inspectors are not empowered to make unannounced inspections and this inhibits their ability to investigate suspected breaches of the legislation.⁸⁰ The Lockhart Committee stated that its view was that ‘inspectors should have adequate powers under both Acts to investigate suspected breaches of either Act.’⁸¹ It also commented that ‘[t]here is a legal question whether these powers already clearly exist’.⁸²

Accordingly, the Lockhart Committee recommended that:

- the NHMRC Licensing Committee continue to perform its functions (**recommendation 38**), and
- NHMRC Licensing Committee inspectors be empowered under both Acts, if such powers do not clearly exist, to enter and inspect non-licensed facilities with the same enforcement powers and pursuant to the same requirements as relate to search warrants under Commonwealth legislation (**recommendation 39**).⁸³

The NHMRC Licensing Committee

The Lockhart Committee reported that there was widespread support of the NHMRC Licensing Committee for its regulatory oversight of the type of research the subject of review.⁸⁴

One particular problem identified by the Lockhart Committee was that:

due to the specific expertise of each Licensing Committee member, a vacancy on the committee poses a significant problem, because licensing applications cannot be handled effectively. As appointment to the committee involves approval by all States and Territories, there have been lengthy delays in filling vacancies. The [Lockhart] Committee noted that there is not scope in the [RIHE] Act as presently framed to address this problem, which is because the Licensing Committee is a national committee that oversees research in all States and Territories. The Committee therefore draws this to the attention of the Australian Parliament and the [COAG] for consideration and recommends that they give urgent attention to this problem.⁸⁵

The recommendation is **recommendation 36**.

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Export of reproductive material to be permitted for ART treatment

At present the *exportation* from Australia of a human embryo is prohibited unless permission has been granted by the Minister for Customs pursuant to regulation 7 of the *Customs (Prohibited Exports) Regulations 1958*.⁸⁶ This regulation provides that an application to the Minister for such permission may only be made in certain limited circumstances, namely:

- ‘by the prospective mother or, in the event that the prospective mother has died, the spouse of the prospective mother at the time that the embryo was created or donated’,⁸⁷ and
- ‘for the sole purpose of implantation in the prospective mother or a relevant woman (as described in the Regulations) to achieve her pregnancy’.⁸⁸

The Lockhart Committee reported that it had:

heard from ART consumers that the current export prohibitions and custom regulations regarding human embryos have made it difficult for couples to *export* their embryos overseas for their own reproductive use. The Committee’s view is that the current arrangements, which involve personal application to the Minister for Customs to export embryos for personal reproductive use, are too cumbersome and stressful for users and should be streamlined.⁸⁹ [Emphasis added]

Accordingly, in **recommendation 41**, the Lockhart Committee recommended that the *import*⁹⁰ or *export* of a patient’s reproductive material for their own ongoing ART treatment should only be subject to existing quarantine regulation.⁹¹

Establishment of a national stem cell bank and national register of excess ART embryos

The Report by the Lockhart Committee states:

As the number of human stem cell lines has increased throughout the world, it has become apparent that there is a need for the creation of stem cell registries and stem cell banks to enable researchers to locate cell lines of interest, along with appropriate information about source and quality. While the current focus of interest in stem cell banks is on the registration and storage of embryonic stem cell lines for research, it is possible that in subsequent years advances in stem cell engineering and transplant immunology may mean that stem cell banks also come to fulfil an important clinical function.⁹²

The Lockhart Committee reported its view that:

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an Australian national stem cell bank would make stem cells, including embryonic and adult stem cells, more widely available to researchers and also limit the number of embryos required for further derivation of stem cell lines.⁹³

Accordingly, the Committee recommended that a national stem cell bank be established (**recommendation 47**).

The Committee also recommended that a national register of donated excess ART embryos be established (**recommendation 49**).⁹⁴ In the Committee's view, the functions of such a register could be to:

- facilitate embryo donation for research
- provide a transparent record of the number of donated excess ART embryos held, and,
- possibly, facilitate embryo donation to another couple.⁹⁵

Further review of the Acts

As mentioned above, the Lockhart Committee had 'heard a number of concerns about the capacity of legislation to respond to research needs in a fast-moving area of technology.'⁹⁶ In view of these 'fast moving developments in the field'⁹⁷ and because of the number of amendments proposed by the Lockhart Committee, **recommendation 53** suggested that both Acts 'should be subject to further review either six years after royal assent of the current Acts or three years after royal assent to any amended legislation.'⁹⁸

International background

It is beyond the scope of this Digest to cover the international state of play in relation to cloning and stem cell development. For a recent comparative overview of regulatory frameworks for stem cell and cloning research in 50 countries, refer to 'Beyond the Permissibility of Embryonic and Stem Cell Research: Substantive Requirements and Procedural Safeguards'.⁹⁹

Ethical arguments regarding the human embryo

Permitting SCNT or the use of excess ART embryos for scientific purposes raises significant arguments about the moral status of the human embryo.

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Is the stem cell debate a political debate?

Any developments and advances, whether they are societal or technological, require constant identification, analysis and, if necessary, regulation. Such regulation most commonly is achieved through laws – either by application of existing laws or through the creation of new ones. Existing laws can be utilised by expanding their application as the result of judicial interpretation. However, where courts are unable to stretch the application of a particular law far enough to bring the development or advance within its reach, it can become necessary for lawmakers to provide new, or modify existing, regulatory frameworks.

In 2002, the Australian Federal Parliament was faced with the task of reacting to new developments in molecular genetics and biomedicine. It passed new legislation to regulate human cloning and provided a regime for research involving human embryos.

With this Bill, Federal Parliament is again concerned with this issue, proposing to pass amendments that will refine and develop the existing legislation concerning reproductive and other forms of cloning, combining countervailing and adaptive regulatory measures to accommodate the scientific advances that occurred since the last debates in Parliament.

It is not difficult to predict that the ensuing parliamentary debate will be passionate and controversial. Vigorous debates ensued the last time this topic was discussed in Parliament.¹⁰⁰

Parliament is regularly confronted with the proposals to implement complex and/or controversial policies. Controversy is usually the result of different political ideologies or agendas. Complexity is often caused by the need to skilfully craft very complex legal solutions to implement policies; sometimes the legal complexity of the proposed laws is part of the controversy.

This Bill is very controversial. This is not necessarily due to different political ideologies; rather the controversy arises because the proposed changes are founded upon significant moral and ethical considerations of the genesis and evolution of life.

As these considerations are guided strongly by personal beliefs and convictions rather than by political views, it seems only proper that the ensuing debate is not conducted along party lines. This is not a political, but a personal debate.

The ensuing debate strikes at the heart of humanity and dignity. The following brief discourse is not an attempt to give conclusive answers to any of the issues which may influence the debate. Rather, it is to serve as an overview of the underlying moral and ethical considerations, their origins and, if possible, as a primer for further thought. As such it is aimed at avoiding a reduction of the debate to a ‘battle of beneficial and knowledgeable cleverness versus ignorant and superstitious anxiety.’¹⁰¹

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Creation and destruction – of what?

At the outset, it is important to identify the core and scope of the controversy surrounding stem cell research.

The sliding scales of controversy

There is a sliding scale of controversy depending upon the source of the stem cells.

The less controversial sources include those that do not require the destruction of a blastocyst, a form of embryo developed at the earliest stages of embryogenesis.¹⁰² Examples include adult stem cells or stem cells derived from the blood of the umbilical cord.¹⁰³ Some jurisdictions have decided that the use of stem cell lines that are already in existence raise fewer moral objections. Prominently, the United States and Germany have decided to prohibit the creation of stem cell lines, but permitted research on lines that were already in existence at the time the prohibition came into force or was announced. The underlying arguments for this distinction are discussed further below in the context of differentiating between the *creation* and the *use* of stem cells.¹⁰⁴

The more controversial sources include those that require the harvesting of stem cells from embryos that were:

- created and stored in the context of an assisted reproductive program for an individual couple for the purpose of procreation or overcoming childlessness
- created for the purpose of producing stem cells for therapeutic purposes (therapeutic cloning), or
- the result of procedures resulting in a *chimeric* or *hybrid* embryo.

These sources for stem cells are more controversial because their harvesting will require the embryo's destruction.¹⁰⁵ This destruction poses one of the central ethical quandaries for this debate.

The substance of the controversy

The substance of this controversy relates to the moral *status* of the embryo. What will be destroyed when the stem cells are harvested: a plain cell mass or an early embryo? If it is an early embryo, is it already human life with the same moral status as a human being? Or does this early embryo constitute ante-nascent human life, which has not gained sufficient personality or 'personhood'; that is, it has not yet acquired the same moral status as a born human being? And, finally, is there a moral difference between an embryo created by sperm and egg and those created by SCNT, parthenogenesis or other laboratory means?

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The answers are important because *born* human life is considered to have the highest moral status that correlates with the full protection against destruction. This protection stems from concepts such as inviolable human dignity and human rights. The intentional destruction of a born human being is generally considered homicide. Thus, if it is argued that the embryo possesses the same moral status as a born human being, the logical consequence is inescapable: the destruction of this embryo equates to homicide.

If it can be reasoned that the embryo is merely a cell mass or an early embryo without the same moral status when compared to born human life, its intentional destruction would not necessarily equate to homicide. To argue in favour of the destruction of an embryo without moral status would reduce or even fully eliminate the moral or ethical dilemma.

These considerations amount to the search for a justification of why the destruction of an embryo is not homicide which is deemed by society to be the most reprehensible of all crimes. Two threshold questions underpin these considerations, including:

- *when* does life begin—to assess whether a blastocyst is in fact a new life or independent organism,¹⁰⁶ and
- whether the moment in which a new life begins *also* the moment in which a human being begins—that is, to assess the moral *status* of the blastocyst.

A further issue discussed in the literature is whether the *purpose* for which the embryo was created should be considered in the context of this debate.

The complexity of genesis and evolution: when does life begin?

Two immediately obvious moments mark the point in time in which a new life or ‘the life of a new organism’ may begin.¹⁰⁷ The first moment is the conception or cell fusion, that is, the moment in which oocyte and sperm amalgamate. The second possible moment is the birth of a human being itself. Neither can be discredited comprehensively. However, there are also strong arguments in favour of why one moment is considered too early and the other too late.

The interim period between conception and birth is marked by a continuum of evolutionary steps. Examples from the early stages of this evolution include the:

- fusion of the genetic material of the oocyte and the sperm
- completion of fertilisation with the creation of the zygote, a genetically unique entity
- end of the first mitotic cell division
- formation of the blastocyst
- development of the primitive streak, or
- the development of blood in the foetus.

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At least theoretically, each of the above moments could be the point in time in which life commences. Indeed, all of them have been used to define this moment.

The choice of one moment in time over the other is generally rationalised based on a belief system or conviction, promoting arguments derived, for example, from science or religion.

However, regardless of the persuasiveness of the supporting arguments, the fact remains that any point in time within this continuum of evolution will be an arbitrary point with the potential to spark considerable disagreement. German philosopher Jürgen Habermas noted that:

The fact that every attempt to draw a definite line somewhere between fertilization, or the fusion of nuclei, on the one hand, and birth on the other hand is more or less arbitrary because of the high degree of continuity prevailing in the development from the organic origins to, first, life capable of feeling and, then, to personal life.¹⁰⁸

For him, the very fact of the continuum between conception and birth speaks against any attempt to ascertain an absolute beginning for the purpose of lawmaking.

Does the beginning of 'life' mark the beginning of a 'human being'?

A separate question is whether the moment in which life begins is also the moment in which life assumes the qualities of born human life or a human being. Conceptually, the discussion considers that even if it is possible to determine exactly when life commences, further developmental steps are required to form a human being and the acquisition of a moral status is gradual.

If this proposition is accepted, then it follows that the protection that correlates with the moral status also increases gradually during the embryogenesis. The apex of this gradual acquisition of moral status and protection is reached with the birth of the human being.

For example, despite accepting that a human embryo is a member of the human species, 'not a member of some other species such as frogs or cows', Harvard Professor D W Brock has noted that:

[...] this is not sufficient to give it the same moral status as humans who are incontestably persons. That is because the moral status of human persons does not derive simply from their species membership. Rather, it must be some properties of humans that endow them with personhood and in particular make it seriously wrong to kill them.¹⁰⁹

Whilst this distinction seems somewhat artificial, it is quite common. In her book *Stem Cells, Controversy at the Frontiers of Science*, science journalist and biochemist Elizabeth Finkel has written that the Catholic church is taking the view that the question when an embryo acquires 'personhood' or the moral status of a 'human being' is governed by

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science rather by theology.¹¹⁰ Accordingly, this varied throughout history. According to Finkel, this point is currently reached with the fusion of female and male genetic material, that is, after conception.¹¹¹

Other Christian churches and religions apparently also distinguish between the creation of life and the acquisition of personhood. Finkel refers to examples from the Anglican Church, Judaism and Islam, all of which believe in the gradual evolution of personhood over time. Interestingly, the author reports that Judaism and Islam consider this evolution to be completed after a period of forty days – the time Catholic cleric and philosopher Thomas Aquinas assigned to the ‘ensoulment’ of an embryo.¹¹²

Two issues are, however, important to note. First, despite apparently accepting the acquisition of personhood at a later stage than conception, the Catholic church deems the protection of human life to attach from the moment of conception.

Second, the observation that Christian teachings advocated the gradual acquisition of personhood is controversial. Professor G Dunstan, who is one of the leading proponents of the gradual acquisition and claimed that the full protection of even the early embryo from the point of fertilisation is a result of late-19th century Christian teachings, has recently been challenged.¹¹³

Professor D A Jones argues that Professor Dunstan’s work is based on the omission of important authorities, and is reliant on flawed sources and the failure to distinguish between divergent categories.¹¹⁴ He is particularly critical of Professor Dunstan’s conclusions that the medieval western church believed in a delay between fertilisation and ‘ensoulment’, arguing that this conclusion is derived from a flawed early translation of the Bible. In his opinion, throughout Christian history, the deliberate destruction even of early embryonic life was considered to be homicide.¹¹⁵

Whether a human embryo is a human life with a moral status equal to that of born human life is also an influential issue during any abortion debate. American medical doctor and biochemist Leon R Kass, Chair of the *President’s Council of Bioethics* between 2002 and 2005, suggested that these debates are ‘analogous, if not identical’.¹¹⁶ And British Theologist Robin Gill discussed the re-emergence of the ‘gradualist position’ abortion debates, applying it to the stem cell debate.¹¹⁷ However, despite obvious similarities, questions have been asked whether sound and neutral arguments differentiating between an early embryo such as a blastomere facing destruction and a foetus facing abortion can be derived from the abortion debates.¹¹⁸ For example, Habermas observed that although the abortion debates alert society to the issue of the ‘moral status of the unborn life’:

all attempts to describe early human life in terms that are neutral with respect to world views, that is, not prejudging, and thus not acceptable for all citizens of a secular society, have failed.¹¹⁹

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Divorcing the commencement of life from the moment in which life acquires the status of a human being offers two advantages to the proponents of stem cell research and the legislature, including that it:

- allows arguments in favour of the destruction of the early embryo without the need to justify further the moral implications of the destruction of the embryo, and
- creates a new category of prenatal life – a human embryo without, or with only limited, moral status – which can be used by the legislature as the subject matter of a new legal framework.

It is important to realise, however, that the gradual acquisition of personhood takes place in the same continuum in which the commencement of life takes place – the period between conception and birth. This gradual acquisition may even continue after birth. Therefore, it must be stressed that any attempt to specify individual grades of moral status along the time line between conception and birth are inevitably arbitrary. Parallels to the discussion in relation to the genesis of life referred to above are in order. Thus, to mark the line when a human embryo is deemed to have acquired a moral status sufficient to refute any justification of its destruction is likewise arbitrary. Consequently, the criticism that such arbitrariness confounds any attempt to draw a line as the basis for legal implications in this period must apply here as well.¹²⁰

The relevance of the 'purpose' for the creation

A further distinction used to justify the destruction of early embryos is based on differentiating between purposes for which embryos are created. The key issue is to assign a different moral status to the embryo depending upon the purpose for which it was created. This approach is often chosen to overcome the apparent inconsistency between:

- permitting, accepting or tolerating the destruction of embryos created as the result of an assisted reproductive treatment (ART), and
- opposing the destruction of embryos when they were created for research.

Embryos created for their use in an ART program are initially created for the purpose of procreation or, as it is also put, to overcome childlessness. As soon as one of these embryos is successfully implanted and continues to develop, the other embryos become excess material. They are no longer needed for their intended purpose.

Theoretically, such excess embryos can be kept in cryostorage over prolonged periods of time.¹²¹ However, whilst some embryos will already not survive the freezing or thawing process, the majority will later be discarded, that is, destroyed. This destruction is in some cases permitted, or in many Australian States even mandated by law, and it seems that it is generally morally accepted or at least tolerated.¹²² On the other hand, the thought of creating embryos for the sole purpose of consumption through research is not always met with the same tolerance or acceptance.¹²³ For example, Professor Habermas calls this

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‘conditionally created human life’ that is instrumentalised by researchers for an ulterior purpose.¹²⁴

There have been moral concerns against the creation of embryos with a view to destroying them for research purposes. To discredit a distinction based upon the purpose for which the embryo was created, it has been argued that if:

embryos may be used for research into the causes of treatment infertility, [...] it is inconsistent to reject research into the possible treatment of serious invalidating diseases as being not sufficiently important.¹²⁵

Or, similarly:

once they accept the creation and sacrifice of embryos to benefit infertile people with a child-wish, they do not have a sound reason to condemn the creation and sacrifice of embryos to benefit ill and injured people who could be helped by stem cell therapies.¹²⁶

The distinction between use and creation

As has been noted above, some jurisdictions have based their legislative framework on the understanding that the use of stem cell lines that are already in existence raise fewer moral objections. For example, the US and Germany have decided to prohibit the creation of stem cell lines, but permitted research on lines which were already in existence at the time the prohibition came into force or was announced.

One German politician who supported Germany’s ban on stem cell research with newly created stem cell lines reportedly stated that:

The “killing of embryos for research purposes must remain illegal” [...] But “we cannot cancel” the fact that embryos were already killed for existing cell lines.¹²⁷

This view underlies the value judgement that:

An embryo, which has been created in vitro, must be consumed neither for research not for therapeutic purposes, but must – in line with its natural “telos” – be given the chance instead of developing into a human being and of being born.¹²⁸

The US administration used a similar rationale and value judgement to justify its decision to make federal funding of stem cell research dependent upon the cells’ existence at the moment in time the policy was announced.¹²⁹

To permit the use of stem cells whilst prohibiting their creation allows scientists to research with existing lines without having to face the moral dilemmas arising from the need to destroy embryos in order to obtain lines.

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It has been noted that this:

Distinction between use and derivation is neither cynical nor disingenuous for it reflects the basic distinction in the ethics of complicity between causing an immoral or wrongful act to occur and benefiting from it once it has occurred.¹³⁰

Distinguishing between research with stem cells that already have been created at a particular point in time and those which would require the destruction of further embryos has been likened to the use of organs from a murder victim, that is, the gain of a benefit from a wrongful act.¹³¹

The rights and freedoms debate

In addition to the issues discussed above, the justification debates often invoke the rights or freedoms of a particular class of stakeholders. A detailed discussion of the arguments comprising this debate would go beyond the scope of this Digest; however, some of the key aspects of these debates should be highlighted here, including:

- a woman's right to choose to donate her eggs—is this right absolute or should it be restricted to protect embryos? In addition, should it be restricted to protect women from being exploited for commercial reasons?
- the scientists' freedom of research and their entitlement to explore this avenue—can or should this freedom be legitimately restricted and if so, on what grounds?
- a person's right to optimal treatment for a disease—can the legislature deny a human being the chance of being cured from a grave illness or is there an overriding concern that society at large may face dire consequences as the result of the research?

Generally, these aspects raise issues such as the absoluteness of a right of freedom, and, if it is found not to be absolute, how far it may be restricted. This balancing exercise regularly invokes inquiries into the proportionality of a restricting measure.

Further issues

The slippery slope: the road to reproductive cloning?

There is a fear that permitting therapeutic cloning will ultimately lead to cloning for reproductive purposes: it is the first step on slippery slope towards the cloning of a human being.

The *slippery slope* argument is founded on the prediction that a particular outcome will inevitably occur if a certain preceding step is taken.¹³² Thus, engaging the slippery slope argument equates to the prediction that the knowledge gained from therapeutic cloning is the preceding step that will inevitably lead to research into reproductive cloning. Pointing

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out that the slippery slope in relation to stem cell research is an inevitability, Leon R Kass notes that:

Despite the naïve hopes of many, neither will be able to defend the boundary between therapy and genetic enhancement. [...] the genetic genie, first unbottled to treat disease, will go its own way, whether we like it or not.¹³³

However, the slippery slope argument has also met with resistance. For example, some authors argue that appropriate laws and powerful oversight authorities will provide sufficient safeguards against sliding down the slope.¹³⁴ Others argue that the ‘presumed automatism’ of the continued development towards human cloning ‘is disputable’.¹³⁵ There are, however, scientists who already entertain arguments in favour of human reproductive cloning. It is argued that IVF and reproductive cloning are, in essence, both reproductive technologies. Thus, the moral justification using IVF should, by analogy, also apply to justifying developing human reproductive cloning research.¹³⁶

The trend to normalisation

A separate issue that is, however, closely linked to the slippery slope argument, is the phenomenon that society has a general tendency towards normalisation, that is, people get used to developments and processes once they are set in motion and become more common.¹³⁷ Thus, it has been argued that once research into therapeutic cloning yields its first promising results or, later, even therapeutic successes, society will become accustomed to the issue and moral concerns subside. In support of this proposition, comparisons have been drawn between the debates surrounding other medical developments that were regarded by many, at least initially, morally or ethically controversial or plain wrong. Examples where normalisation occurred include heart transplantation procedures which were considered wrong, too dangerous or even to be ‘playing God’.¹³⁸ Similarly, IVF was initially extremely controversial. Today, these procedures are ‘an accepted part of modern medicine’¹³⁹ and ‘highly valued by both the scientific and lay communities.’¹⁴⁰

An attack on equality?

Especially in the initial stages where new treatments are available, the clinical application of such treatments is possibly so costly that it may only be available to those who have the required financial means. Whether this exclusiveness can comply with demands of equality in society. This concern has been rebutted by Dworkin, who argues that the initially limited availability will, in the long term, result in developments and discoveries of much more general application.¹⁴¹

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Excessive control and the genetic identity of the human being

It has been suggested that mastering any cloning technique would allow the human species to gain too much control over nature. In turn, this control over nature has the potential to blur the line between choice and chance, a significant dichotomy underlying our moral framework.¹⁴² Thus, the answers we find based on values, beliefs and convictions, are critical to our understanding of our species and our moral underpinnings. As Professor Dworkin notes:

The crucial boundary between chance and choice is the backbone of our ethics and our morality, and any serious shift in that boundary is seriously dislocating.¹⁴³

However, it must also be noted that shifts in moral values *are* quite common in society and it has been noted that the last decades have seen:

Significant revolutions in what counts as an object of moral concern—the civil rights revolution, the women’s liberalisation movement, the rise of environmentalism and environmental ethics, and the animal rights movements.¹⁴⁴

The interference with the genetic integrity of human beings may also lead to a change in the genetic identity of a person. This new or altered identity can be used as a reference point for establishing the ‘otherness’ of people and therewith an alteration of the perception of equality. Querying whether a human being is nature’s creation or ours, Habermas has asked whether we:

May [...] consider the genetic self-transformation and self-optimisation of the species as a way of increasing the autonomy of the individual? Or will it undermine our normative self-understanding as person leading their own lives and showing one another equal respect?¹⁴⁵

That there is the potential for a different normative self-understanding of humans as a result of genetic medicine has recently surfaced in relation to persons who are the result of assisted conception. The ABC reported in its *7:30 Report* that these so-called ‘test-tube babies’ struggle to come to terms with their often unknown genetic heritage, feel like a ‘product’ of reproductive technology rather than a human being and perceive ‘a lack of identity’.¹⁴⁶

Financial implications

Both the Explanatory Memorandum and the Revised Explanatory Memorandum are silent on the issue of financial implications. It is not evident that there will be a financial impact on the Commonwealth.

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Main provisions

Schedule 1 of the Bill amends the PHC Act and **Schedule 2** amends the RIHE Act. The Explanatory Memorandum states that the amendments are consistent with the LRC's recommendations.¹⁴⁷ **Schedule 3** is a saving provision which outlines the effect the Bill will have, once passed, on applications for licences not yet decided and on licences already issued (existing licences are to continue in force). **Schedule 4** amends the *Customs (Prohibited Exports) Regulations 1958* by repealing regulation 7. This regulation prohibits the export of human embryos except in certain limited circumstances where Ministerial permission has been granted. The main provisions of Schedules 1, 2 and 4 are dealt with thematically rather than numerically. Schedule 3 is not discussed further.

Definition of human embryo

Aspects of the legislative scheme to change

The current definition of 'human embryo' in both Acts (subsection 8(1) of the PHC Act and subsection 7(1) of the RIHE Act) is repealed and replaced with the following:

human embryo means a discrete entity that has arisen from either:

- (a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
- (b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;

and has not yet reached 8 weeks of development since the first mitotic division.

The Lockhart Committee recommended that the definition of a 'human embryo' that is used in both Acts should be changed (**recommendation 28**).¹⁴⁸ The Explanatory Memorandum notes that the definition proposed in the Bill differs from that recommended by the Lockhart Committee in its report.¹⁴⁹ It explains that:

- the Lockhart Report used a draft definition devised by the NHMRC
- the definition proposed in this Bill is the NHMRC's final version, and
- members of the Lockhart Committee have since stated that it was their intention to use the final definition developed by the NHMRC.¹⁵⁰

The Explanatory Memorandum states that the key differences between this definition and the current definition in the Acts are:

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- *the point at which a human embryo is defined to commence existence.* The identification of the first mitotic division as the time when fertilization is complete and the time at which the fertilized egg becomes an embryo. This recognises that fertilization is a process and that an embryo does not arise until the process is complete; and
- *the definition used for embryos created other than by human egg and sperm.* In the new NHMRC definition, the capacity to develop to the stage of the appearance of the “primitive streak” is taken as the marker of an entity that is an embryo. This is a conservative definition and acknowledges that entities such as those that have arisen by SCNT are indeed embryos.¹⁵¹ [Emphasis added]

New paragraphs 8(8)(a) and (b)¹⁵² of the PHC Act and new paragraphs 7(5)(a) and (b) of the RIHE Act clarify that references in each Act to a human embryo do *not* include references to a hybrid embryo or a human embryonic stem cell line.

Aspects of the legislative scheme to remain the same

In working out the length of the period of development of a human embryo any period when the development of the embryo is suspended¹⁵³ is not included (current subsection 8(3) of the PHC Act and current subsection 7(2) of the RIHE Act).

Licensing of the creation and use of embryos and use of human eggs

Currently, subsection 20(1) of the RIHE Act only permits a person to apply to the NHMRC Licensing Committee for a licence authorising use of excess ART embryos.¹⁵⁴ **New subsection 20(1) of the RIHE Act** will contain a similar provision but will also permit persons to apply for licences in relation to a number of other activities. These activities are currently prohibited and involve the creation and/or use of other embryos and the use of human eggs. These changes are detailed below.

Before discussing the new permitted activities, it should be noted that **new subsection 24(1) of the RIHE Act** provides that such licences will be subject to the condition that:

- each person donating an embryo or egg must have given proper consent¹⁵⁵ to the creation or use¹⁵⁶ of that embryo or egg and
- the licence holder must have reported in writing to the NHMRC Licensing Committee that such consent has been obtained, and any restrictions to which the consent is subject.

This reflects **recommendation 31** of the Lockhart Report.

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Creation, development and/or other use of embryos

Creation, development and/or other use of human embryo clones

As noted above, subsection 8(1) of the PHC Act defines a human embryo clone as ‘a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by human sperm.’

Aspects of the legislative scheme to change

Currently, section 9 of the PHC Act stipulates that it is a criminal offence intentionally to create a human embryo clone with a maximum penalty of 15 years’ imprisonment.

As there is no equivalent provision in **new Part 2 of the PHC Act**, the Bill effectively implements the Lockhart Committee’s recommendations to permit the creation of human embryo clones in some circumstances (**recommendations 23–25**). The Explanatory Memorandum explains that the change will permit human embryo clones to be created for research up to 14 days if the creation is licensed.¹⁵⁷

New paragraph 20(1)(b) of the RIHE Act provides that a person may apply for a licence authorising:

- the creation of human embryos other than by fertilisation of a human egg by a human sperm, and
- use of such embryos.

New subsection 20(1A) of the RIHE Act confirms that the NHMRC Licensing Committee is not permitted to authorise any use of the embryo that would result in development for longer than 14 days (excluding any period when development is suspended).

It is a criminal offence, with a maximum penalty of:

- 5 years’ imprisonment, to intentionally engage in use without a licence authorising the use by that person (**new section 10A of the RIHE Act**), and
- 10 years’ imprisonment, to intentionally engage in creation or development without a licence authorising the creation or development by that person (**new section 22 of the PHC Act**).

New section 23C of the PHC Act provides that Regulations are to be made *permitting*, subject to appropriate conditions or restrictions, the *import or export of human embryonic stem cell lines* which have been *derived from human embryo clones* using practices consistent with Australian legislation. This reflects the Lockhart Committee’s **recommendation 42**.

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It will be a criminal offence, with a maximum penalty of 15 years' imprisonment, to:

- develop a human embryo (including a human embryo clone)¹⁵⁸ outside the body of a woman for more than 14 days (**new section 14 of the PHC Act**), or
- place a human embryo clone in the human body or the body of an animal (**new section 9 of the PHC Act**).

At present, these activities are criminal offences in the PHC Act (current sections 16 and 10 respectively) but the maximum penalty is 10 years' imprisonment. On 7 November 2006, the Senate passed an amendment moved by Senator Stott Despoja, also on behalf of Senator Webber, to increase the maximum penalty from 10 years' imprisonment to 15 years' imprisonment.

Aspects of the legislative scheme to remain the same

It is, and will remain, a criminal offence, with a maximum penalty of 15 years' imprisonment, to intentionally:

- import a human embryo clone into Australia (current subsection 11(1); **new subsection 10(1) of the PHC Act**), or
- export a human embryo clone from Australia (current subsection 11(2); **new subsection 10(2) of the PHC Act**).

The Bill also retains the provision that stipulates that it is not a defence to an offence under **new section 9** or **new section 10 of the PHC Act** that the human embryo clone did not survive or could not have survived (**new section 11 of the PHC Act**). This provision is essentially the same as current section 12 of the PHC Act.

Creation, development and other use of human embryos containing genetic material provided by more than 2 persons

Currently, section 15 of the PHC Act stipulates that it is a criminal offence, with a maximum penalty of 10 years' imprisonment, for a person to intentionally create or develop a human embryo containing genetic material provided by more than 2 persons.

The Bill seeks to implement the Lockhart Committee's **recommendations 13 and 26**,¹⁵⁹ and accordingly distinguishes between creation of such a human embryo by a process:

- of the fertilisation of a human egg by a human sperm outside a woman's body, and
- other than the fertilisation of a human egg by a human sperm.

(See the section below which prohibits the creation of a human embryo by a process of the fertilisation of a human egg by a human sperm outside a woman's body for a purpose

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other than achieving pregnancy in a woman (**new section 12 of the PHC Act** implementing the Lockhart Committee's **recommendation 13**)).

Aspects of the legislative scheme to change

New paragraph 20(1)(c) of the RIHE Act provides that a person may apply for a licence authorising:

- the creation of human embryos *other* than by fertilisation of a human egg by a human sperm that contain genetic material provided by more than 2 persons, and
- use of such embryos.

The penalty regime devised by **new subsection 20(1A) and new section 10A of the RIHE Act** applies. For details see discussion above.

It will also be a criminal offence, with a maximum penalty of 15 years' imprisonment, to intentionally:

- create or develop a human embryo *by a process of the fertilisation of a human egg by a human sperm outside a woman's body* where the human embryo contains genetic material provided by more than 2 persons (**new section 13 of the PHC Act**)¹⁶⁰
- develop a human embryo outside the body of a woman for more than 14 days (**new section 14 of the PHC Act**)
- place a embryo in a woman's body knowing that, or being reckless as to whether, the embryo is a human embryo containing genetic material provided by more than 2 persons (**new subsection 20(3) and new paragraph 20(4)(c) of the PHC Act**)
- import an embryo into Australia knowing that, or being reckless as to whether, the embryo is a human embryo so created (**new subsection 20(1) and new paragraph 20(4)(c) of the PHC Act**), or
- export an embryo from Australia knowing that, or being reckless as to whether, the embryo is a human embryo so created (**new subsection 20(2) and new paragraph 20(4)(c) of the PHC Act**).

At present, these activities are criminal offences in the PHC Act (current section 13;¹⁶¹ section 16; subsection 22(3) and paragraph 22(4)(c); subsection 22(1) and paragraph 22(4)(c); subsection 22(2) and paragraph 22(4)(c) respectively), but the maximum penalty is 10 years' imprisonment. This change in maximum penalty is the result of amendments in the Senate on 7 November 2006.

The retention of the provision in the third bullet point (disregarding the change in maximum penalty) reflects the Lockhart Committee's **recommendation 8**.

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Creation, development and other use of a human embryo using precursor cells from a human embryo or a human fetus

Currently section 17 of the PHC Act provides that it is a criminal offence, with a maximum penalty of 10 years' imprisonment, to:

- use precursor cells taken from a human embryo or a human fetus, intending to create a human embryo, or
- intentionally develop such an embryo.

The Bill seeks to implement the Lockhart Committee's **recommendation 27**.¹⁶²

Aspects of the legislative scheme to change

New paragraph 20(1)(d) of the RIHE Act provides that a person may apply for a licence authorising:

- the creation of human embryos using precursor cells from a human embryo or a human fetus, and
- use of such embryos.
- **PHC Act**).

The penalty regime devised by **new subsection 20(1A) and new section 10A of the RIHE Act** applies. For details see discussion above.

It will also be a criminal offence, with a maximum penalty of 15 years' imprisonment, to intentionally:

- develop a human embryo outside the body of a woman for more than 14 days (**new section 14 of the PHC Act**)
- place an embryo in a woman's body knowing that, or being reckless as to whether, the embryo is a human embryo created using precursor cells taken from a human embryo or a human fetus (**new subsection 20(3) and new paragraph 20(4)(e) of the PHC Act**)
- import an embryo into Australia knowing that, or being reckless as to whether, the embryo is a human embryo that was so created (**new subsection 20(1) and new paragraph 20(4)(e) of the PHC Act**), or
- export an embryo from Australia knowing that, or being reckless as to whether, the embryo is a human embryo that was so created (**new subsection 20(2) and new paragraph 20(4)(e) of the PHC Act**).

At present, the activities outlined in these four bullet points are criminal offences in the PHC Act (current section 16; subsection 22(3) and current paragraph 22(4)(e); subsection 22(1) and paragraph 22(4)(e); subsection 22(2) and paragraph 22(4)(e) respectively) but

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the maximum penalty is 10 years' imprisonment. This change in maximum penalty is the result of amendments in the Senate on 7 November 2006.

The retention of the provision in the second bullet point (disregarding the change in maximum penalty) reflects the Lockhart Committee's **recommendation 9**.

Creation, development and other use of hybrid embryos

Currently, subsection 20(2) of the PHC Act stipulates that it is a criminal offence, with a maximum penalty of 10 years' imprisonment, to intentionally *create* a hybrid embryo.¹⁶³ There is no specific prohibition on the *development* of such an embryo.

The Bill seeks to implement the Lockhart Committee's **recommendation 17**.¹⁶⁴

Originally the Bill also sought to implement **recommendation 24**.¹⁶⁵ This recommendation is as follows.

In order to reduce the need for human oocytes, transfer of human somatic cell nuclei into animal oocytes should be allowed, under licence, for the creation and use of human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.¹⁶⁶

However, the relevant provisions which would have implemented this recommendation were removed from the Bill in the Senate. Accordingly, now **recommendation 24** is not accepted.¹⁶⁷ This change is explained further below.

Aspects of the legislative scheme to change

New paragraph 20(1)(f) of the RIHE Act provides that a person may apply for a licence authorising:

- the creation of hybrid embryos by the fertilisation of an animal egg by a human sperm, and
- use of such embryos up to, but not including, the first mitotic division

provided the creation or use is for the purposes of testing sperm quality, and the creation or use will occur in an accredited ART centre.¹⁶⁸

On 7 November 2006 the Senate passed an amendment moved by Senator Bartlett to delete **new paragraph 20(1)(g) of the RIHE Act**. That paragraph would have provided that a person may apply for a licence authorising:

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- the creation of hybrid embryos by introducing the nucleus of a human cell into an animal egg, and
- use of such embryos.

New subsection 20(1A) of the RIHE Act would have confirmed that in this latter mentioned case the NHMRC Licensing Committee was not permitted to authorise any use of the embryo that would result in development for longer than 14 days (excluding any period when development is suspended). However, as the Senate passed an amendment removing new paragraph 20(1)(g) of the RIHE Act, it also passed an amendment removing the reference to new paragraph 20(1)(g) in new subsection 20(1A).

It will be a criminal offence, with a maximum penalty of:

- 5 years' imprisonment, to intentionally use a hybrid embryo without a licence authorising the use by that person (**new section 10A of the RIHE Act**)
- 10 years' imprisonment, to intentionally create or develop a hybrid embryo without a licence authorising the creation or development by that person (**new section 23B of the PHC Act**), and
- 15¹⁶⁹ years' imprisonment, to intentionally develop a hybrid embryo for a period of more than 14 days, excluding any period when development is suspended¹⁷⁰ (**new section 18 of the PHC Act**).

It will be a criminal offence, with a maximum penalty of 15 years' imprisonment, to intentionally:

- place an embryo in the body of a woman knowing that, or being reckless as to whether, the embryo is a hybrid embryo (**new subsection 20(3) and new paragraph 20(4)(h) of the PHC Act**)
- import an embryo into Australia knowing that, or being reckless as to whether, the embryo is a hybrid embryo (**new subsection 20(1) of the PHC Act**), or
- export an embryo from Australia knowing that, or being reckless as to whether, the embryo is a hybrid embryo (**new subsection 20(2) and new paragraph 20(4)(h) of the PHC Act**).

At present the activities outlined in these three bullet points are criminal offences in the PHC Act (current subsection 22(3) and paragraph 22(4)(h); subsection 22(1); subsection 22(2) and paragraph 22(4)(h) respectively) but the maximum penalty is 10 years' imprisonment. This change in maximum penalty to 15 years is the result of amendments in the Senate on 7 November 2006.

The retention of the provision in the first of the above three bullet points (disregarding the change in maximum penalty) reflects the Lockhart Committee's **recommendation 5**.

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Creation and use of chimeric embryos

Subsection 8(1) of the PHC Act states that a chimeric embryo is a:

- human embryo into which a cell, or any component part of a cell, of an animal has been introduced, or
- thing declared by the Regulations to be a chimeric embryo.

Aspects of the legislative scheme to change

It will be a criminal offence, with a maximum penalty of 15 years' imprisonment, to intentionally:

- create a chimeric embryo (**new section 17 of the PHC Act**)
- place an embryo in the body of a woman knowing that, or being reckless as to whether, the embryo is a chimeric embryo (**new subsection 20(3) and new paragraph 20(4)(h) of the PHC Act**)
- import an embryo into Australia knowing that, or being reckless as to whether, the embryo is a chimeric embryo (**new subsection 20(1) of the PHC Act**), or
- export an embryo from Australia knowing that, or being reckless as to whether, the embryo is a chimeric embryo (**new subsection 20(2) and new paragraph 20(4)(h) of the PHC Act**).

At present, these activities are criminal offences in the PHC Act (current subsection 20(1); subsection 22(3) and paragraph 22(4)(h); subsection 22(1); subsection 22(2) and paragraph 22(4)(h) respectively) but the maximum penalty is 10 years' imprisonment. This change in maximum penalty to 15 years is the result of amendments in the Senate on 7 November 2006.

The retention of the first provision (disregarding the change in maximum penalty) reflects the Lockhart Committee's **recommendation 6**,¹⁷¹ and retention of the second provision (disregarding the change in maximum penalty) reflects **recommendation 5**.

Creation or development of a human embryo for a purpose other than achieving pregnancy in a woman

Aspects of the legislative scheme to change

It will be a criminal offence, with a maximum penalty of 15 years' imprisonment, to intentionally *create a human embryo by a process of the fertilisation of a human egg by a human sperm outside a woman's body* unless the person's intention in creating the embryo is to attempt to achieve pregnancy in a particular woman (**new subsection 12(1) of the PHC Act**).

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At present, this activity is a criminal offence in the PHC Act (current subsection 14(1)) but the maximum penalty is 10 years' imprisonment. This change in maximum penalty to 15 years is the result of amendments in the Senate on 7 November 2006.

Aspects of the legislative scheme to remain the same

The defendant does not bear the evidential burden (current subsection 14(2); **new subsection 12(2) of the PHC Act**) in relation to the above mentioned offence.

The Explanatory Memorandum states that **new section 12 of the PHC Act** reflects the Lockhart Committee's **recommendations 12 and 13**.¹⁷²

It is, and will remain, a criminal offence, with a maximum penalty of 5 years' imprisonment, to intentionally *use outside a woman's body a human embryo that was created by a process of the fertilisation of a human egg by a human sperm* and that is not an excess ART embryo and the use is not for a purpose relating to the assisted reproductive technology treatment of a woman carried out by an accredited ART centre and the person knows or is reckless as to that fact (current section 11;¹⁷³ **new section 11 of the RIHE Act**).

Removal of a human embryo from a woman's body with the intention to collect a viable embryo/placement or other use of such an embryo

Aspects of the legislative scheme to change

It will be a criminal offence, with a maximum penalty of 15 years' imprisonment, to:

- remove a human embryo from a woman's body with the intention to collect a viable human embryo (**new section 16 of the PHC Act**)
- intentionally place such a removed embryo into a woman's body knowing that, or being reckless as to whether, the human embryo was so removed (**new subsection 20(3) and new paragraph 20(4)(g) of the PHC Act**)
- intentionally import such a removed embryo into Australia knowing that, or being reckless as to whether, the human embryo was so removed (**new subsection 20(1) and new paragraph 20(4)(g) of the PHC Act**), or
- intentionally export such a removed embryo from Australia knowing that, or being reckless as to whether, the human embryo was so removed (**new subsection 20(2) and new paragraph 20(4)(g) of the PHC Act**).

At present, these activities are criminal offences in the PHC Act (current section 19; subsection 22(3) and paragraph 22(4)(g); subsection 22(1) and paragraph 22(4)(g); subsection 22(2) and paragraph 22(4)(g) respectively) but the maximum penalty is 10

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years' imprisonment. This change in maximum penalty to 15 years is the result of amendments in the Senate on 7 November 2006.

The retention of the first provision (disregarding the change in maximum penalty) reflects the Lockhart Committee's **recommendation 11**.¹⁷⁴

Alteration to genome of a human cell/Use of embryo containing altered human cell

Aspects of the legislative scheme to change

It will be a criminal offence, with a maximum penalty of 15 years' imprisonment, to:

- alter the genome of a human cell (that is, a human embryonal cell, a human fetal cell, human sperm or a human egg)¹⁷⁵ in such a way that the alteration is heritable by descendants of the human whose cell was altered, intending the alteration to be so heritable (**new subsection 15(1) of the PHC Act**)
- place an embryo in a woman's body knowing that, or being reckless as to whether, the embryo is a human embryo that contains a human cell with such an altered genome (**new subsection 20(3) and new paragraph 20(4)(f) of the PHC Act**)
- import an embryo into Australia knowing that, or being reckless as to whether, the embryo is a human embryo that contains a human cell with such an altered genome (**new subsection 20(1) and new paragraph 20(4)(f) of the PHC Act**), or
- export an embryo from Australia knowing that, or being reckless as to whether, the embryo is a human embryo that contains a human cell with such an altered genome (**new subsection 20(2) and new paragraph 20(4)(f) of the PHC Act**).

At present, these activities are criminal offences in the PHC Act (current subsection 18(1); subsection 22(3) and paragraph 22(4)(f); subsection 22(1) and paragraph 22(4)(f); subsection 22(2) and paragraph 22(4)(f) respectively) but the maximum penalty is 10 years' imprisonment.

The Explanatory Memorandum explains that the provision in the first bullet point above:

bans what is commonly referred to as germ line gene therapy. In germ line gene therapy, changes would be made to the genome of egg or sperm cells, or even to the cells of the early embryo. The genetic modification would then be passed on to any offspring born to the person whose cell was genetically modified and also to subsequent generations.¹⁷⁶

The retention of the provision in the second bullet point (disregarding the change in maximum penalty) reflects the Lockhart Committee's **recommendation 10**.

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Placement or other use of prohibited embryos

Aspects of the legislative scheme to remain the same

The Bill retains the current definition of ‘prohibited embryo’ (current subsection 22(4); **new subsection 20(4) of the PHC Act**).¹⁷⁷ The provisions concerning some prohibited embryos have already been addressed.¹⁷⁸ Other human embryos which come within the definition of a ‘prohibited embryo’ include a human embryo:

- created by a process other than the fertilisation of a human egg by a human sperm (current paragraph 22(4)(a); **new paragraph 20(4)(a) of the PHC Act**)
- created outside the body of a woman, unless the intention of the person who created the embryo was to attempt to achieve pregnancy in a particular woman (current paragraph 22(4)(b); **new paragraph 20(4)(b) of the PHC Act**), and
- that has been developing outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended (current paragraph 22(4)(d); **new paragraph 20(4)(d) of the PHC Act**).

Aspects of the legislative scheme to change

It will be a criminal offence, with a maximum penalty of 15 years’ imprisonment, to intentionally:

- place an embryo in a woman’s body knowing that, or being reckless as to whether, the embryo is a prohibited embryo (**new subsection 20(3) of the PHC Act**)
- import an embryo into Australia knowing that, or being reckless as to whether, the embryo is a prohibited embryo (**new subsection 20(1) of the PHC Act**), or
- export an embryo from Australia knowing that, or being reckless as to whether, the embryo is a prohibited embryo (**new subsection 20(2) of the PHC Act**).

At present, these activities are criminal offences in the PHC Act (current subsections 22(3), (1) and (2) respectively) but the maximum penalty is 10 years’ imprisonment. This change in maximum penalty to 15 years is the result of amendments in the Senate on 7 November 2006.

The relevant Lockhart Committee recommendation, in relation to the first provision, is **recommendation 3** which provides that ‘[i]mplantation into the reproductive tract of a woman of a human embryo created by any means other than fertilisation of an egg by a sperm should continue to be prohibited.’¹⁷⁹

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Other provisions concerning the placement of human embryos

Aspects of the legislative scheme to change

It will be a criminal offence, with a maximum penalty of 15 years' imprisonment, to intentionally place a human embryo in:

- an animal (**new subsection 19(1) of the PHC Act**), or
- the body of a human, other than in a woman's reproductive tract (**new subsection 19(2) of the PHC Act**).

At present, these activities are criminal offences in the PHC Act (current subsections 21(1) and (2) respectively) but the maximum penalty is 10 years' imprisonment. This change in maximum penalty to 15 years is the result of amendments in the Senate on 7 November 2006.

The Explanatory Memorandum states that the retention of these provisions (disregarding the change in maximum penalties) reflects the Lockhart Committee's **recommendation 7**.¹⁸⁰

Placement of animal embryos

Aspects of the legislative scheme to change

It will be a criminal offence, with a maximum of 15 years' imprisonment, to intentionally place an animal embryo in a human's body for any period of gestation (**new subsection 19(3) of the PHC Act**).

At present, this activity is a criminal offence in the PHC Act (current subsection 21(3)) but the maximum penalty is 10 years' imprisonment. This change in maximum penalty to 15 years is the result of amendment in the Senate on 7 November 2006.

The Explanatory Memorandum states that the retention of this provision (disregarding the change in maximum penalty) reflects the Lockhart Committee's **recommendation 7**.¹⁸¹

Trading human embryos

Aspects of the legislative scheme to change

It will be a criminal offence, with a maximum penalty of 15 years' imprisonment, to intentionally:

- give or offer valuable consideration to another person for the supply of a human embryo (**new subsection 21(1) of the PHC Act**), or

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- receive or offer to receive valuable consideration from another person for the supply of a human embryo (**new subsection 21(2) of the PHC Act**).

At present, these activities are criminal offences in the PHC Act (current subsections 23(1) and (2) respectively) but the maximum penalty is 10 years' imprisonment. This change in maximum penalty to 15 years is the result of amendment in the Senate on 7 November 2006.

The Explanatory Memorandum states that the retention of these provisions (disregarding the change in maximum penalty) reflects the Lockhart Committee's **recommendation 33**.¹⁸²

Aspects of the legislative scheme to remain the same

The reimbursement of reasonable expenses will continue to be permitted (current subsection 23(3); **new subsection 21(3) of the PHC Act**). Again this reflects the Lockhart Committee's **recommendation 33**.

Activities involving human eggs and human sperm

Trading human eggs and human sperm

Aspects of the legislative scheme to change

It will be a criminal offence, with a maximum penalty of 15 years' imprisonment, to intentionally:

- give or offer valuable consideration to another person for the supply of a human egg or human sperm (**new subsection 21(1) of the PHC Act**), or
- receive or offer to receive valuable consideration from another person for the supply of a human egg or human sperm (**new subsection 21(2) of the PHC Act**).

At present these activities are criminal offences in the PHC Act (current subsections 23(1) and (2) respectively) but the maximum penalty is 10 years' imprisonment. This change in maximum penalty to 15 years is the result of amendments in the Senate on 7 November 2006.

The Explanatory Memorandum states that the retention of these provisions (disregarding the change in maximum penalty) reflects the Lockhart Committee's **recommendation 33**.¹⁸³

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Aspects of the legislative scheme to remain the same

The reimbursement of reasonable expenses will continue to be permitted (current subsection 23(3); **new subsection 21(3) of the PHC Act**). Again this reflects the Lockhart Committee's **recommendation 33**.

Other activities involving the use of human eggs and human sperm

Aspects of the legislative scheme to change

New paragraph 20(1)(e) of the RIHE Act provides that a person may apply for a licence authorising research and training involving the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division, outside the body of a woman for the purposes of research or training in ART. This reflects the Lockhart Committee's **recommendation 15**.

New section 10B of the RIHE Act stipulates that it is a criminal offence, with a maximum penalty of 5 years' imprisonment, to engage in such an activity without a licence authorising the research or training by that person.

Other aspects of the licensing system

Personal liability of researchers

As noted above, the Revised Explanatory Memorandum states that there were possible constitutional problems with implementing the Lockhart Committee's **recommendations 50–52**.¹⁸⁴ Instead, **new section 12A of the RIHE Act** is proposed in order to avoid the constitutional issues and address the basic concern of the Lockhart Committee.¹⁸⁵

New section 12A of the RIHE Act provides that a person will not be criminally responsible for an offence against the RIHE Act in respect of particular conduct if:

- their conduct is purportedly authorised by a provision of a licence
- the licence or the provision is invalid, and
- the person did not know, and could not reasonably be expected to have known, of the invalidity of the licence or the provision.

The Explanatory Memorandum states that this clause is intended to address the underlying policy objective of the Lockhart Committee's **recommendations 50–52**.¹⁸⁶

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Monitoring powers

Aspects of the legislative scheme to remain the same

Subsection 35(1) of the RIHE Act provides that in order for an inspector¹⁸⁷ to find out whether there has been compliance with the RIHE Act or the Regulations,¹⁸⁸ an inspector may:

- enter any premises, and
- exercise certain monitoring powers set out in section 36.

Subsection 35(2) outlines the grounds upon which an inspector is authorised to enter premises.

Aspects of the legislative scheme to change

New paragraph 35(2)(c) provides a new ground, namely pursuant to a warrant made under **new section 37A of the RIHE Act**.¹⁸⁹

The warrant must specify the day on which it ceases to have effect (**new paragraph 37A(4)(c) of the RIHE Act**). The Bill originally provided that this date not be more than *one month* after the issue of the warrant. On 7 November 2006 the Senate passed an amendment moved by Senator Stott Despoja, also on behalf of Senator Webber, to change this to not more than *15 days* after the issue of the warrant.

Before entering premises pursuant to a warrant an inspector must announce that they are authorised to enter (**new section 37C of the RIHE Act**). During the execution of a warrant if the occupier or other representative is present then the inspector must:

- make a copy of the warrant available to them (**new section 37B of the RIHE Act**), and
- permit them observe the conduct of the search (but not if they impede the search) (**new section 37D of the RIHE Act**).

Additional powers are exercisable by the inspector in the case of entry pursuant to a warrant, namely the inspector may require any person in or on the premises to:

- answer any of the inspector's questions (**new subparagraph 36(1)(g)(i)**), and
- produce any book, record or document requested (**new subparagraph 36(1)(g)(ii)**).

These changes appear to respond to the LRC's **recommendation 39**.

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The NHMRC Licensing Committee

New subsections 16(7) and (8) of the RIHE Act provide, respectively, that it is Parliament's intention that any vacancy on the NHMRC Licensing Committee be filled as soon as possible and if there is a vacancy for three months then the Minister must table written reasons for the failure to fill the vacancy.

The Explanatory Memorandum states that this clause is intended to address the Lockhart Committee's **recommendation 36**.¹⁹⁰

Export of reproductive material to be permitted for ART treatment

Schedule 4 amends the *Customs (Prohibited Exports) Regulations 1958* by repealing regulation 7 which prohibits the *export* of human embryos except in certain limited circumstances, namely where there is the requisite Ministerial permission. The regulation was to cease to have effect at the end of 31 July 2007 (current subregulation 7(16)) but Schedule 4 repeals the entire regulation.

The Explanatory Memorandum states:

This is consistent with **Recommendation 41** of the Lockhart Review that states that the import or export of a patient's reproductive material, including ART embryos, for the purpose of that person's ongoing ART treatment should not require any regulation other than that required under existing quarantine regulation.¹⁹¹

Establishment of a national stem cell bank and national register of excess ART embryos

New section 47B of the RIHE Act stipulates that the Minister administering the Act must table a written report in Parliament about the establishment of a National Stem Cell Centre and a national register of donated excess ART embryos and, if applicable, the making of guidelines. This report is to be completed no later than six months after the commencement of the amending Act (that is, the Bill) and tabled in each House within 15 sitting days of that House after the day on which the report was completed. The Lockhart Committee had recommended that a national stem cell bank be established (**recommendation 47**) and that a national register of donated excess ART embryos be established (**recommendation 49**).

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Report into feasibility of governance on non-blood human tissue based therapies

On 7 November 2006, the Senate passed an amendment moved by Senator Colbeck to introduce **new section 47C of the RIHE Act**. This new section stipulates that the Minister must cause a report to be prepared concerning the feasibility of establishing a national legislative or regulatory approach for effective governance of non-blood human tissue based therapies. This report is to be completed no later than 18 months after the day on which the amending Act (that is, the Bill) receives Royal Assent, with copies to be provided to both Houses of Parliament and the Council of Australian Governments. The report must be tabled in each House within 15 sitting days of that House after the day on which the report was completed.

Further review of the Acts

New section 25A of the PHC Act and **new section 47A of the RIHE Act** are in essentially the same terms and provide for further independent review of the operation of each Act to be commenced within three years from the date of Royal Assent of the the Bill. This reflects the Lockhart Committee's **recommendation 53**. The review of each Act is to be undertaken concurrently and by the same people (**new subsection 47A(2) of the RIHE Act**). A number of considerations are to be taken into account in the review (**new subsection 25A(4) of the PHC Act** and **new subsection 47A(4) of the RIHE Act**). The written report must be provided to both Houses of Parliament and the Council of Australian Governments before the fourth anniversary of the day on which the amending Act received Royal Assent (**new subsection 25A(3) of the PHC Act**; **new subsection 47A(3) of the RHIE Act**).

Concluding comments

This Bill raises more ethical and moral, than legal issues and, as the Hon. Tony Abbott has said, the debate will ultimately turn on 'ethical considerations, not scientific considerations'.¹⁹²

To encounter some of the ethical concerns raised in relation to the proposed changes, Parliament may want to consider whether to include into the Bill legal measures based on the principles of *subsidiarity* and *precaution*.¹⁹³ These principles include:

- *principle of subsidiarity*—the principle encompasses the idea that where there is a choice between two things which serve the same objective, one should choose the subordinate or 'lesser of two evils'. According to this view, embryos should only be used if there is no suitable alternative that would serve the same research goals.¹⁹⁴ In

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other words, '[t]herapeutic cloning can only be morally acceptable if there are no good alternatives.'¹⁹⁵

- *precautionary principle*—the principle encompasses the idea that precaution is relevant where there is scientific uncertainty.¹⁹⁶ As one academic has noted:

At its heart, precaution is a reminder of the limitations of scientific knowledge as a guide to decision-making, and a warning to heed the lessons of the past to prevent the occurrence of environmental damage in the future. But how this simple message is interpreted depends on the risk attitude of the interpreter.¹⁹⁷

However, it must be acknowledged that both principles may have their own disadvantages, including that excessive precaution potentially could prevent important and beneficial future developments or that it could be difficult to ascertain whether there is a suitable alternative which achieves the same research results.

Further, it is important to remember that the resolution of the debate will not bring the matter to a close. Issues which will continue to draw attention to the new legislative regime will include:

- **intellectual property**—it is questionable whether stem cell research can be patented.¹⁹⁸ Academic Matthew Rimmer has argued that 'the Federal Government will need to reform patent law if it intends to foster the commercialisation of stem cell research.'¹⁹⁹ In sum, this is because subsection 18(2) of the *Patents Act 1990* stipulates that 'Human beings, and the biological processes for their generation, are not patentable inventions.' Rimmer concludes that this section is 'fundamentally ambiguous'.²⁰⁰ In 2004, the Australian Law Reform Commission (ALRC) released its report on *Genes and Ingenuity: Gene Patenting and Human Health*. Part of the report addressed the issue of stem cell technologies. The ALRC reported that it:

... does not favour amendments to the *Patents Act* that would expressly address the patentability of inventions involving stem cell technologies. ... [This is because] the requirements for patentability in the *Patents Act* are nearly all technology-neutral and are therefore capable of adapting to new technologies as they arise.²⁰¹

Rather, the ALRC recommended that IP Australia develop examination guidelines (consistent with existing law) to explain how the criteria for patentability applies to inventions involving stem cells and related technologies.²⁰² The ALRC also recommended that the issue of the exploitation of intellectual property rights over stem cells should be considered when the issue of the establishment of a National Stem Cell Bank is considered as part of the independent reviews of the PHC Act and the RIHE Act.²⁰³ As at the date of publication of this Digest the Government has not released its response to the ALRC's report.

- **regulation/administration of clinical therapies**—the regulation/administration of clinical therapies arising from such research and involving novel human products will need to be addressed

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- **review of the legislation**—the review clause will ensure that the issue comes before the Parliament in a few years’ time. Given the rapid rate of change in the field, it is fundamental that the law keep abreast with, and respond to, such change and thereby provide certainty for those working in it – no matter what the actual ethical response is to those advances in science and technology.

Finally, the legislative measures implemented at Federal level will have to be reflected need for harmonising the legislation in the States and Territories.

Glossary

Excess ART embryos	those human embryos that were created for assisted reproductive treatments but are no longer required for that purpose. ²⁰⁴
Somatic cell	Any cell from an animal at any stage of development except for gametes (egg or sperm) or their precursors.
Reproductive cloning	Using cloning technology (usually somatic cell nuclear transfer) to create an embryo that is implanted into a woman for gestation and birth.
Therapeutic cloning	Term previously used to describe cloning to generate embryonic stem cells.
Oocyte	An egg cell.
Zygote	The product of fusion between oocyte and sperm cell.

Endnotes

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1. The authors are indebted to the following people without whom the completion of this digest would not have been possible: Professor Loane Skene, University of Melbourne, Professor Peter Schofield, University of New South Wales; and the following Parliamentary Library staff members: Dr Jane Romeyn, Jane Grace, Effi Tomaras and Rosemary Polya.
 2. The Revised Explanatory Memorandum notes that the Bill amends the Acts and the Regulations ‘consistent with’ the recommendations. Explanatory Memorandum, pp. 1, 29. Revised Explanatory Memorandum, pp. 1, 28.

The Bill only seeks to implement *some* of the recommendations. This is illustrated by review of Appendix 1 of the Explanatory Memorandum and Revised Explanatory

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Memorandum which summarises the Lockhart recommendations and how they are addressed in the Bill.

For example, the entries related to **recommendations 18, 29, 30 and 32** state that no legislative change is required, in some instances because the relevant recommendation is for the National Health and Medical Research Council to consider.

The entry in relation to **recommendation 24** notes that the recommendation is not accepted. Originally, the Bill sought to implement this recommendation, but on 7 November 2006, the Senate, upon the movement by Senator Bartlett, passed amendments deleting provisions that would have permitted the creation and use of certain hybrid embryos. Explanatory Memorandum, p. 30. No equivalent in the Revised Explanatory Memorandum.

3. Legislation Review Committee, *Issues Paper: Outline of existing legislation and issues for public consultation*, p. 1.
4. *Infertility Treatment Act 1995* (Vic), Reproductive Technology (Code of Ethical Research Practice) Regulation 1995 made under the *Reproductive Technology Act 1988* (SA), and the *Human Reproductive Technology Act 1991* (WA). Also refer to J. Norberry, 'Research Involving Embryos and Prohibition of Human Cloning Bill 2002', *Bills Digest*, No. 17, Parliamentary Library, Canberra, 2002–03, p. 10.
5. 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 (The Andrews Report), p. 128.
6. D. Cooper, 'The Lockhart Review: Where now for Australia?', *Journal of Law and Medicine*, Vol. 14, 2006, p. 31.
7. The Andrews Report, p. 129.
8. The Andrews Report, p. 130.
9. Cooper, loc. cit..
10. Norberry, loc. cit..
11. Legislation Review Committee, *Issues Paper: Outline of existing legislation and issues for public consultation*, p. 1.
12. The terms of reference directed the Committee 'to review the report of the Australian Health Ethics Committee of the National Health and Medical Research Council, *Scientific, Ethical and Regulatory Considerations relevant to Cloning of Human Beings* (16 December 1998).' The Andrews Report, p. xviii.
13. Section 192B of the *Gene Technology Act 2000*
14. The Andrews Report, p. 133–134.
15. The Andrews Report, see <http://www.aph.gov.au/house/committee/laca/humancloning/report.pdf>

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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*, Canberra, August 2001, p. xix.
17. Cooper, op. cit., p. 30.
18. Legislation Review Committee, *Issues Paper: Outline of existing legislation and issues for public consultation*, p. 1.
19. See Legislation Review Committee, *Issues Paper: Outline of existing legislation and issues for public consultation*, p. 13. These practices are also discussed in the Main Provisions section of this Bills Digest.
20. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002, Issues Paper: Outline of existing legislation and issues for public consultation*, Canberra, August 2005, p. 1. See: [http://www.lockhartreview.com.au/files/Issues%20Papers\(3Aug05\).pdf](http://www.lockhartreview.com.au/files/Issues%20Papers(3Aug05).pdf)
21. Cooper, loc. cit.. Footnote 29 of this article details the various Acts passed by the States and Territories.
22. Section 25 of the *Prohibition of Human Cloning Act 2002* and section 47 of the *Research Involving Human Embryos Act 2002*.
23. Section 25 of the *Prohibition of Human Cloning Act 2003*.
24. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005. See: <http://www.lockhartreview.com.au/> .
25. The Hon Julie Bishop MP, Minister for Ageing, 'Lockhart review delivered to government', *Media Release*, 19 December 2005
[http://www.health.gov.au/internet/ministers/publishing.nsf/Content/5019A437D5388015CA2570DC0018200A/\\$File/bis201.pdf](http://www.health.gov.au/internet/ministers/publishing.nsf/Content/5019A437D5388015CA2570DC0018200A/$File/bis201.pdf).
26. The Hon John Howard MP, Prime Minister of Australia 'Lockhart Review', *Media release*, 23 June 2006. See:
http://www.pm.gov.au/news/media_releases/media_Release1989.html.
27. Council of Australian Governments, Communiqué, July 14 2006. See:
<http://www.coag.gov.au/meetings/140706/index.htm#Lockhart> .
28. The Hon John Howard MP, Prime Minister of Australia 'Embryonic Stem Cell Research', *Media release*, 31 August 2006.
http://www.pm.gov.au/news/media_releases/media_Release2110.html
29. Beazley backs cloning, *Daily Telegraph*, Thursday 17 August, p. 13. See:
http://parlinfoweb.parl.net/parlinfo/Repository1/Media/npaper_5/ZYKK60.pdf
30. Senate. Community Affairs Committee. Inquiry into the Legislative responses to Recommendations of the Lockhart Review. Legislation and documentation relating to the Inquiry. See:

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http://www.aph.gov.au/Senate/committee/clac_ctte/leg_response_lockhart_review/legis_doc/leg_doc.htm.

31. Legislation Review Committee, *Reports*, p. 93.
32. H. Mertes, G. Pennings, and A. Van Steirteghem, 'An ethical analysis of alternative methods to obtain pluripotent stem cells without destroying embryos' *Human Reproduction*, November 1, 2006; 21(11): 2749 – 2755 and Strelchenko, N et al 'Morula-derived Human Embryonic Stem Cells', *Reproductive BioMedicine Online* 2004 Vol. 9, No. 6. 623–629.
33. R. Beran, 'The great divide: therapeutic cloning', *Australian Life Scientist*, November/December 2005, p. 31.
34. J. A. Thomson et al, 'Embryonic stem cells derived from human blastocysts', *Science*, vol. 282 (1198), pp. 1145-7.
35. G. D. Fischbach and R. L. Fischbach, 'Stem cells: science, policy and ethics, *The Journal of clinical investigation*, Vol. 114, No. 10, November 2004, p. 1364.
36. Legislation Review Committee, *Issues Paper: Outline of existing legislation and issues for public consultation*, August 2005, p. 11.
37. Legislation Review Committee, *Reports*, p. 61.
38. Legislation Review Committee, *Reports*, p. 62.
39. Legislation Review Committee, *Reports*, p. 62.
40. Legislation Review Committee, *Reports*, p. 169.
41. Legislation Review Committee, *Reports*, p. 62.
42. Legislation Review Committee, *Reports*, p. 40.
43. Legislation Review Committee, *Reports*, p. 40
44. Legislation Review Committee, p. 40.
45. Legislation Review Committee, p. 47-52.
46. Legislation Review Committee, p. 170.
47. Legislation Review Committee, p. 53.
48. Legislation Review Committee, p. 67.
49. Mpconsulting, Analysis of advice on developments in assisted reproductive technology and related medical and scientific research, June 2006, p. iii.
50. *ibid*
51. *ibid*.
52. *ibid*, p. 21.
53. N. Gough, Key recent advances in human embryonic stem cell research. A review of scientific literature commissioned by the Department of Innovation, Industry and

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Regional Development, Government of Victoria, Australia. 2006. See:
<http://parlinfoweb.parl.net/parlinfo/Repository1/Library/miscitem/254L62.pdf> .

54. Legislation Review Committee, *Reports*, p. 61.
55. Legislation Review Committee, *Reports*, p. 61.
56. Legislation Review Committee, *Reports*, p. 47.
57. Legislation Review Committee, *Reports*, p. 30.
58. Legislation Review Committee, *Reports*, p. 31.
59. Legislation Review Committee, *Reports*, p. 93.
60. Legislation Review Committee, *Reports*, p. 93.
61. Legislation Review Committee, *Reports*, p. 29.
62. Legislation Review Committee, *Reports*, p. 30.
63. Legislation Review Committee, *Reports*, p. 32-33.
64. Legislation Review Committee, *Reports*, p. 32-33.
65. Legislation Review Committee, *Reports*, p. 33.
66. Legislation Review Committee, *Reports*, p. 30.
67. Legislation Review Committee, *Reports*, p. 30.
68. Legislation Review Committee, *Reports*, p. 33.
69. Legislation Review Committee, *Reports*, p. 34.
70. Legislation Review Committee, *Reports*, p. 30.
71. Legislation Review Committee, *Reports*, p. 30.
72. Legislation Review Committee, *Reports*, p. 168.
73. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. 153.
74. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. 153.
75. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. 154.
76. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. 153.
77. Explanatory Memorandum, p. 21. Revised Explanatory Memorandum, p. 21.

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78. Explanatory Memorandum, p. 22. Revised Explanatory Memorandum, p. 21.
79. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. 113.
80. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. 178.
81. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. 178.
82. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. 178.
83. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. xxv.
84. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. 176.
85. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. 177.
86. Paragraph 7(4)(a) of the *Customs (Prohibited Exports) Regulations 1958*.
87. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. 12.
88. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. 12.
89. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. 179.
90. The Lockhart Committee reported that human embryos ‘can be imported for human therapeutic use (including implantation), artificial insemination or in vitro fertilisation (IVF).’ It would appear that there is no current prohibition on the *importation* of a human embryo unless it is a type not permitted to be created in Australia (a so-called ‘prohibited embryo’ in the PHC Act).

Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. 12.

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91. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. xxv.
92. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. 143.
93. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. 181.
94. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. xxvi.
95. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. 181.
96. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. 182.
97. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. 182.
98. Legislation Review Committee, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Reports*, Canberra, December 2005, p. xxvi.
99. Isasi R.M., Knoppers B.M., 'Beyond the Permissibility of Embryonic and Stem Cell Research: Substantive Requirements and Procedural Safeguards', *Human Reproduction*, vol 21, Number 10 pp. 2474-2481.
100. To a certain degree, these debates are comparable with those concerning the topics euthanasia and abortion. However, see comments below, p. 28.
101. L. R. Kass, *Life, Liberty and the Defence of Dignity, The Challenge for Bioethics*, Encounter Books, San Francisco, 2002, p. 122.
102. For convenience, the term 'embryo' is used subsequently.
103. For further examples, see D. W. Brock, 'Is a consensus possible on stem cell research? Moral and political obstacles', *Journal of Medical Ethics*, Vol.32, 2006, p. 37.
104. See below, p. 29.
105. It is acknowledged that recently media reported about American scientists that have been able to remove one cell of an embryo at the eight-cell stage. Claiming that this cell could be used to derive stem cell, this technology has been hailed a breakthrough because it would not require the destruction of the early embryo. Due to the serious questions raised about the technology – including whether the separated cell is in itself an embryo which

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- is destroyed to harvest stem cells – this technology is not further considered in this context. H. Mertes, G. Penning, A. Van Steirteghem, ‘An ethical analysis of alternative methods to obtain pluripotent stem cells without destroying embryos’, *Human Reproduction*, Vol. 21, No. 11, pp. 2749-55.. For a critical comment in relation to this research, see P. Singer, A. Sagan, Choose Life, *Bulletin with Newsweek*, 5 September 2006, p. 36.
106. It should be noted that the term ‘life’ is not used in a strict biological sense, but rather in the sense that something is ‘alive’.
107. From a biological point of view, there is a distinction between living tissue, which is unable to support itself independently, and an independently living organism. A zygote can be understood as a form of life without being a human being yet.
108. J. Habermas, *The Future of Human Nature*, Polity Press, Cambridge, 2003, p. 32.
109. Brock, op. cit., p. 38.
110. E. Finkel, *Stem Cells, Controversy at the Frontiers of Science*, ABC Books, Sydney, 2005, p. 33-4. She refers to interviews conducted with Father Norman Ford, Director of the Caroline Chisholm Centre for Health Ethics, Melbourne, and Father Peter Carnley, former Archbishop of Perth and Primate of the Anglican Church of Australia.
111. *ibid.*
112. *ibid.*, pp. 34-6.
113. G. R. Dunstan ‘The moral status of the human embryo: a tradition recalled’, *Journal of Medical Ethics*, Vol. 1, 1988, p.
114. D. A. Jones, The human embryo in the Christian tradition: a reconsideration, *Journal of Medical Ethics*, Volume 31, 2005, p. 711.
115. *ibid.*, pp. 712-3.
116. Kass, op. cit., p. 86.
117. R. Gill, Response to: The human embryo in the Christian tradition, *Journal of Medical Ethics*, Volume 31, 2005, p. 713-4.
118. Instructive: C. Starck, ‘Embryonic Stem Cell Research according to German and European Law’, *German Law Journal*, Vol. 7, No. 7, 2005, p. 651-3.
119. Habermas, op. cit., p. 31
120. See the reference above to Habermas, op. cit., p. 32.
121. The Canadian *Victorian Fertility Centre* reports that: ‘Recent reports have described pregnancies that have occurred from embryos cryopreserved and stored for over ten years. The only current limiting factor is for these older embryos is the quality of the cryopreservation protocol in place at the time of storage.’ *Victorian Fertility Centre*, Embryo Freezing and Thawing, available at:

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- <http://www.victoriafertility.com/services/embryo-freezing.htm> (accessed: 26 November 2007).
122. Some States have legislation restricting the storage of excess embryos beyond five years. The Age reported in 2005, that Victorian IVF clinics destroyed 6642 excess embryos between 1998 and 2005. H. Nader, 'Legal limit destroys 6642 embryos', *The Age*, 26 September 2005, p. 5.
 123. E. Parens, 'On the Ethics and Politics of Embryonic Stem Cell Research', in S Holland, K Lebacqz, L Zoloth (eds), *The Human Embryonic Stem Cell Debate Science, Ethics, and Public Policy*, Bradford Book, MIT Press: Cambridge, 2001, pp. 43-4.
 124. Habermas, op. cit., p. 30.
 125. G. de Wert and C. Mummery, Human embryonic stem cells: research ethics and policies, *Human Reproduction*, Vol. 18, No. 4, p. 675.
 126. K. Devolder, 'Creating and sacrificing embryos for stem cells', *Journal of Medical Ethics*, Vol. 31, 2005, p. 370.
 127. Member of the German *Bundestag* (Federal Parliament) M Böhmer, CDU, cited in G. Vogel, 'German Researchers get green light, just', *Science*, Vol. 295, 8 February 2002, p. 943.
 128. Starck, op. cit., p. 641.
 129. Brock, op. cit., p. 36.
 130. J. A. Robertson, 'Human embryonic stem cell research: ethical and legal issues', *Nature*, Vol. 2, January 2001, p. 76.
 131. *ibid.*
 132. It has been suggested that this argument has two facets, including, first, the acceptance of the practice X will inevitably lead to the acceptance of the undesirable practice Y, so that X must be banned in order to prevent Y, and, second, the justification of the practice X implies the acceptance of undesirable practice. de Wert and Mummery, op. cit., p. 675.
 133. Kass, op. cit., pp. 123-4.
 134. Fischbach and Fischbach, op. cit, p. 1370.
 135. de Wert and Mummery, loc. cit..
 136. D. Elsner, 'Just another reproductive technology? The ethics of human reproductive cloning as an experimental medical procedure', *Journal of Medical Ethics*, Vol. 32, No. The Age reported in 2005, that Victorian IVF clinics destroyed 6642 excess embryos between 1998 and 2005. H. Nader, 'Legal limit destroys 6642 embryos', *The Age*, 26 September 2005, p. 5.
 136. E. Parens, 'On the Ethics and Politics of Embryonic Stem Cell Research', in S Holland, K Lebacqz, L Zoloth (eds), *The Human Embryonic Stem Cell Debate Science, Ethics, and Public Policy*, Bradford Book, MIT Press: Cambridge, 2001, pp. 43-4.
 136. Habermas, op. cit., p. 30.

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136. G. de Wert and C. Mummery, Human embryonic stem cells: research ethics and policies, *Human Reproduction*, Vol. 18, No. 4, p. 675.
136. K. Devolder, 'Creating and sacrificing embryos for stem cells', *Journal of Medical Ethics*, Vol. 31, 2005, p. 370.
136. Member of the German *Bundestag* (Federal Parliament) M Böhmer, CDU, cited in G. Vogel, 'German Researchers get green light, just', *Science*, Vol. 295, 8 February 2002, p. 943.
136. Starck, op. cit., p. 641.
136. Brock, op. cit., p. 36.
136. J. A. Robertson, 'Human embryonic stem cell research: ethical and legal issues', *Nature*, Vol. 2, January 2001, p. 76.
136. *ibid.*
136. It has been suggested that this argument has two facets, including, first, the acceptance of the practice X will inevitably lead to the acceptance of the undesirable practice Y, so that X must be banned in order to prevent Y, and, second, the justification of the practice X 10, 2006, p. 596-7.
137. Habermas, op. cit., p. 19.
138. Fischbach and Fischbach, loc. cit..
139. B. Steinbock, Cloning Human Beings: Sorting through Ethical Issues, in B. MacKinnon (ed.) *Human Cloning – Science, Ethics, and Public Policy*, Urbana and Chicago, University of Illinois Press, Chicago, 2000, p. 82.
140. Fischbach and Fischbach, loc. cit..
141. R Dworkin, *Sovereign Virtue: The Theory and Practice of Equality*, Harvard University Press, Cambridge, 2000, p. 440.
142. For example: B. E. Rollin, 'Ethics and Species Integrity', *The American Journal of Bioethics*, Vol. 3, No. 3, 2003, p. 16, referring to the works of J. S. Roberts and F. Bayliss, 'Crossing Species Boundaries', *The American Journal of Bioethics*, Vol. 3, No. 3, 2003, pp. 1-13.
143. Dworkin, op. cit., p. 444.
144. Rollin, loc. cit..
145. Habermas, op. cit., p. 29.
146. Australian Broadcasting Corporation, Genetic Anger, *7:30 Report*, 23 November 2006.
147. Explanatory Memorandum, p. 1. Revised Explanatory Memorandum, p. 1. See Appendix I of the Explanatory Memorandum and the Revised Explanatory Memorandum for details about how the Bill addresses the recommendations.

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148. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. xxiv.
149. Explanatory Memorandum, p. 5. Revised Explanatory Memorandum, p. 5.
150. Explanatory Memorandum, p. 5. Revised Explanatory Memorandum, p. 5.
151. Explanatory Memorandum, p. 5. Revised Explanatory Memorandum, p. 5.
152. **Item 6 of Schedule 1** also inserts **new subsections 8(6) and (7) of the PHC Act** which clarify, respectively, that references in the PHC Act to an embryo mean a living embryo and references to a human egg mean a human oocyte.
153. For example, when frozen.
154. An ‘excess ART embryo’ is defined in section 9 of the RIHE Act. Essentially it refers to a human embryo that was created by assisted reproductive technology (‘ART’) for use in the ART treatment of a woman and is in excess to the needs of that woman or her (then) spouse. An ART embryo is deemed to be in excess of those needs if each of those people has given the requisite written authority or written determination.
155. **New section 8 of the RIHE Act** defines ‘proper consent’ as the consent obtained in accordance with guidelines issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* and prescribed by the Regulations. **New subsection 24(8) of the RIHE Act** provides that where the excess ART embryos are unsuitable for implantation (that is, diagnosed by preimplantation genetic diagnosis or determined by certain objective guidelines to be unsuitable: **new subsection 7(1) of the RIHE Act**) a licence may provide that those guidelines apply in a modified form in relation to the use of such embryos. See the LRC’s **recommendations 20–22** for recommendations regarding use of such fresh ART embryos.
156. **New subsection 7(1) of the RIHE Act** provides that ‘use *includes* develop, or development, as the case requires.’ Emphasis added.
157. Explanatory Memorandum, p. 7. Revised Explanatory Memorandum, p. 7.
158. The Note to **new section 9 of the PHC Act** states ‘The development of a human embryo (*including a human embryo clone*) outside the body of a woman for more than 14 days is prohibited by section 14.’ Emphasis added.
159. Explanatory Memorandum, p. 14. Revised Explanatory Memorandum, p. 14.
160. This provision is narrower than current section 15 of the PHC Act in order to accommodate the change effected by **new section 23 of the PHC Act**.
161. Note the offence in current section 15 of the PHC Act is broader than **new section 13 of the PHC Act** as the new offence is confined to the situation where there is fertilisation of a human egg by a human sperm outside a woman’s body whereas the current offence is not so confined.
162. Explanatory Memorandum, p. 15. Revised Explanatory Memorandum, p. 15.
163. A ‘hybrid embryo’ is defined in current subsection 8(1) of the PHC Act.

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164. Explanatory Memorandum, pp. 15, 30. Revised Explanatory Memorandum, pp. 15, 30.
165. Explanatory Memorandum, p. 11. No equivalent in the Revised Explanatory Memorandum.
166. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. xxiii.
167. Explanatory Memorandum, p. 30. Revised Explanatory Memorandum, p. 30.
168. An ‘accredited ART centre’ is defined in section 8 of the RIHE Act.
169. On 7 November 2006, the Senate passed an amendment moved by Senator Stott Despoja, also on behalf of Senator Webber, to increase the maximum penalty from 10 years’ imprisonment to 15 years’ imprisonment.
170. Note that because a hybrid embryo is excluded from the definition of a human embryo, **new section 14 of the PHC Act** (offence of developing a human embryo outside a woman’s body for more than 14 days) is not applicable.
171. Explanatory Memorandum, p. 11. Revised Explanatory Memorandum, p. 11.
172. Explanatory Memorandum, p. 9. Revised Explanatory Memorandum, p. 9.
173. Note the current offence is broader than **new section 11 of the RIHE Act** as the new offence is confined to the situation where there is fertilisation of a human egg by a human sperm outside a woman’s body whereas the current offence is not so confined.
174. Explanatory Memorandum, p. 10. Revised Explanatory Memorandum, p. 10.
175. Current subsection 18(2); **new subsection 15(2) of the PHC Act**.
176. Explanatory Memorandum, p. 10. Revised Explanatory Memorandum, p. 10.
177. Subject to the change of definition to ‘human embryo’.
178. Namely the provisions concerning the following ‘prohibited embryos’: a human embryo that contains genetic material provided by more than 2 persons (**new paragraph 20(4)(c) of the PHC Act**), a human embryo created using precursor cells taken from a human embryo or a human fetus (**new paragraph 20(4)(e) of the PHC Act**), a human embryo that contains a human cell (within the meaning of [new] section 15) whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered (**new paragraph 20(4)(f) of the PHC Act**), a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo (**new paragraph 20(4)(g) of the PHC Act**), and a chimeric embryo or a hybrid embryo (**new paragraph 20(4)(h) of the PHC Act**).
179. Legislation Review Committee, Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, *Reports*, Canberra, December 2005, p. xxii.
180. Explanatory Memorandum, p. 12. Revised Explanatory Memorandum, p. 11.
181. Explanatory Memorandum, p. 12. Revised Explanatory Memorandum, p. 12.

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182. Explanatory Memorandum, p. 13. Revised Explanatory Memorandum, p. 13.
183. Explanatory Memorandum, p. 13. Revised Explanatory Memorandum, p. 13.
184. Explanatory Memorandum, p. 22. Revised Explanatory Memorandum, p. 21.
185. Explanatory Memorandum, p. 22. Revised Explanatory Memorandum, p. 21.
186. Explanatory Memorandum, p. 21. Revised Explanatory Memorandum, p. 21.
187. Subsection 7(1) defines an inspector as a person appointed as an inspector under subsection 33(1) of the RIHE Act. That is, a person employed, or appointed, by the Commonwealth or a State who has been appointed as an inspector by the Chairperson of the NHMRC Licensing Committee.
188. As well as presumably the PHC Act. Section 41 of the RIHE Act provides that a reference in this Part on Monitoring Powers to ‘this Act’ includes a reference to the PHC Act.
189. Again, it would appear that this new provision will also apply in relation to investigating whether the two Acts or the Regulations have been complied with. See Explanatory Memorandum, p. 27. Revised Explanatory Memorandum, p. 26.
190. Explanatory Memorandum, p. 22. Revised Explanatory Memorandum, p. 22.
191. Explanatory Memorandum, p. 28. Revised Explanatory Memorandum, p. 28. Emphasis added.
192. J. Bunce, ‘Stem cell report not commissioned to influence debate’, PM, *AAP*, 1 September 2006, Story No. 1034.
193. de Wert and C. Mummery, *op. cit.*, p.674.
194. *ibid.*, p.675.
195. *ibid.*, p.678.
196. It has been noted that this principle has its genesis in German environmental policy. J. Peel, ‘Precaution – A Matter of Principle, Approach or Process?’, in *Melbourne Journal of International Law*, Vol. 5, No. 2, 2004, pp. 483–485.
197. *ibid.*, pp. 484–485.
198. Australian Law Reform Commission, Report 99, *Genes and Ingenuity: Gene Patenting and Human Health*, 2004, par 15.61. See also M. Rimmer, ‘The Attack of the Clones: Patent Law and Stem Cell Research’, in *Journal of Law and Medicine*, Vol. 10, May 2003, pp. 488–505.
199. M. Rimmer, ‘The Attack of the Clones: Patent Law and Stem Cell Research’, in *Journal of Law and Medicine*, Vol. 10, May 2003, p. 489.
200. M. Rimmer, ‘The Attack of the Clones: Patent Law and Stem Cell Research’, in *Journal of Law and Medicine*, Vol. 10, May 2003, p. 504.
201. Australian Law Reform Commission, Report 99, *Genes and Ingenuity: Gene Patenting and Human Health*, 2004, par 15.65.

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202. Australian Law Reform Commission, Report 99, *Genes and Ingenuity: Gene Patenting and Human Health*, 2004, recommendation 15–1.
203. Australian Law Reform Commission, Report 99, *Genes and Ingenuity: Gene Patenting and Human Health*, 2004, recommendation 15–2.
204. Legislation Review Committee, *Issues Paper: Outline of existing legislation and issues for public consultation*, p. 1.

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