2004-2005-2006

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

THE SENATE

PROHIBITION OF HUMAN CLONING FOR REPRODUCTION AND THE REGULATION OF HUMAN EMBRYO RESEARCH AMENDMENT BILL 2006

EXPLANATORY MEMORANDUM

(Circulated by authority of Senator Patterson)

PROHIBITION OF HUMAN CLONING FOR REPRODUCTION AND THE REGULATION OF HUMAN EMBRYO RESEARCH AMENDMENT BILL

OUTLINE

Purpose of this Bill

This Bill amends the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* consistent with the 2005 recommendations of the Legislative Review Committee (also known as the Lockhart Committee).

Background

In June 2005, the Minister for Ageing, the Hon. Julie Bishop MP (who then had portfolio responsibility for human cloning and stem cell research), appointed a six-member Legislative Review Committee to independently review the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*. This was in accordance with a requirement in both Acts that they be reviewed by an independent committee by December 2005.

The Legislative Review Committee was chaired by the late John S Lockhart AO QC, a former Justice of the Federal Court of Australia. The other members were Associate Professor Ian Kerridge (New South Wales) a clinical ethicist; Professor Barry Marshall (Western Australia), a specialist gastroenterologist and community advocate; Associate Professor Pamela McCombe (Queensland), a clinical neurologist; Professor Peter Schofield (New South Wales), a neuroscientist; and Professor Loane Skene (Victoria), a lawyer and ethicist. All appointments to the Legislation Review Committee were agreed by each State and Territory as required by the Acts themselves.

The Committee reported to the Minister in December 2005 noting that it had "consulted the community extensively through a review website, written submissions, face-to-face meetings with key stakeholders, public hearings and some private meetings (at stakeholders' requests), facilitated stakeholder discussion forums, and selected site visits. In addition, the Committee reviewed the latest results of focus group and telephone survey research by the Public Awareness Program of Biotechnology Australia, and a literature review (commissioned by the NHMRC on behalf of the Minister for Ageing) of recent scientific and technological advances in human cloning, human embryo research and related matters, including stem cell technologies." (page xxiii)

The Committee made 54 recommendations and outlined its rationale for the recommendations as follows:

> "Australian society is made up of diverse 'communities' with different perspectives, interests and values. Furthermore, an individual may be the member of multiple communities, each with divergent perspectives, or 'standards', and these standards vary between and within communities and over time. Because of these divergent values and interests represented within Australian society, the Committee has accepted that some disagreement will remain, whether or not any changes are made to the two Acts.

> However, certain moral values are held in common by all communities, such as commitment to social justice and equity and to the care of vulnerable people. This is reflected in broad community support for medical research aimed at understanding, preventing or treating disease, and for research and clinical practice aimed at assisting people to have children (including a general acceptance that this process may involve the 'wastage' of some embryos). Therefore, in considering whether certain activities should be made illegal, the social and moral value that some communities attach to the human embryo needs to be balanced against the social and moral value that other communities attach to the treatment of disease and to helping people to have a family". (page xiii)

In framing its recommendations, "the Committee considered that the higher the potential benefits of an activity, the greater the need for ethical objections to be of a high level and widely accepted in order to prevent that activity. Conversely, where benefits are not yet established, or where there is widespread and deeply held community objection, then total prohibition through the legal system may be justified. In addition, even though some people think that an activity is unethical, it does not necessarily follow that the activity should be made illegal. Furthermore, the wider the range of ethical views on a particular activity, the weaker becomes the case for declaring that activity to be illegal, with all the attendant consequences of criminal conduct." (page xiv)

The Committee noted that "despite the divergent views received by the Committee during the reviews, both proponents and opponents of embryo research agreed that the current system of legislation is valuable. Therefore, the Committee recommended a continuation of national legislation imposing prohibitions on human reproductive cloning and some other ART practices, as well as strict control and monitoring, under licence, of human embryo research." (page xiv)

The amendments in this Bill are based on the recommendations of the Lockhart Review (Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002, Reports, December 2005, Legislation Review Committee. (www.lockhartreview.com.au) The Lockhart recommendations, and how they have been addressed in this Bill, are detailed in Appendix I of this Explanatory Memorandum.

Summary of proposed changes to the Acts

In summary, the proposed amendments to the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*:

- retain existing prohibitions on activities such as:
  - placing a human embryo clone in the human body or the body of an animal;
  - importing or exporting a human embryo clone;
  - creating a human embryo by fertilisation of a human egg by human sperm, for a purpose other than achieving pregnancy in a woman;
  - creating or developing a human embryo by fertilisation of human egg by human sperm which contains genetic material provided by more than 2 persons;
  - developing a human embryo outside the body of a woman for more than 14 days;
  - making heritable alterations to a human genome;
  - collecting a viable human embryo from the body of a woman;

- creating or developing a chimeric embryo;
- developing a hybrid embryo beyond 14 days;
- placing a human embryo in an animal, a human embryo into the body of a human other than into the female reproductive tract or an animal embryo in a human; and
- importing, exporting or placing in the body of a woman, a prohibited embryo.

- enable certain types of research involving embryos to be permitted provided that the research is approved by the NHMRC Licensing Committee (in accordance with legislated criteria) and that the activity is undertaken in accordance with a licence issued by the NHMRC Licensing Committee. In summary, a person may apply for a licence to:

  - use excess ART embryos;
  - create human embryos other than by fertilisation of a human egg by a human sperm, and use such embryos;
  - create human embryos (by a process other than fertilisation of human egg by human sperm) containing genetic material provided by more than 2 persons, and use such embryos;
  - create human embryos using precursor cells from a human embryo or a human fetus, and use such embryos;
  - undertake research and training involving the fertilisation of a human egg, up to but not including the first mitotic division, outside the body of a woman for the purposes of research or training;
  - create hybrid embryos by the fertilisation of an animal egg by human sperm, and develop such embryos up to, but not including, the first mitotic division provided that the creation or use is for the purposes of testing sperm quality and will occur in an accredited ART centre; and
  - create hybrid embryos by introducing the nucleus of a human cell into an animal egg, and use of such embryos.

Unless a shorter time is specified, the uses of embryos that may be authorised by a licence may **only** be authorised for development up to 14 days (excluding any period during which development is suspended). In **no** circumstances can any embryo be developed, outside the body of a woman, beyond 14 days.

PROHIBITION OF HUMAN CLONING FOR REPRODUCTION AND THE REGULATION OF HUMAN EMBRYO RESEARCH AMENDMENT BILL

NOTES ON CLAUSES

Clause 1—Short title

This clause provides that the Act may be cited as the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006.*

Clause 2—Commencement

Sub-clause 2(1) provides that the various provisions take effect on the date specified in the table.

Item 1 of the table provides that sections 1 to 3 of the Bill commence on the day on which the Bill receives Royal Assent.

Item 2 of the table provides that Schedules 1, 2, 3 and 4 commence 6 months after Royal Assent. The purpose of this delayed commencement is to provide States and Territories with the opportunity to amend their complementary laws before the Commonwealth law takes effect.

Clause 3—Schedule(s)

This clause provides that each Act that is specified in a Schedule to this Bill is amended or repealed as set out in the applicable items in the Schedule concerned and any other item has effect according to its terms.

SCHEDULE 1— PROHIBITION OF HUMAN CLONING ACT 2002

Item 1 (Title)

This item amends the long title of the Prohibition of Human Cloning Act to read ‘An Act to prohibit human cloning for reproduction and other unacceptable practices associated with reproductive technology and for related purposes”.

The change to the title reflects the fact that the Bill no longer prohibits the creation, for research purposes, of embryos using techniques such as somatic cell nuclear transfer. The Act, does however, continue to absolutely prohibit the development of embryos beyond 14 days and the implantation of human embryo clones in the body of a woman (cloning for the purposes of reproduction).

Item 2 (Section 1)

This item amends the short title of the Act to read “*Prohibition of Human Cloning for Reproduction Act 2002*”.

Item 3 (Definition of human embryo)

This item amends the definition of human embryo to replace the existing definition with a new definition developed by the NHMRC.

The NHMRC arrived at this definition by forming the Biological Definition of Embryo Working Party, comprising three NHMRC Embryo Research Licensing Committee members and three other Australian experts. Their Draft Report of the Biological Definition of Embryo Working Party was peer reviewed by Australian and international experts.

This definition differs slightly from the definition included in the Lockhart Report. This is because the NHMRC had not finalised its recommended definition at the time that the Lockhart Report was finalised in December 2005. Following the release of the Lockhart Report, the NHMRC finalised the definition of a human embryo and this was slightly different from the draft definition that was referenced in the Lockhart Report.

This issue has been discussed with the members of the Lockhart Committee and they have agreed that their intention was that the definition of human embryo used should be that developed by the NHMRC.

The key differences between the NHMRC definition (as endorsed by the Lockhart Committee since the release of their Report) and the existing definition in the *Prohibition of Human Cloning Act 2002* are as follows:

- 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.

It is intended that paragraph (b) of the NHMRC definition would capture the following types of embryos:

- a human egg which has had its nucleus replaced by the nucleus of a somatic cell (that is a cell from a human body) by the process referred to as somatic cell nuclear transfer (SCNT); and

- a parthenogenic human embryo. It is possible that a human egg could be mechanically or chemically stimulated to undergo spontaneous activation and exhibit some of the characteristics of a fertilised human egg. A parthenogenetic human embryo may have the capacity to continue limited development in a similar manner to a human embryo created by fertilisation.

Subclause 8(3) of the existing *Prohibition of Human Cloning Act 2002* is retained and this clarifies that for the purposes of the definition of "human embryo", in working out the length of period of development of a human embryo, any period when development of the embryo is suspended (for example, while it is frozen) is not included. For example, if an embryo is

placed in storage 2 days after fertilisation and is held in storage for 10 weeks, it is still considered to be a 2 day embryo in terms of its development.

Items 4 and 5 (Definition of licence and NHMRC Licensing Committee)

These items insert a definition of "licence" and "NHMRC Licensing Committee" into the definitions section of the *Prohibition of Human Cloning Act 2002*. These terms are already defined in the *Research Involving Human Embryos Act 2002* and now need to be included in the *Prohibition of Human Cloning Act 2002* because a number of the proposed new provisions reference to certain activities requiring a licence from the NHMRC Licensing Committee.

A "licence" is defined as being a licence issued under section 21 of the *Research Involving Human Embryos Act 2002* and the "NHMRC Licensing Committee" is defined as the Committee established under section 13 of the *Research Involving Human Embryos Act 2002.*

Item 6 (At the end of section 8)

This item clarifies a number of words used in the Bill. For example, the item clarifies that "human embryo" refers to a living embryo only and does not include a human embryonic stem cell line or a hybrid embryo. While this should be clear from the definition of "human embryo" itself, it is considered important that this be put beyond doubt.

The item also inserts a new sub-paragraph, clarifying that a reference to a human oocyte is the same as a reference to a human egg. This provision recognises that the NHMRC definition of a human embryo refers to a human oocyte whereas the existing prohibitions in the *Prohibition on Human Cloning Act 2002* refer to a human egg. Rather than changing all of the existing references from human egg to human oocyte, subclause 8(7) has been included to make it clear that both expressions are intended to have exactly the same meaning.

Item 7 (Part 2)

This item repeals Part 2 of the *Prohibition of Human Cloning Act 2002* and replaces it with a new Part. While many of the sections in Part 2 remain the same, they have been repealed and restated in order to provide clarity and better equip people to understand the proposed changes to the *Prohibition of Human Cloning Act 2002.*

Following is a table explaining the main changes.

Table 1: Summary of proposed changes to prohibitions detailed in the *Prohibition of Human Cloning Act 2002*

	Current Section	**New section**	**Short description of the change**
Offence – creating a human embryo clone	Section 9	Deleted	Human embryo clones will be allowed to be created for research only up to 14 days and provided the creation is licensed
Offence – placing a human embryo clone in the human body or the body of a woman	**Section 10**	**Section 9**	**No change**
Offence – importing or exporting a human embryo clone	**Section 11**	**Section 10**	**No change**
No defence that human embryo clone could not survive	**Section 12**	**Section 11**	**No change (except to internal cross referencing of sections)**
Offence - creating a human embryo other than by fertilisation, or developing such an embryo	Section 13	Deleted	Creation of an embryo other than by human sperm and egg will only be permitted under licence and only up to 14 days
Offence – creating a human embryo for a purpose other than achieving pregnancy in a woman	Section 14	Section 12	Embryos created using sperm and egg may only be created for achieving pregnancy. Embryos created by any other means will only be able to be created under licence
Offence – creating or developing a human embryo containing genetic material provided by more than 2 persons	Section 15	Section 13 Section 23	Creation of an embryo by human sperm & egg & involving genetic material from 2 or more people will be prohibited. Creation of an embryo by other means (where it includes genetic material from 2 or more people) will only be permitted under licence
Offence – developing a human embryo outside the body of a woman for more than 14 days	**Section 16**	**Section 14**	**No change**
Offence – using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo	Section 17	Section 23A	Only permitted under licence (up to 14 days development)
Offence – heritable alterations to genome	**Section 18**	**Section 15**	**No change**
Offence – collecting a viable embryo from the body of a woman	**Section 19**	**Section 16**	**No change**
Offence – creating a chimeric embryo	**Section 20(1)**	**Section 17**	**No change**
Offence – creating a hybrid embryo	Section 20(2)	Section 18 Section 23B	Creating & developing a hybrid embryo up to 14 days will only be permitted under licence and in very limited circumstances
Offence – placing of an embryo	**Section 21**	**Section 19**	**No change**
Offence – importing, exporting or placing a prohibited embryo	**Section 22**	**Section 20**	**No change**
Offence – commercial trading in human eggs, human sperm or human embryos	**Section 23**	**Section 21**	**No change**

Part 2 – Prohibited practices

Item 7 replaces the existing Part 2 with a new Part 2 which contains two Divisions. Division 1 describes those practices which are completely prohibited and Division 2 describes those practices which are prohibited unless they are authorised by a licence issued by the NHMRC Licensing Committee.

Division 1 – Practices that are completely prohibited

Clause 9 (Offence – placing a human embryo clone in the human body or the body of an animal)

This provision bans a person intentionally placing a human embryo clone in the body of a human or in the body of an animal. This is identical to the existing section 10 of the *Prohibition of Human Cloning Act 2002*. The effect of this provision is to ban human cloning for the purposes of reproduction.

The maximum penalty for this offence is imprisonment for 15 years. This is the same as it currently is in section 10 of the *Prohibition of Human Cloning Act 2002*.

The retention of this ban is consistent with Recommendation 2 of the Lockhart Report.

Clause 10 (Offence – importing or exporting a human embryo clone)

This clause makes it an offence to import a human embryo clone into Australia or export a human embryo clone from Australia. This clause is the same as the existing section 11 of the *Prohibition on Human Cloning Act 2002*. It is not intended that this prohibit the import or export of human embryonic stem cell lines which may be derived from human embryo clones. This is proposed to be regulated through the *Customs Act 1901* (refer proposed clause 23C).

The maximum penalty that may be applied for importing or exporting a human embryo clone is 15 years imprisonment.

Clause 11 (No defence that human embryo clone could not survive)

This clause clarifies that it is no defence that the human embryo clone could not survive (this mirrors existing section 12 of the *Prohibition of Human Cloning Act 2002*).

The effect of this clause is that a human embryo clone does not have to survive to the point of live birth in order for an offence to be established under clauses 9 or 10. For example, an offence would still be committed if:

- a human embryo clone is placed in a woman's reproductive tract, but does not successfully implant in the uterus;
- a human embryo clone is successfully implanted and begins to develop and then spontaneously terminates;
- a human embryo clone is successfully implanted and begins to develop and is deliberately terminated; or
- if a human embryo clone is successfully implanted, develops to full term but is still-born.

Clause 12 (Offence—creating a human embryo for a purpose other than achieving pregnancy in a woman)

This provision prohibits a person from intentionally creating a human embryo by a process of the fertilisation of a human egg by a human sperm outside the body of a woman, unless the person's intention in creating the embryo is to attempt to achieve pregnancy in a particular woman. This offence attracts a maximum penalty of 10 years imprisonment.

The effect of this prohibition is that a person must not create an embryo by the fertilisation of human egg and human sperm for the purposes of research. Such an embryo may only be created for the ART treatment of a particular woman.

This clause reflects Recommendations 12 and 13 of the Lockhart Report.

Clause 13 (Offence – creating or developing a human embryo by fertilisation that contains genetic material provided by more than 2 persons)

This clause provides that a person commits an offence if the person intentionally creates or develops a human embryo by a process of the fertilisation of a human egg by a human sperm outside the body of a woman and the human embryo contains genetic material provided by more than 2 persons.

The maximum penalty for this offence is 10 years imprisonment. This is the same as the existing penalty for creation of an embryo involving genetic material from more than two people.

The Lockhart Committee recommended that development of a human embryo using genetic material from more than two people be permitted under licence. However, if this involves the creation of an embryo by fertilisation of human egg by human sperm then this would be inconsistent with Lockhart recommendation 13 that recommends that embryos, created by human egg and human sperm, should not be created for the purposes of research. Therefore this offence has been drafted so at to prohibit the creation of an embryo by human egg and human sperm regardless of whether that also involves genetic material from more than two people. If the creation of the human embryo involves genetic material from more than two people but it has been created by other means (i.e. not by fertilisation of human egg by human sperm) then this can potentially be licensed by the NHMRC Licensing Committee (refer proposed sub-clause 23). This approach reflects the spirit of both Recommendation 13 and Recommendation 26 of the Lockhart Review.

Clause 14 (Offence—developing a human embryo outside the body of a woman for more than 14 days)

This clause requires that a human embryo must not be allowed to develop, outside the body of a woman, beyond 14 days (excluding any time that the embryo's development is suspended whilst frozen in storage).

This provision applies regardless of how the embryo was created and whether or not it was created using human sperm and human egg or by any other means. This means that a human

embryo created by asexual means, such as by parthenogenesis, embryo splitting or somatic cell nuclear transfer, cannot be developed beyond 14 days.

In the case of embryos created for ART, this provision does not adversely impact ART clinical practice where it is standard clinical practice for embryos to be implanted when they have reached between three and seven days of development.

This clause provides that the maximum penalty for developing a human embryo outside the body of a woman for more than 14 days is 10 years imprisonment.

This clause is the same as existing section 16 and reflects Recommendation 4 of the Lockhart Review (development of a human embryo created by any means beyond 14 days gestation in any external culture or device should continue to be prohibited).

Clause 15 (Offence—heritable alterations to genome)

This clause is the same as existing section 18 and prohibits any manipulation of a human genome that is intended to be heritable, that is, able to be passed on to subsequent generations of humans.

This clause 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.

The maximum penalty for manipulating the human genome so that the change is heritable to future generations is 10 years imprisonment.

Clause 16 (Offence—collecting a viable human embryo from the body of a woman)

This clause prevents the removal of viable human embryos from the body of a woman after fertilisation has taken place *in vivo* – a practice sometimes referred to as embryo flushing. Embryo flushing is commonly used in animal husbandry and while there have been no recent reports of it being used in humans there is a concern that a healthy human embryo could be removed from a woman's uterus before it implants so that it could be used for research or for transfer to another woman.

This clause continues to ban such a practice (in the current *Prohibition of Human Cloning Act 2002* this is banned in section 19).

The maximum penalty for intentionally collecting a viable human embryo from a woman continues to be 10 years imprisonment (as it currently is in section 19 of the *Prohibition of Human Cloning Act 2002*).

The retention of this prohibition reflects recommendation 11 of the Lockhart Report (collection of a viable human embryo from the body of a woman should continue to be prohibited).

Clause 17 (Offence—creating a chimeric embryo)

This section prohibits the intentional creation of a chimeric embryo (as defined in the Act) and is the same as existing section 20(1). A chimeric embryo is a human embryo into which a cell of an animal, or any component part of a cell of an animal, has been introduced. A chimeric embryo is also defined to include anything else that is declared by the regulations to be a chimeric embryo. As at September 2006, there were no additional types of chimeric embryo prescribed in the Regulations.

The retention of this prohibition is consistent with the Lockhart review which recommended that chimeric embryos should continue to be prohibited (recommendation 6).

Recommendation 6 also addressed the issue of human-animal hybrid embryos and notes that in certain limited circumstances, human-animal hybrids should be permitted to be created under licence. There does not appear to be any recommendation suggesting that chimeric embryos be created under licence. As such, the complete ban on the creation of any chimeric embryos has been retained through this clause.

Failure to comply with the prohibition attracts a maximum penalty of 10 years imprisonment (this is the same penalty as is currently in the *Prohibition of Human Cloning Act 2002*).

Clause 18 (Offence—developing a hybrid embryo)

This clause provides that a person commits an offence if the person intentionally develops a hybrid embryo for a period of more than 14 days, excluding any period when development is suspended.

This clause should be read in conjunction with clause 23B which enables the creation and development of certain hybrid embryos under licence. Clause 18 makes it clear that even if a person is authorised to create a hybrid embryo under a licence issued by the NHMRC Licensing Committee they are not ever permitted to develop such a hybrid embryo beyond 14 days.

This clause is consistent with Recommendations 17 and 24 of the Lockhart Review. In these Recommendations, the Lockhart Committee suggests that only very specific types of interspecies fertilisation and hybrid embryos be permitted to be created. In order to implement this intent, three interacting clauses are proposed. Clause 18 bans the development of a hybrid embryo beyond 14 days (but does not ban the creation of hybrid embryos), proposed clause 23B provides that if someone wishes to create a hybrid embryo they must only do so in accordance with a licence and proposed amended section 20 of the *Research Involving Human Embryos Act 2002* makes it clear that the only types of hybrid embryos for which a licence may be granted are the two specific types mentioned in the Lockhart Recommendations (refer further explanation in relation to Clause 23B of this Explanatory Memorandum).

Clause 19 (Offence – placing of an embryo)

This clause is the same as existing section 21 of the *Prohibition of Human Cloning Act 2002* and reflects Recommendation 7 of the Lockhart Review. The clause prevents the placement of:

- a human embryo in an animal;

- a human embryo into the body of a human, including a man or any part of a woman's body, other than the female reproductive tract; or

- an animal embryo in a human, for any period of gestation.

This clause should be read in conjunction with clause 9 which bans the placement of a human embryo clone in the body of a woman or animal and clause 20(3) which bans the placement of any "prohibited embryo" in the body of a woman.

Clause 20 (Offence—importing, exporting or placing a prohibited embryo)

This clause is the same as existing section 22 of the *Prohibition of Human Cloning Act 2002*.

The clause prevents the intentional import into Australia, intentional export from Australia or the intentional placement in the body of a woman of "prohibited embryos". A "prohibited embryo" is defined to mean:

- a human embryo created by a process other than the fertilisation of a human egg by human sperm;

- a human embryo 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;

- a human embryo that is created using human egg and human sperm and contains genetic material provided by more than 2 persons;

- human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period throughout which development is suspended;

- a human embryo created using precursor cells taken from a human embryo or a human fetus;

- a human embryo that contains a human cell whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered;

- a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo; or

- a chimeric embryo or a hybrid embryo.

The maximum penalty for importing, exporting or placing a prohibited embryo in the body of a woman, is 10 years imprisonment.

As detailed in Schedule 4 to this Bill (the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006), it is proposed that Regulation 7 of the *Customs (Prohibited Exports) Regulations 1958* be repealed in order to remove restrictions on couples who wish to take their ART embryos from Australia in order to continue their ART treatment in another country.

It is intended that the practice of importing or exporting embryos (that have been created by fertilisation of a human egg by human sperm) for the ART treatment of a particular couple, will be permitted, subject to the *Quarantine Act 1908*.

This is consistent with Recommendation 41 of the Lockhart Report that stated 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.

Clause 21 (Offence—commercial trading in human eggs, human sperm or human embryos)

This clause is the same as existing section 23 of the *Prohibition of Human Cloning Act 2002* and reflects recommendation 33 of the Lockhart Report which states that the present prohibition of the sale of sperm, eggs and embryos should continue, but the reimbursement of reasonable expenses should continue to be permitted.

The clause prevents the commercial trading of human eggs, sperm and embryos. Both parties involved in commercial trading of such material would be committing an offence (for example, the person who sells the egg, sperm or embryo and the person who purchases the egg, sperm or embryo). The only consideration which may be given in relation to the supply of gametes or embryos is reimbursement of reasonable expenses related to that supply, including expenses incurred for the collection, storage and transport where relevant. This means if, for example, semen is transferred from one clinic to another, the second clinic could reimburse the first clinic for the costs of storage and transport of the semen. A further example is where a woman who is to be treated with donated eggs could pay for the cost of the egg retrieval from another woman.

Reasonable expenses in relation to the supply of a human embryo, where that embryo is donated to another couple, do not include any expenses incurred by the person or couple (for whom the embryo was originally created), before the embryo was determined to be excess to their needs. That is, if a person has excess embryos and they wish to donate the embryos to other people, they cannot have the costs of their IVF treatment reimbursed by the person receiving the donated embryos.

This clause is not intended to address the issue of surrogacy. It is proposed that surrogacy continue to be dealt with through State and Territory legislation and that it not be addressed as part of this particular national scheme.

The maximum penalty for trading in human embryos, sperm or eggs is 10 years imprisonment.

Division 2—Practices that are prohibited unless authorised by a licence

Clause 22 (Offence—creating a human embryo other than by fertilisation, or developing such an embryo)

This clause provides that a person must not create a human embryo by a process other than the fertilisation of a human egg by a human sperm (or develop a human embryo so created) unless they are authorised to do so by a licence issued by the NHMRC Licensing Committee.

This allows researchers to apply to the NHMRC Licensing Committee to create embryos using techniques such as somatic cell nuclear transfer. This reflects Recommendation 23 of the Lockhart Report. Rather than specifically prohibiting human somatic cell nuclear transfer without a licence, the clause has been drafted more generally to cover creation of embryos by any means other than fertilisation of human egg by human sperm. This is consistent with the NHMRC definition of a human embryo, which recognises that technology may change and that all embryos however created must be captured by the legislation.

It is important that this clause be read in the context of clause 14 which bans the development of a human embryo outside the body of a woman for more than 14 days and clauses 9 and 20(3) which ban the placement in the body of a woman of a human embryo clone, or any other human embryo created other than by the fertilisation of a human egg by a human sperm.

The maximum penalty for failure to comply with this provision is imprisonment for 10 years.

Clause 23 (Offence—creating or developing a human embryo containing genetic material provided by more than 2 persons)

This clause provides that a person may only create or develop a human embryo (by a process other than the fertilisation of human egg by human sperm) that contains genetic material provided by more than 2 persons if it is authorised by a license issued by the NHMRC Licensing Committee.

This clause only allows creation of embryos containing genetic material from 2 or more people if the embryo has been created by a means other than fertilisation.

As noted in relation to proposed clause 13, the Lockhart Committee recommended that development of a human embryo using genetic material from more than two people be permitted under licence. However, if this involves the creation of an embryo by fertilisation of human egg by human sperm then this would be inconsistent with Lockhart recommendation 13 that suggests that embryos, created by human egg and human sperm, should not be created for the purposes of research. Therefore this offence has been drafted so as to only allow the licensing of the creation and development of a human embryo involving genetic material from more than two people if it has been created by means other than fertilisation of human egg by human sperm. This approach reflects the spirit of both Recommendation 13 and Recommendation 26 of the Lockhart Review.

The notes at the base of the provision remind readers that the development of a human embryo outside the body of a woman for more than 14 days is prohibited by clause 14.

The maximum penalty for an offence against this provision is imprisonment for 10 years.

Clause 23A (Offence—using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo)

This clause provides that a person commits an offence if the person uses precursor cells taken from a human embryo or a human fetus to create (or develop) an embryo unless they are authorised to do so by a licence issued by the NHMRC Licensing Committee.

The maximum penalty for non-compliance with this clause is imprisonment for 10 years.

This clause implements Recommendation 27 of the Lockhart Review which provided that creation of embryos using precursor cells from a human embryo or a human fetus should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research 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.

Clause 23B (Offence—creating a hybrid embryo)

This section bans the creation or development of a hybrid embryo unless the creation or development of the hybrid embryo is authorised by a licence issued by the NHMRC Licensing Committee. It is important that this section be read in conjunction with proposed amended section 21 of the *Research Involving Human Embryos Act 2002* that further restricts the circumstances in which someone may apply for a licence to create or develop a hybrid embryo.

Proposed amended section 21 of the *Research Involving Human Embryos Act 2002* makes it clear that a licence may only be issued in the following circumstances:

- for the purposes of testing sperm quality in an accredited ART centre. In this case, the hybrid embryo may only be developed up to (but not including) the first mitotic division. This is consistent with Recommendation 17 of the Lockhart Review and would enable ART tests that were carried out by ART clinics prior to the commencement of the *Prohibition of Human Cloning Act 2002*, to once again be permitted. In the context of the changes that this Bill proposes, it could be argued that there may be doubt surrounding whether the definition of a "hybrid embryo" captures sperm quality tests where the animal egg is combined with human sperm but does not develop past the first mitotic division. To put this beyond doubt, it is suggested that Regulations be made prescribing animal eggs in the process of fertilisation by a human sperm (but yet to reach the first cell division) as hybrid embryos; and

- for the creation of a hybrid embryo created by introducing the nucleus of a human cell into an animal egg. In this case, the hybrid embryo may be developed up to 14 days. This is consistent with Lockhart Recommendation 24 that states that "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.

This offence attracts a maximum penalty of 10 years imprisonment.

Clause 23C (Regulations under Customs Act)

This clause provides that the Minister who administers the *Customs Act 1901* must take all reasonable steps to ensure that regulations are made, within 6 months after the commencement of this section, permitting, subject to appropriate conditions or restrictions, the import and export of embryonic stem cell lines derived from human embryo clones which have been derived using practices consistent with Australian legislation.

The reason for the inclusion of this provision is as follows:

- Lockhart Recommendation 42 provides that the import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority. The Lockhart Report did not include detailed information about how this recommendation should be implemented;

- Schedule 1, item 27 of the *Customs (Prohibited Imports) Regulations 1956* prohibits absolutely the import of "viable material derived from human embryo clones". The effect of this is to ban the import of human embryonic stem cell lines;

- one means by which to implement the Lockhart Recommendation 42 is to repeal item 27 of Schedule 1 of the *Customs (Prohibited Imports) Regulations 1956* and this would enable the import of viable materials from human embryo clones including human embryonic stem cells lines. However, if this item was repealed without anything put in its place then there would be no guarantee that the material imported has been derived using practices consistent with Australian legislation;

- it is therefore considered that the best means for addressing these issues is to enable the Minister for Customs to develop appropriate regulations to enable the import and export of ethically and legally derived viable material from human embryo clones; and

- the insertion of clause 23C makes it clear that it is Parliament's intention that the Minister for Customs make appropriate Regulations.

Item 8 (After section 25)

Clause 25A (Further review of operation of Act)

This section provides for a further review of the Act in three years time. In summary:

- the review must be undertaken as soon as possible after the third anniversary of the day on which the amending Act received the Royal Assent;

- the review is to be undertaken by persons chosen by the Minister, with the agreement of each State. The review team must consult the Commonwealth and the States and a broad range of persons with expertise in or experience of relevant disciplines and the views of these organisations/individuals must be reflected in the review Report;

- the results of the review must be given to the Council of Australian Governments and both Houses of the Parliament (within four years); and

- the review must examine issues such as:

- developments in assisted reproductive technology, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;
- developments in embryonic stem cell research, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;
- community standards;
- a brief analysis of international developments and legislation relating to the use of human embryos and related research;
- an analysis of research resulting from the authorisations granted under the amending Act;
- any National Stem Cell Centre and any national register of donated excess ART embryos;
- an evaluation of the effectiveness of legislative provisions and NHMRC guidelines relating to proper consent;
- an evaluation of the range of matters for which the NHMRC Licensing Committee may issue an authorising licence and any recommendations to increase, decrease or alter these arising from the evaluation;
- an analysis of any research or clinical practice which has been prevented as a result of legislative restrictions;
- the extent to which the NHMRC Licensing Committee has effectively used information and education tools to assist researchers working in the field, and any ongoing need for legally binding rulings; and
- the extent of Commonwealth/State cooperation in the area of human embryo research and the requirement for further Commonwealth or State legislation on the matter.

SCHEDULE 2—RESEARCH INVOLVING HUMAN EMBRYOS ACT 2002

Item 1 (At the end of section 3)

Section 3 of the RIHE Act 2002 describes the object of the Act. The object of the Act is "to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos by regulating activities that involve the use of certain human embryos created by assisted reproductive technology".

This item adds the words "or by other means" onto the end of the object statement to make it clear that the amended Act regulates activities involving not just uses of embryos created by ART but also creation and use of embryos created by other means.

Item 2 (Subsection 7(1) definition of human embryo)

This item repeals the existing definition of human embryo and replaces it with the new definition of human embryo developed by the NHMRC. Human embryo is defined as follows:

> ***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.

Item 3 (Subsection 7(1))

This item inserts the definition of "hybrid embryo" from the *Prohibition of Human Cloning Act 2002* into the *Research Involving Human Embryos Act 2002*. There is no change to the definition as it currently appears in the *Prohibition of Human Cloning Act 2002*.

hybrid embryo means:
(a) an embryo created by the fertilisation of a human egg by animal sperm; or
(b) an embryo created by the fertilisation of an animal egg by human sperm; or
(c) a human egg into which the nucleus of an animal cell has been introduced; or
(d) an animal egg into which the nucleus of a human cell has been introduced; or
(e) a thing declared by the regulations to be a hybrid embryo.

As previously noted, consideration should also be given to prescribing in the regulations, that animal eggs in the process of fertilisation by a human sperm (but yet to reach the first cell division) are hybrid embryos. This would put the issue beyond doubt and is consistent with the proposed provisions detailed in the Bill which require any sperm viability tests (that utilise animal eggs and human sperm) to be licensed by the NHMRC Licensing Committee and that they not be able to develop beyond the first mitotic division.

Item 4 (Subsection 7(1))

This item inserts into the *Research Involving Human Embryos Act 2002*, a new definition of unsuitable for implantation.

In summary, a human embryo that is ***unsuitable for implantation***, is one that:

- is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004);* or

- is determined to be unsuitable for implantation in accordance with objective criteria to be specified in guidelines developed by the NHMRC and prescribed in regulations.

Item 5 (Subsection 7(1))

This item inserts a new definition in section 7 which clarifies that, for the purposes of this Act, "use" includes develop, or development, as the case requires. This has been included for convenience only so that when the Act refers to use of an embryo (for example, as authorised by the Act) this includes development of an embryo. It should be noted that all of the provisions that reference "use" (including development) also operate in conjunction with

section 14 of the *Prohibition of Human Cloning Act 2002* which prohibits development of an embryo beyond 14 days.

Item 6 (At the end of section 7)

This includes the same clarifications as are proposed to be included in the *Prohibition of Human Cloning Act 2002*. Namely that, a reference in the Act to:

- an embryo (including a human embryo) is a reference to a living embryo;
- a human egg is a reference to a human oocyte; and
- a human embryo does not include a reference to a hybrid embryo or a human embryonic stem cell line.

Item 7 (Heading to Part 2)

This section repeals the current heading of Part 2 of the *Research Involving Human Embryos Act 2002* (which is currently entitled "Regulation of certain uses involving excess ART embryos") and replaces it with a new heading "Part 2—Regulation of the use of excess ART embryos, other embryos and human eggs".

Item 8 (Section 8 definition of proper consent)

This item repeals the definition or proper consent and replaces it with a new definition as follows:

> ***proper consent***, in relation to the use of an excess ART embryo or a human egg, or the creation or use of any other embryo, means 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 for the purposes of this definition.

Item 9 (Section 8 - definition of responsible person)

This item defines ***responsible person*** to mean:

(a) in relation to an excess ART embryo:
   i. each person who provided the egg or sperm from which the embryo was created; and
   ii. the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and
   iii. any person who was the spouse of a person mentioned in subparagraph (i) at the time the egg or sperm mentioned in that paragraph was provided; and
   iv. any person who was the spouse of the woman mentioned in subparagraph (ii) at the time the embryo was created; or

(b) in relation to an embryo other than an excess ART embryo—each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation or use of the embryo; or

(c) in relation to a human egg—the woman who was the biological donor of the egg.

There has been no change to the definition of responsible person in relation to an excess ART embryo. Sub-clauses (b) and (c) have been added to ensure that all appropriate people provide consent in relation to the use of a human egg for research or the creation and use of an embryo created by means other than fertilisation of human egg by human sperm.

Item 10 (After section 10)

This item inserts the following two new offences related to licensing.

Clause 10A Offence—use of other embryos

This clause provides that a person commits an offence if a person intentionally uses the following types of embryos without a licence issued by the NHMRC Licensing Committee:

- a human embryo created by a process other than the fertilisation of a human egg by a human sperm; or
- a human embryo that contains genetic material provided by more than 2 persons; or
- a human embryo created using precursor cells from a human embryo or a human fetus; or
- a hybrid embryo.

This provision is needed because the *Prohibition of Human Cloning Act 2002* relates specifically to creation and development of embryos and the requirement for licensing in these circumstances. This provision relates to "use" of embryos that have been created or developed under licence. This provision makes it clear that not only must the creation or development of these types of embryos be authorised by a licence but the use of such embryos must also be authorised by a licence.

The maximum penalty for non-compliance with this provision is imprisonment for 5 years. This is consistent with the existing offences in this Part of the *Research Involving Human Embryos Act 2002*.

Clause 10B Offence—certain activities involving use of human eggs

This clause establishes an offence if someone undertakes research or training involving the fertilisation of a human egg by human sperm, up to but not including the first mitotic division, outside the body of a woman for the purposes of ART research or training without a licence issued by the NHMRC Licensing Committee.

This implements Recommendations 15 and 16 of the Lockhart Review.

The offence attracts a maximum penalty of imprisonment for up to 5 years. This is consistent with similar existing offences in the Act.

Item 11 (Paragraph 11(a))

Section 11 of the *Research Involving Human Embryos Act 2002* currently bans the use, outside the body of a woman, of an embryo that is not an excess ART embryo unless the use is for the purposes of ART. The purpose of existing section 11 is to prohibit people from using non-excess ART embryos for research purposes. This item amends this section by continuing the ban on the use of use non-excess ART embryos created by the fertilisation of human egg by human sperm but making it clear that the ban does not extend to use of embryos that have been created by means other than fertilisation of human egg by human sperm. Use of any such embryos is only permitted under licence by the NHMRC Licensing Committee. This is an amendment that is consequential to the recommendations of the Lockhart Review which allow the creation of embryos for research if such embryos are created other than by fertilisation of a human egg by human sperm.

Item 12 (At the end of Division 2 of Part 2)

This item inserts a new clause 12A after section 12.

Clause 12A Person not liable for conduct purportedly authorised

This clause clarifies that a person is not criminally responsible for an offence against the Act if:

- the conduct by the person is purportedly authorised by a provision of a licence; and
- the licence or the provision is invalid, whether because of a technical defect or irregularity or for any other reason; and
- the person did not know, and could not reasonably be expected to have known, of the invalidity of the licence or the provision.

This clause is intended to address the underlying policy objective of Recommendations 50 – 52 of the Lockhart Review. 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.

This recommendation raises significant constitutional issues relating to the impermissible exercise of judicial power by a non-judicial body. For example, in the Brandy case, the High Court unanimously held that the power of Human Rights and Equal Opportunities Commission to decide whether conduct was unlawful and to award damages was an impermissible conferral of judicial power, because of the binding and conclusive nature of the Commission's determinations.

Recognising these concerns, a provision has been included in the Bill (clause 12A) which avoids these constitutional issues, but attempts to address the basic concern of the Lockhart Committee which appeared to be the potential liability of researchers where they are acting in

good faith in accordance with a licence but where the NHMRC Licensing Committee in fact had no power to issue the licence.

Item 13 (Paragraph 16(3)(c))

Subsection 16(3) of the *Research Involving Human Embryos Act 2002* describes the process for making appointments to the NHMRC Licensing Committee. One of the existing requirements is that the Minister must be satisfied that any members proposed to be appointed do not have a direct or indirect pecuniary interest in a body that undertakes uses of excess ART embryos, being an interest that could conflict with the proper performance of the member's functions.

This item amends this subsection to ensure that not only is a person's interest in the use of excess ART embryos taken into account but also any interest they may have in the creation or use of other embryos or the use of human eggs. This reflects the expanded scope of the NHMRC Licensing Committee's responsibilities

Item 14 (At the end of section 16)

This item adds two additional subclauses to section 16. The intent of these additional sub-clauses is to address the concern raised by the Lockhart Committee (and reflected in recommendation 36) about the problem of delays in the filling of vacancies on the NHMRC Licensing Committee.

To this end, the additional sub-clauses provide that:

- it is the intention of the Parliament that any vacancy on the NHMRC Licensing Committee be filled as soon as possible; and

- if there is a vacancy in the membership of the NHMRC Licensing Committee for a period of 3 months the Minister must, within three sitting days of the expiration of those 3 months, table in each House of the Parliament a written statement of reasons for the failure to fill the vacancy.

The Lockhart Committee did not make any recommendations in relation to the composition of the NHMRC Licensing Committee in the light of the expanded functions of the Committee. However the current membership is expressed relatively broadly in section 16 and the CEO of the NHMRC also has the capacity to appoint sub-committees in accordance with the NHMRC Act.

Item 15 (Subsection 20(1))

Subsection 20(1) of the *Research Involving Human Embryos Act 2002* currently provides that a person may apply to the NHMRC Licensing Committee for a licence authorising the use of excess ART embryos.

Consistent with the recommendations of the Lockhart Review, the proposed amendments to the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* enable certain activities to be undertaken provided that a licence has been granted by the NHMRC Licensing Committee.

The purpose of this amendment to subsection 20(1) is to set out all of the activities for which a person may request a licence from the NHMRC Licensing Committee. If the activity does not fall within this list, it is not able to be licensed by the NHMRC Licensing Committee (this means that it is either prohibited absolutely or does not fall within the scope of this legislation).

It is proposed that a person may apply to the NHMRC Licensing Committee for a licence authorising one or more of the following:

- use of excess ART embryos;

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

- creation of human embryos (other than by fertilisation of a human egg by a human sperm) and containing genetic material provided by more than 2 persons, and use of such embryos;

- creation of human embryos using precursor cells from a human embryo or a human fetus, and use of such embryos;

- research and training involving the fertilisation of a human egg, up to the first mitotic division, outside the body of a woman for the purposes of research or training;

- creation of hybrid embryos by the fertilisation of an animal egg by human sperm, and use of such embryos up to the first mitotic division, if:
  - the creation or use is for the purposes of testing sperm quality; and
  - the creation or use will occur in an accredited ART centre;

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

Sub-clause 20(1A) has been included to make it clear that amended section 20(1) does not permit the NHMRC Licensing Committee to authorise any use of an excess ART embryo or other embryo that would result in the development of the embryo for a period of more than 14 days, excluding any period when development is suspended.

Item 16 (Subparagraph 21(3)(a)(i))

Subparagraph 21(3)(a)(i) provides that the NHMRC Licensing Committee must not issue a licence unless it is satisfied that appropriate protocols are in place to enable proper consent to be obtained before an excess ART embryo is used under licence. This item amends this subparagraph to make it clear that if the NHMRC Licensing Committee is considering an application in relation to any other embryo or human egg then the same issue must be taken into account.

Items 17 and 18 (Paragraphs 21(4)(a) and (b))

Paragraph 21(4)(a) provides that when deciding whether to grant a licence the NHMRC Licensing Committee must take into account restricting the number of embryos necessary to achieve the goals of the project and also whether there are likely to be any significant advances in knowledge or improvements in technologies for treatment as the result of the use of the excess ART embryos. This item amends the provision to insert the same requirements when the NHMRC Licensing Committee is considering any other licence application (including any licence application in relation to, for example, the creation of embryos by SCNT or the fertilisation of human eggs up to the first mitotic division).

Item 19 (Subsection 24(1))

This item repeals subsection 24(1) and replaces it with the following:

(1) A licence is subject to the condition that before an excess ART embryo or human egg is used, or other embryo is created or used, as authorised by the licence:
   (a) each responsible person in relation to the excess ART embryo, other embryo or human egg must have given proper consent to that creation or use; and
   (b) 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.

Items 20, 21, 22 and 23 (Subsection 24(2), paragraphs 24(5)(a), 24(5)(b) and 24(5)(e) and subsections 24(6) and (7))

These items amend section 24 so that wherever there is a reference to "excess ART embryos" (or similar), this is replaced with a reference to excess ART embryos, human egg and other embryos. This ensures that all of the licensing conditions that can be imposed in relation to the use of excess ART embryos can also be imposed in relation to the use of human eggs under licence and the creation and use of any other embryos under licence.

Item 24 (At the end of section 24)

This item inserts a new subsection (8) at the end of section 24 which provides that a licence in relation to embryos that are unsuitable for implantation (as defined) may provide that the NHMRC guidelines referred to in the definition of proper consent may apply in a modified form in relation to the use, under the licence, of excess ART embryos that are unsuitable for implantation.

The purpose of this provision is to address Lockhart Recommendations 20, 21 and 22. The Lockhart Committee recommended that fresh ART embryos that are unsuitable for implantation, as defined by objective criteria, be able to be licensed for use for training and research.

Currently the *Research Involving Human Embryos Act 2002* does not expressly prohibit this. However, there is a statutory condition of licence that the responsible people in relation to an excess ART embryo must give proper consent to any research, in accordance with NHMRC guidelines. The relevant guidelines are the Australian Health Ethics Committee (AHEC) *Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research* (2004). These Guidelines provide that:

> "A person responsible for an embryo must be free at any time to withdraw consent to further involvement in the research. In view of the fact that once an embryo has been destroyed it cannot be restored, it is recommended that the consent of the persons responsible to a use that will damage or destroy an embryo must not be acted upon until a suitable fixed period of time for reconsideration has been allowed, normally at least two weeks after their consent to such research. This 'cooling-off' period before consent becomes effective must be explained to the persons responsible when consent is obtained." (page 53)

Based on the Lockhart Committee discussion of the issue, it would appear that researchers and the NHMRC Licensing Committee has been interpreting this requirement such that embryos that are unsuitable for implantation and are not frozen (because they are unable to be frozen or because they are unsuitable for implantation), cannot be used for research because the 14 day cooling-off period would preclude this.

In order to address this issue, it is proposed that a new sub-clause be added into section 24 (subsection 24(8)) that clarifies that if the NHMRC Licensing Committee considers it appropriate, they may approve the use of embryos that are unsuitable for implantation and alter the cooling-off period that would be "normally at least two weeks" as recommended by the NHMRC. This would allow the use of excess ART embryos that are unsuitable for implantation and would still ensure that appropriate consent is obtained from the responsible people. In no circumstances would embryos that are not excess be able to be used.

It is proposed that the NHMRC develop clear and objective criteria defining those embryos that are unsuitable for implantation.

Items 25 and 26 (Paragraphs 29(1)(b) and (d))

These items amend section 29 so that wherever there is a reference to "excess ART embryos" (or similar), this is replaced with a reference to excess ART embryos, human egg and other embryos. This means that the NHMRC must now also include on its database information about licences issues authorising the creation and use of other embryos and the use of human eggs.

Items 27 and 28 (Section 31 and 32(1)(c))

Recognising the new decision-making role of the NHMRC under subsection 24(8) (in terms of being able to modify a statutory condition of licence such that different rules should apply in relation to proper consent for use of embryos that are unsuitable for implantation), these items amend sections 31 and 32(1)(c) to make this decision reviewable by the Administrative Appeals Tribunal.

This amendment is consequential to the amendment to section 24 which implements Lockhart Recommendations 20-22.

Item 29 (At the end of subsection 35(2))

The Lockhart review recommends that the monitoring powers available under the Acts be strengthened to enable entry, inspection and enforcement in relation to non-licensed facilities

in the same manner and by the observance of the same procedures as applicable to search warrants under Commonwealth legislation (Recommendation 39).

In order to give effect to this recommendation, changes have been made throughout Part 3 of the *Research Involving Human Embryos Act 2002* to enable inspectors to apply to a Magistrate for a search warrant in relation to non-licensed premises. The approach adopted is consistent with the approach detailed in the *Gene Technology Act 2000* (as referenced by the Lockhart Committee) and with general Australian Government law enforcement policy.

Item 29 amends section 35 (which deals with powers available to inspectors for monitoring compliance) to enable inspectors to enter premises where the entry is made under a warrant under section 37A.

Item 30 (Paragraph 36(1)(b))

This item inserts the words "other embryo, human egg" after the word "human embryo".

Item 31 (At the end of subsection 36(1))

This item amends subsection 36(1) by adding two additional powers that may be exercised by inspectors authorised to enter premises by a warrant under section 37A. An inspector may require any person in or on the premises to answer any questions put by the inspector and produce any book, record or document requested by the inspector.

Items 32 and 33 (Section 37)

This item ensures that the power to secure applies not just to a human embryo but also to any other embryo or human egg.

Item 34 (After section 37)

Clause 37A Monitoring warrants

This item inserts a new clause (clause 37A) in the *Research Involving Human Embryos Act 2002*. The new clause provides that an inspector may apply to a magistrate for a warrant and the magistrate may issue a warrant if he/she is satisfied that it is reasonably necessary that one or more inspectors should have access to the premises for the purposes of finding out whether the *Prohibition of Human Cloning Act 2002* or the *Research Involving Human Embryos Act 2002* (or Regulations) have been complied with.

The warrant enables one or more inspectors to enter premises and exercise the powers set out in clause 36 in relation to the premises.

Clause 37B Details of warrant to be given to occupier etc.

This clause provides that if a warrant under clause 37A is being executed and the occupier of the premises or another person who represents the occupier is present at the premises, then the inspector must:

- make a copy of the warrant available to the person; and

- identify himself or herself to that person.

Clause 37C Announcement before entry

This clause provides that an inspector must, before entering premises under a warrant, announce that he or she is authorised to enter the premises and give any person at the premises an opportunity to allow entry to the premises.

Clause 37D Occupier entitled to be present during search

This clause provides that if a warrant is being executed and the occupier of the premises (or another person who represents the occupier) is present at the premises, the person is entitled to observe the search being conducted but must not impede the search.

Item 35 (After section 47)

This item inserts two new clauses (clauses 47A and 47B) into the *Research Involving Human Embryos Act 2002*.

Clause 47A Further review of operation of Act

Clause 47A provides for a further review of the operation of the amended Act. The terms of the review are the same as for the review of the *Prohibition of Human Cloning Act 2002* as described in proposed clause 25A of that Act.

Clause 47B Minister to report to Parliament

Clause 47B requires the Minister to report to Parliament on certain matters not later than 6 months after the day on which the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* commenced.

SCHEDULE 3—SAVING PROVISION

Item 1 (Saving provision)

The purpose of this provision is to clarify that the amendments to the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* in no way impact or invalidate any existing licences that may have been issued by the NHMRC Licensing Committee.

Further, if a person applied for a licence under section 20(1) before these amendments take effect and the licence application has not been decided by the NHMRC Licensing Committee then the person is taken, on and from the commencement of the new legislation, to have applied for the licence under subsection 20(1) of the amended Act.

SCHEDULE 4—AMENDMENT OF REGULATIONS

Customs (Prohibited Exports) Regulations 1958

Item 1 (Regulation 7)

This item repeals Regulation 7 of the *Customs (Prohibited Exports) Regulations 1958*. 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.

Appendix 1:
Summary of Lockhart recommendations and how these are addressed in the Bill

	Lockhart Review recommendation	How the issue is addressed in the Bill
1	Clinical practice and scientific research involving assisted reproductive technologies (ART) and the creation and use of human embryos for research purposes should continue to be subject to specific national legislation.	The national legislative scheme will continue to exist.
2	Reproductive cloning should continue to be prohibited.	Proposed clauses 9 and 14 continue to ban the development of a human embryo clone for longer than 14 days and the implantation of such a clone in a human or animal. Amended section 20 also bans the development and implantation of **any** embryo that does not result from the fertilisation of a human egg by human sperm.
3	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 should continue to be prohibited.	This is banned in proposed clause 20 of the PHC Act.
4	Development of a human embryo created by any means beyond 14 days gestation in any external culture or device should continue to be prohibited.	This is banned in proposed clause 14 of the PHC Act.
5	Implantation into the reproductive tract of a woman of a human–animal hybrid or chimeric embryo should continue be prohibited.	This is banned in proposed clause 20 of the PHC Act.
6	Development of a human–animal hybrid or chimeric embryo should continue to be prohibited, except as indicated in Recommendation 17.	Creation of chimeric embryos is banned in proposed clause 17 of the PHC Act. The creation and development of hybrid embryos is banned by proposed clause 23B, unless authorised by licence. The only licences that may be issued are ones giving effect to recommendations 17 and 24. Development of hybrid embryos beyond 14 days is banned in all cases by proposed clause 18.
7	Placing a human embryo into an animal or into the body of a human apart from into a woman's reproductive tract, or placing an animal embryo into the body of a human, for any period of gestation, should all remain prohibited.	This is banned in proposed clause 19 of the PHC Act.
8	Implantation into the reproductive tract of a woman of an embryo created with genetic material provided by more than two people should continue to be prohibited.	This is banned in proposed clause 20 of the PHC Act.
9	Implantation into the reproductive tract of a woman of an embryo created using precursor cells from a human embryo or a human fetus should continue to prohibited.	This is banned in proposed clause 20 of the PHC Act.
10	Implantation into the reproductive tract of a woman of an embryo carrying heritable alterations to the genome should continue to prohibited	This is banned in proposed clause 20 of the PHC Act.
11	Collection of a viable human embryo from the body of a woman should continue to be prohibited.	This is banned in proposed clause 16 of the PHC Act.
12	Creation of human embryos by fertilisation of human eggs by human sperm should remain restricted to ART treatment for the purposes of reproduction.	This will continue to be the case (proposed clause 12 of the PHC Act).
13	Creation of human embryos by fertilisation of human eggs by human sperm to create embryos for the purposes of research should continue to be prohibited except in the situation described in Recommendation 15.	This is banned in proposed clause 12 of the PHC Act, which makes it an offence to create a human embryo by fertilisation of human egg with human sperm for any purpose other than achieving pregnancy.
14	Use of excess ART embryos in research should continue to be permitted, under licence, as under current legislation.	Use of excess ART embryos in research will continue to be permitted, under licence (proposed amended section 20 of the RIHE Act).
15	Research involving fertilisation of human eggs by human sperm up to, but not including, the first cell division should be permitted for research, training and improvements in clinical practice of ART.	The proposed amendments to section 20 of the RIHE Act allow a person to apply to the Licensing Committee to undertake research involving fertilisation of human eggs by human sperm up to, but not including, the first cell division. Such activity not authorised by a licence is banned under proposed clause 10B of the RIHE Act.
16	Testing of human oocytes for maturity by fertilisation up to, but not including, the first cell division or by parthenogenetic activation should be permitted for research, training and improvements in clinical practice of ART.	Testing by fertilisation up to the first mitotic division will be permitted under licence (proposed clauses 10B and 20 of the RIHE Act). Parthenogenic activation will be also be permitted under licence in accord with recommendation 25 (amended clause 20 of the RIHE Act allows a person to apply for a licence to create an embryo by any

		means other than fertilisation of human egg by human sperm).
17	Certain interspecies fertilisation and development up to, but not including, the first cell division should be permitted for testing gamete viability to assist ART training and practice.	Proposed paragraph 20(1)(f) enables the granting of a licence to permit this.
18	The Licensing Committee should develop a simple proforma application for licences to undertake training and quality assurance activities for ART clinics.	No legislative change required.
19	Consideration should be given to the use of cytoplasmic transfer (including transfer of mitochondrial DNA), under licence, for research on mitochondrial disease and other uses to improve ART treatment.	Proposed amended section 20(1) of the RIHE Act will permit, under licence, certain types of research that may be useful in relation to cytoplasmic transfer. However, an embryo containing genetic material from more than two people (and created by the fertilisation of human egg and sperm) will not be able to be created for research purposes.
20	An expert body should formulate objective criteria to define those embryos that are unsuitable for implantation.	The new definition of "unsuitable for implantation" in subsection 7(1) of the RIHE Act provides for this.
21	Fresh ART embryos that are unsuitable for implantation, as defined by the objective criteria, should be permitted to be used, under licence, for research, training and improvements in clinical practice.	New subclause 24(8) in the RIHE Act enables the Licensing Committee to modify the requirements for "proper consent" in relation to use of such embryos. This will enable the current 14 day cooling-off period to be shortened, so as to allow the use of fresh embryos.
22	Fresh ART embryos that are diagnosed by preimplantation genetic diagnosis (according to the ART guidelines) as being unsuitable for implantation should be permitted to be used, under licence, for research, training and improvements in clinical practice.	New subsection 24(8) in the RIHE Act (described immediately above) will enable this.
23	Human somatic cell nuclear transfer should be permitted, under licence, to create and use 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.	Section 22 of the PHC Act bans the creation or development of a human embryo by a process other than fertilisation unless this is licensed. Section 20 of the RIHE provides for the licensing of the creation and use of such embryos. This has the effect of allowing SCNT under licence. The PHC Act also bans the development of any human embryo (including a human clone) outside the body of a woman beyond 14 days (clause 14), and the implantation of a human embryo clone (or any embryo that has not been created using sperm and egg) (clauses 9 and 20(3)).
24	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.	Paragraph 20(1)(g) of the RIHE Act enables the granting of a licence to permit this. Section 18 of the PHC Act bans the development of such embryos for more than 14 days.
25	Creation of human embryos and human embryo clones by means other than fertilisation of an egg by a sperm (such as nuclear or pronuclear transfer and parthenogenesis) should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research 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.	Proposed clause 22 of the PHC Act bans such activity, except under licence. Proposed clause 20 of the RIHE provides for the granting of licences. Clause 9 of the PHC Act bans the implantation of such embryos and proposed clause 14 of the PHC Act bans their development for longer than 14 days.
26	Creation of human embryos using the genetic material from more than two people, or including heritable genetic alterations, should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research 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.	The combined effect of proposed clauses 13 and 23 of the PHC Act and clause 20(1) of the RIHE Act is that the Licensing Committee may licence the creation of embryos that include genetic material from more than two people provided that the embryo is created by means other than fertilisation of a human egg by human sperm. Fertilisation studies may also be undertaken, under licence, up to (but not including) the first mitotic division.
27	Creation of embryos using precursor cells from a human embryo or a human fetus should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research 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.	Proposed clause 23A of the PHC Act bans such activity, except under licence. Proposed clause 20 of the RIHE provides for the granting of licences. Clause 20 of the PHC Act bans the implantation of such embryos and clause 14 of the PHC Act bans their development for longer than 14 days.
28	The definition of a 'human embryo' in both Acts should be	This was the NHMRC's draft definition at the time the Lockhart

	changed to: 'A human embryo is a discrete living entity that has a human genome or an altered human genome and that has arisen from either: (i) the first mitotic cell division when fertilisation of a human oocyte by a human sperm is complete; or (ii) 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, 14 days and has not yet reached eight weeks of development.'	Report was written. The final NHMRC definition differed slightly from the draft definition. The proposed new definition in the PHC Act and the RIHE Act is the final NHMRC definition.
29	The National Health and Medical Research Council (NHMRC) should review its guidelines in relation to consent to research on excess ART embryos, in order to clarify the consent process in relation to the following issues: • the circumstances, if any, where those who choose to donate excess ART embryos to research may be able to choose not to be contacted at some later stage to give consent to a particular research proposal • the circumstances, if any, where a human research ethics committee can determine that the researcher need not ask for further consent to use embryos already declared 'excess' • the development of an appropriate form of consent that could be completed by the responsible persons for excess ART embryos shortly after the declaration that the embryos are excess • the manner in which those who donate embryos or gametes for the creation of ART embryos may express any preference for the type of research for which the tissue will be used, once the embryo is declared excess.	For consideration by the NHMRC - No changes to the legislation required.
30	The NHMRC should develop ethical guidelines for the use of embryos that are unsuitable for implantation for research, training and improvements in clinical practice (see Recommendations 20–22).	For consideration by the NHMRC - No changes to the legislation required.
31	The current principles of consent for participation in medical research must apply to sperm, egg and embryo donors, so as to ensure that decisions are freely made.	The proposed amendments to the RIHE Act make it clear that proper consent must be gained for any research involving human eggs or human embryos.
32	The NHMRC should develop guidelines for egg donation.	For consideration by the NHMRC - No changes to the legislation required.
33	The present prohibition of the sale of sperm, eggs and embryos should continue, but the reimbursement of reasonable expenses should continue to be permitted.	Proposed clause 21 of the PHC Act is the same as the existing prohibition.
34	The Embryo Research Licensing Committee of the NHMRC (the Licensing Committee) should continue to be the regulatory body responsible for assessing licence applications, issuing licences and monitoring compliance, as under current arrangements.	This continues to be the case – no changes to the legislation required.
35	The role of the Licensing Committee should be extended to include assessment of licensing applications and issuing licences for any additional activities permitted, under licence (see Recommendations 14–27).	Proposed amendments to subclause 20(1) of the RIHE Act will enable the Licensing Committee to do this.
36	The Australian Parliament and the Council of Australian Governments should give urgent attention to the problem of delays in the filling of vacancies on the Licensing Committee.	Proposed amendments to clause 16 of the RIHE Act (new subsections (7) and (8)) address this recommendation.
37	There should be no attempt to recover the cost of administration, licensing, monitoring and inspection activities associated with the legislation from researchers at this point in time.	This continues to be the case.
38	The Licensing Committee should continue to perform its functions in relation to licences and databases for research permitted by licences under the Research Involving Human Embryos Act.	This continues to be the case.

39	Licensing Committee inspectors should be given powers, under the Prohibition of Human Cloning Act and the Research Involving Human Embryos Act, of entry, inspection and enforcement in relation to non-licensed facilities in the same manner and by the observance of the same procedures as applicable to search warrants under Commonwealth legislation, if such powers do not clearly exist.	Proposed clauses 37A, 37B, 37C and 37D in the RIHE Act provide for these powers.
40	There should be a continuation of the role of the Reproductive Technology Accreditation Committee in the regulation of ART.	No changes to legislation required.
41	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.	Regulation 7 of the *Customs (Prohibited Exports) Regulations 1958* is proposed to be repealed by virtue of Schedule 4 of the Bill.
42	The import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority.	Section 23C of the PHC Act requires the Minister for Customs to take all reasonable steps to ensure that regulations are made permitting this.
43	The existing requirements for the import and export of human biological materials are satisfactory and, for ethically derived human embryonic stem cells, no further restrictions are necessary.	No changes to legislation required.
44	Trade in human gametes or embryos, or any commodification of these items, should continue to be prohibited.	This continues to be the case under proposed clause 21 of the PHC Act.
45	Donors of tissue that is going to result in an immortal stem cell line should be informed by means of processes monitored by human research ethics committees about the potential use of that stem cell line, including the potential for commercial gain and the fact that they may not have any rights in potential stem cell developments.	The proposed changes to the Act ensure that there must be proper consent (in accordance with NHMRC guidelines) in relation to any use or creation of embryos.
46	The development of biotechnology and pharmaceutical products arising from stem cell research should be supported.	No changes to legislation required.
47	A national stem cell bank should be established.	Proposed clause 47B of the RIHE Act requires the Minister to report to Parliament (within 6 months) regarding the establishment of a national register of donated excess ART embryos.
48	Consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem cell bank.	No changes to legislation required.
49	A national register of donated excess ART embryos should be established.	Proposed clause 47B of the RIHE Act requires the Minister to report to Parliament (within 6 months) regarding the establishment of a national register of donated excess ART embryos.
50	The Licensing Committee should be authorised under the Prohibition of Human Cloning Act to give binding rulings on the interpretation of that Act, or the regulations made under that Act, on condition that it reports immediately and in detail to the NHMRC and to parliament on such rulings.	Proposed clause 12A avoids constitutional issues associated with binding rulings, but addresses the basic concern of the Lockhart Committee which appeared to be the potential liability of researchers where they are acting in good faith in accordance with a licence but where the NHMRC Licensing Committee in fact had no power to issue the licence.
51	The Licensing Committee should be authorised by the Research Involving Human Embryos Act to give binding rulings and to grant licences on the basis of those rulings for research that is not within the literal wording of the Act, or the regulations made under the Act, but is within their tenor, on condition that the Committee reports immediately and in detail to the NHMRC and to parliament on any rulings it gives, or any licences it grants, in that way.	Proposed clause 12A (as described above).
52	A researcher who conducts research on the basis of a ruling or a licence should be protected from liability under the legislation, provided that they act in accordance with the relevant ruling or licence.	Proposed clause 12A (as described above).
53	In view of the fast-moving developments in the field, and the range of amendments proposed herein, the two Acts should be subject to a further review either six years after royal assent of the current Acts or three years after royal assent to any amended legislation.	The Bill includes a new clause 25A (in the PHC Act) and a new clause 47A (in the RIHE Act) that requires that a review be undertaken.

54	There should be ongoing public education and consultation programs in the areas of science that are relevant to the Acts.	No changes to legislation required.