The Research Involving Human Embryos and Prohibition of Human Cloning Bill 2003 (Qld)

Human reproductive cloning involves the creation of a human being who is a copy of another human, whether or not that other human is living or deceased. The concept of human reproductive cloning is globally condemned by many as an unacceptable affront to human dignity. At the Council of Australian Governments (COAG) meeting on 5 April 2002, the Prime Minister and all Premiers and Chief Ministers agreed that the Commonwealth, States and Territories would introduce nationally consistent legislation to ban human cloning and other practices considered unacceptable. COAG also agreed that research involving the destruction of existing excess ART embryos be permitted under a strict regulatory regime to enable Australia to remain at the forefront of research which may lead to medical breakthroughs in the treatment of disease. At Commonwealth level, the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002 provide a framework for the national scheme. The Queensland Research Involving Human Embryos and Prohibition of Human Cloning Bill 2003 complements the Commonwealth Acts. It provides the Queensland component of the national scheme and reflects to a large extent the Commonwealth provisions to ensure national consistency. This paper examines the COAG agreement, the Commonwealth Acts and the Queensland 2003 Bill, as well as its predecessor, the Cloning of Humans (Prohibition) Bill 2001 (Qld).

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1 A BRIEF INTRODUCTION TO CLONING

Human reproductive cloning involves the creation of a human being who is the copy of another human, whether or not that other human is living or deceased. The concept of human reproductive cloning is globally condemned by many as an unacceptable affront to human dignity. Advances in cloning technologies mean that the possibility of cloning human beings is not scientifically remote. Internationally, both the World Health Organisation and the United Nations Educational, Scientific and Cultural Organisation (UNESCO) have condemned the idea of replicating humans by cloning as unacceptable. The UNESCO Declaration on the Human Genome and Human Rights (Article 11) states: “Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted”; while the World Health Organisation reaffirmed in 1998 that cloning for the replication of human individuals is ethically unacceptable and contrary to human dignity and integrity.¹

In Australia, the National Health and Medical Research Council, the Fertility Society of Australia and the Australian Academy of Science all regard human reproductive cloning as an unacceptable practice.² A ban on human reproductive cloning was recommended by the House of Representatives Standing Committee on Legal and Constitutional Affairs in its August 2001 report – Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research.³


2 The position statements or guidelines of these three organisations are outlined in more detail in the Queensland Parliamentary Library’s Research Brief No 2001/36 at pp 12-13.

Those Queensland biotechnology organisations which subscribe to the Code of Ethical Practice for Biotechnology in Queensland are also prohibited by their commitment to the Code from undertaking human reproductive cloning. In May 2001, Queensland’s Premier Beattie announced the Government’s intention to prohibit human reproductive cloning.

2 A HISTORY OF RECENT NATIONAL DEVELOPMENTS

2.1 THE 2001 REPORT OF THE HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON LEGAL AND CONSTITUTIONAL AFFAIRS

In August 1999, then Health Minister Michael Wooldridge asked the House of Representatives Standing Committee on Legal and Constitutional Affairs to review the 1998 Australian Health Ethics Committee (AHEC) report Scientific, Ethical and Regulatory Considerations relevant to Cloning of Human Beings. At the core of the Standing Committee’s deliberations was the question whether there is any benefit in conducting stem cell research or in the application of cloning technologies to human beings, and if there is, what use of such technologies is permissible to achieve those benefits? The Standing Committee’s August 2001 report recommended:

- the enactment of legislation to regulate human cloning and stem cell research (Recommendation 1);

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4 The Code can be viewed via: http://www.iie.qld.gov.au/publications/biotechnology/default.asp#codeofethics (downloaded 5 March 2003). Cabinet has directed that the Code is to apply automatically to all Queensland government agencies, research centres, laboratories and public hospitals, and to any organisation funded by the Queensland State Government to undertake biotechnology activities. Biotechnology organisations that do not receive State funding are also expected to subscribe to the Code as a voluntary commitment to its principles: see Queensland Department of Innovation and Information Economy at http://www.iie.qld.gov.au/biotechnology/codeofethics.asp and the Public Register of Biotechnology Organisations which can be viewed via http://www.iie.qld.gov.au/publications/biotechnology/default.asp#codeofethics (downloaded 5 March 2003).


that such legislation should include a ban on cloning for reproductive purposes combined with criminal penalties and loss of an individual’s research licence (Recommendation 4); and

- the establishment of a national licensing body empowered to issue licences for research involving the isolation, creation and use of embryonic stem cells (Recommendation 6).

Of the Committee members, a minority opposed any research involving the destruction of human embryos and expressed concerns about the continued use of embryonic stem cells derived from embryos.

2.2 **THE GENE TECHNOLOGY ACT 2002 (CTH)**

In December 2000, the Gene Technology Bill 2000 (Cth) was amended in the Senate in response to community concern about an absence of legislation in some States and Territories to regulate the cloning of human beings. Clauses were inserted in the Bill that banned human cloning, certain experiments involving animal eggs and certain experiments involving putting human and animal cells into a human uterus. Intended only as interim provisions while the Commonwealth, States, Territories and the NHMRC identified the most effective and comprehensive wording for a prohibition on human cloning and the creation of hybrid embryos, they were repealed by the recent Commonwealth Acts which provide for such prohibitions.\[^7\]

2.3 **AUSTRALIAN HEALTH MINISTERS’ CONFERENCE CONSIDERATION OF THE ISSUES**

The issue of human cloning and research involving excess ART embryos has been considered by Australian Health Ministers since 1999, when the recommendations of the AHEC report prompted the Minister for Health and Aged Care to write to State and Territory Health Ministers urging them to consider developing complementary legislation and regulation in the area of human cloning and assisted reproductive technology (ART).

From that time the Australian Health Ministers’ Advisory Council (AHMAC) and then the Australian Health Ministers’ Conference (AHMC) considered the issues.

\[^7\] See Schedule 1 to the *Prohibition of Human Cloning Act 2002* (Cth) which repealed certain sections of the *Gene Technology Act 2000* (Cth), the intention being that matters about cloning be dealt with comprehensively in the *Prohibition of Human Cloning Act 2002*: see the Revised Explanatory Memorandum to the *Prohibition of Human Cloning Bill 2002* (Cth).
In July 2000, AHMC decided that each jurisdiction would independently legislate to regulate ART clinical practice, but agreed to work towards a nationally consistent approach for the prohibition of human cloning. Following AHMC’s decision, Commonwealth, State and Territory officials worked together to prepare a detailed report outlining regulatory options for prohibiting human cloning, to be considered by Health Ministers. At the same time the issue was also placed on the COAG (Council of Australian Governments) agenda.

2.4 **The Council of Australian Governments Communiqué of 5 April 2002**

On 8 June 2001, COAG discussed assisted reproductive technology including human cloning and in a communiqué stated that the Council committed itself to achieving nationally consistent provisions in legislation to prohibit human cloning. COAG also agreed that jurisdictions work towards nationally consistent approaches to regulate assisted reproductive technology and related emerging human technologies and sought a technical report from Health Ministers by the end of 2001, with the aim of a nationally consistent approach being in place in all jurisdictions by June 2002. The Health Ministers endorsed this approach at a meeting on 1 August 2001.

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

At that COAG meeting on 5 April 2002, the Prime Minister and all Premiers and Chief Ministers agreed that the Commonwealth, States and Territories would introduce nationally consistent legislation to ban human cloning and other practices considered unacceptable. COAG agreed that research involving the destruction of existing excess ART embryos be permitted under a strict regulatory regime to enable Australia to remain at the forefront of research which may lead to medical breakthroughs in the treatment of disease. They further agreed that the regulatory regime governing the use of excess ART embryos that would otherwise have been destroyed will be reviewed within three years. Research proposals would need
approval from an ethics committee and to be in accordance with NHMRC and Australian Health Ethics Committee guidelines.8

The relevant sections of the Communiqué dealing with human cloning, ART and related matters are reproduced in full at Appendix ‘B’ of this Brief. The COAG Communiqué is not legally binding on the Commonwealth, the States and the Territories, but is an agreement which depends on the goodwill of each of the governments concerned.

3 CLONING OF HUMANS (PROHIBITION) BILL 2001 (QLD)

As noted above, on 8 June 2001 COAG made a commitment to achieve nationally consistent provisions in legislation to prohibit human cloning, rather than relying on voluntary compliance with guidelines and codes. A framework for nationally consistent legislation was agreed upon by COAG on 5 April 2002.

The Cloning of Humans (Prohibition) Bill 2001 (Queensland), introduced into the Legislative Assembly on 27 November 2001, sought to implement this framework in Queensland. The policy objective of the Bill was to prohibit the creation or attempted creation of cloned humans (‘human reproductive cloning’) by a technological or other artificial process (clause 3) and to prohibit the gestation of a human embryo clone anywhere in the body of a human or animal (clause 4). The maximum penalty for an individual who breached these provisions was set at 4,000 penalty units ($300,000) or 10 years imprisonment.

The Bill was widely drafted so as to prohibit the creation of a human clone by any technological or artificial process, rather than merely prohibiting a specific form of cloning technology. In this way the Bill would have served to prohibit the practice of artificial human cloning through whatever techniques arose in the future.

A ‘clone’ is generally considered to be an identical genetic copy, however a clone could be genetically modified so that it is not identical to the original from which it was copied. For this reason, in a proceeding for an offence against the proposed legislation that a human or human embryo is a genetic copy, it would have been sufficient to prove that the set of nuclear genes had been copied, rather than having to prove that the copy was an identical genetic copy. Also, in proceedings for an offence against the proposed legislation, it would have been immaterial whether the clone or embryo clone did not or could not survive (clause 6).

8 The terms of the agreement reached at the COAG meeting are set out in a Communiqué and Attachment of 5 April 2002. See Prime Minster of Australia, Media Release, ‘Council of Australian Governments – Communiqué’ which can be viewed via: http://www.pm.gov.au/news/media_releases/main02.htm
The Bill’s prohibition on human cloning did not extend to the use of cloning technologies to replicate DNA or individual cells or in medical research and treatment which do not involve human reproductive cloning. Thus stem-cell research or “therapeutic cloning” which may result in new treatments for serious diseases were not caught by the Bill.9  The Queensland Parliamentary Library’s Research Brief (No 2001/36) discusses the 2001 Bill and examines cloning issues in detail.10

The Cloning of Humans (Prohibition) Bill 2001 was withdrawn from the Queensland Legislative Assembly on 25 February 2003 and the more detailed Research Involving Human Embryos and Prohibition of Human Cloning Bill 2003 was introduced on that date in its place. Of this change, Premier Beattie said:

This bill replaces the Cloning of Humans (Prohibition) Bill 2001, which was introduced in the Legislative Assembly in November 2001 as an interim measure. It responds to concerns that the Cloning of Humans (Prohibition) Bill did not go far enough to address safety and ethical issues in medical and research developments involving reproductive material. This bill forms part of a national scheme to effectively ban human cloning. It also prohibits a range of other practices, including the creation of hybrid embryos and commercial trading in human reproductive material not considered safe or ethical. 11

A consideration of the provisions of the 2003 Bill follows below at Section 6 of this Brief.

4 THE PROHIBITION OF HUMAN CLONING BILL 2002 (COMMONWEALTH) AND THE RESEARCH INVOLVING HUMAN EMBRYOS BILL (COMMONWEALTH)

On 27 June 2002, the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 (the Bill) was introduced into the House of Representatives.12 The National Health and Medical Research Council (NHMRC) indicated that the Bill introduced into Parliament was consistent with the majority report of the House of Representatives Committee on Human cloning: scientific, ethical and

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regulatory aspects of human cloning and stem cell research – which is also consistent with the NHMRC/AHEC Ethical Guidelines on ART issued in June 1996.\(^{13}\)

On 21 August 2002, the Senate, on the recommendation of the Selection of Bills Committee (Report 6/2002), referred the Bill to the Senate’s Community Affairs Legislation Committee for report by 24 October 2002.\(^{14}\)

The Bill was debated in the House on 27 June and on 20, 21, 22 August and in the Main Committee of the House on 26, 27 and 28 August 2002 with 105 members involved in the debate. On 29 August 2002 the House agreed, after a lengthy debate, to a procedural motion dividing provisions of the Bill into two Bills, as indicated below:

- The Prohibition of Human Cloning Bill 2002 which consisted of, with associated amendments, the title, enacting formula and Parts 1 and 2 and clauses 56, 61 and 62 and the schedule of the Bill as introduced, and an activating clause.

- The Research Involving Embryos Bill 2002 consisting of, with associated amendments, Parts 3, 4, 5 and 6 of the Bill, and also including with amendments the provisions of clauses 56, 61 and 62 of the Bill as introduced, and a new clause 55A.\(^{15}\)

The Prohibition of Human Cloning Bill 2002 was passed unanimously by the House of Representatives on 29 August 2002 and introduced into the Senate on 18 September. The Research Involving Embryos Bill 2002 was considered in detail on 16, 24 and 25 September and passed by the House on 25 September 2002.

With the two Bills created by the splitting of the original Bill passing in the House of Representatives without amendment, the provisions of the original Bill as referred to the Senate Community Affairs Legislation Committee remained

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\(^{14}\) Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002*, October 2002, pp1-2. The Selection of Bills Committee recommended that the Bill be referred to the Senate Community Affairs Legislation Committee so as “To consult widely with various stakeholders in the community to inform the Senate in its deliberations on the Bill. The Senate last considered embryo and cloning issues in 1986”. Senate Community Affairs Legislation Committee, p 1.

Commenting on the nature of its inquiry, the Senate Committee noted that the inquiry had:

… been undertaken in circumstances where the political parties have given their Senators a ‘free vote’ on the Bill when it is considered in the Senate. Thus, in conducting the inquiry and in the preparation of the report, the Committee has been mindful that the purpose of the inquiry was primarily to gather information to assist Senators make an informed decision on the Bill. The report aims to balance the major issues and arguments relating to the subject of the Bill without attempting to formulate conclusions or recommendations that the Committee considers should be the prerogative of individual Senators in a ‘free vote’.17

The Senate made minimal amendments to the Prohibition of Human Cloning Bill 2002 and passed the Research Involving Human Embryos Bill, also with amendments,18 with a 45 to 26 margin19 (5 did not vote).20

The Bills were subsequently reconsidered by the House of Representatives (because of the amendments) and assented to on 19 December 2002.

In the House of Representatives, the total length of the debate on the Research Involving Embryos and Prohibition of Human Cloning Bill and its two derivatives was 38 hours and 17 minutes. In the Senate, the two Bills were debated for a total of 47 hours and 21 minutes.21

4.1 PROHIBITION OF HUMAN CLONING ACT 2002 (COMMONWEALTH)

The Prohibition of Human Cloning Act 2002 forms part of a national regulatory system to address concerns about scientific developments relating to human

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18 The Schedules of the amendments made by the Senate to the two Bills are available for perusal in the Queensland Parliamentary Library.


20 D Hope, ‘Cell Bill’s passed, now for the research’, The Australian, 6 December 2002, p 6. Of the 45 Senators who voted in favour, 7 were from Queensland. Of the 26 who voted against, 4 were from Queensland.

21 D Hope, ‘Cell Bill’s passed, now for the research’ and D Gray, ‘Senate backs use of human embryos in research’.
reproduction and the utilisation of human embryos and to ban human cloning. The Bill prohibits the creation, importation, exportation or implantation of a human embryo clone and certain other embryos for ethical and safety reasons.\(^{22}\)

### 4.2 RESEARCH INVOLVING HUMAN EMBRYOS ACT 2002 (COMMONWEALTH)

This Act also forms part of that same national regulatory system, the framework of which regulates activities that involve the use of certain human embryos created by assisted reproductive technology (ART). The Act:

- establishes a Principal Committee within the National Health and Medical Research Council (NHMRC), the NHMRC Embryo Research Licensing Committee (the NHMRC Licensing Committee), for the purposes of performing functions and exercising powers under the Bill;

- establishes a scheme for the assessment and licensing of certain activities involving the use of excess embryos created by assisted reproductive technology (excess ART embryos); and

- provides for a centralised, publicly available database of information about all licences issued by the NHMRC Licensing Committee.\(^{23}\)

### 5 THE RESEARCH INVOLVING HUMAN EMBRYOS AND PROHIBITION OF HUMAN CLONING BILL 2003 (QUEENSLAND)

This Bill complements the Commonwealth’s *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002* and reflects what was endorsed in the Federal Parliament.\(^{24}\) It provides the Queensland component of the national scheme and relies to a large extent on the Commonwealth Acts to ensure national consistency.\(^{25}\)

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As noted above, the 2003 Bill replaced the Cloning of Humans (Prohibition) Bill 2001 which was introduced into the Legislative Assembly in November 2001 as an interim measure and withdrawn on 25 February 2003 immediately prior to the introduction of this 2003 Bill. Premier Beattie’s comments on this replacement are noted above at p 6 of this Brief.

The 2003 Bill also:

…supports the establishment of a comprehensive national regulatory system to govern the use of excess assisted reproductive technology embryos. All states and territories have committed to enacting complementary legislation to ensure that all Australian researchers working in both public and private sectors are covered by the national regulatory scheme. Researchers and scientists proposing to undertake work on excess assisted reproductive technology embryos will be required to meet strict criteria and obtain a licence. The regulatory regime will cover all uses of excess assisted reproductive technology embryos except for specified activities in existing fertility treatment services. Current fertility treatment services will continue to be regulated through existing state legislation and the Reproductive Technology Accreditation Committee of the Fertility Society of Australia. Observation, transport and storage of embryos by fertility treatment clinics will be exempt from requiring a licence. Importantly, any research will only be allowed on excess assisted reproductive technology embryos, and if the research may damage or destroy, it will only be allowed to occur if the embryo to be used was in existence at 5 April 2002.26

5.1 BACKGROUND TO THE 2003 QUEENSLAND BILL

The objectives of the Research Involving Human Embryos and Prohibition of Human Cloning Bill 2003 are to address ethical and safety concerns about scientific developments associated with reproductive technology by –

• prohibiting human cloning;
• prohibiting certain other practices associated with reproductive technology; and
• regulating the use of excess assisted reproductive technology (ART) embryos for research and other activities.

The policy objectives of the Bill are to form part of a national scheme of State, Territory and Commonwealth legislation.27

In keeping with the COAG agreement of 5 April 2002, the Bill prohibits a range of other practices associated with reproductive technology including –

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26 Hon PD Beattie, MP, Queensland Parliamentary Debates, p 104.

• creation of a human embryo for research purposes;
• creation or implantation of chimeric or animal/human hybrid embryos;
• creation of a human embryo that contains genetic material provided by more than two people; and
• commercial trading in human eggs, human sperm or human embryos.

At present, these practices prohibited by the Bill are considered unacceptable for ethical and safety reasons.28

Consistent with its object, and as complementary legislation to a national regulatory scheme, the Bill –
• supports prohibition of the creation, importation, exportation or implantation of certain other embryos for ethical and safety reasons under the Commonwealth Prohibition of Human Cloning Act 2002;
• supports establishment of a principal committee of the National Health and Medical Research Council (NHMRC), the NHMRC Embryo Research Licensing Committee (the NHMRC Licensing Committee) whose purpose is to perform functions and exercise powers under the national regulatory scheme outlined in the Commonwealth Research Involving Human Embryos Act 2002;
• establishes a scheme for the assessment and licensing of certain activities involving the use of excess embryos created by assisted reproductive technology (excess ART embryos); and
• provides for a centralised, publicly available database of information about all licences issued by the NHMRC Licensing Committee.29

As explained in the Explanatory Notes, given the dynamic nature of reproductive technology science, it is considered necessary to monitor developments and assess the operation of the regulatory framework. COAG has agreed that the legislation should be reviewed in three years.30

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30 Explanatory Notes, Research Involving Human Embryos And Prohibition Of Human Cloning Bill 2003, (Qld), pp 3-4. Under the terms of the COAG agreement, the regulatory scheme governing the use of excess ART embryos that would otherwise have been destroyed is to be reviewed within three years. See the text of the Council of Australian Governments’ Communiqué in Appendix B to this Brief.
The 2003 Bill is complementary to the Commonwealth Acts, which in turn were largely based on recommendations of the *Report on Human Cloning, Assisted Reproductive Technology and Related Matters* provided by Health Ministers to COAG on 5 April 2002. As this is a national scheme involving complementary legislation to ensure consistency, the national consultative process has informed the development of this Bill. This Bill replicates the relevant provisions of the Commonwealth Acts to form part of the national regulatory regime.31

6  KEY PROVISIONS OF THE 2003 QUEENSLAND BILL

Section 6 of this Brief discusses key clauses of the Queensland 2003 Bill. The corresponding provisions of the two Commonwealth Acts are given in parentheses, where applicable. Key provisions of the Queensland Bill are also discussed by reference to submissions made to the Senate Community Affairs Legislation Committee in relation to the equivalent provisions of the Commonwealth legislation.

6.1  PROHIBITED PRACTICES INCLUDING HUMAN CLONING

6.1.1  Definitions

*Definition of a Human Embryo Clone*

“*Human embryo clone*” is defined in the Schedule to the Bill (ie the Dictionary) as:

>A human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by human sperm.

Sub-clause 5(2) clarifies matters relating to the term “human embryo clone”. To establish that a human embryo clone is a genetic copy of a living or dead human:

- it is sufficient to establish that a copy has been made of the genes in the nuclei of the cells of another living or dead human; and
- the copy of the genes does not have to be an identical genetic copy.

Therefore, as the Explanatory Notes explain, the human embryo clone does not have to be genetically identical to the human who was cloned.\textsuperscript{32}

\section{6.1.2 Prohibited Practices}

\textit{Creating a human embryo clone}

Part 2 of the Bill outlines prohibited practices. \textbf{Clause 7} [s9, Cth Prohibition of Human Cloning Act] makes it an offence to intentionally create, by technological means, an embryo that is a genetic copy of another living or dead human. This clause is not intended to capture the circumstance where a human embryo created by assisted reproductive technology, spontaneously divides into two or more identical embryos (commonly known as identical twins, triplets etc). The maximum penalty for creating a human embryo clone is 15 years’ imprisonment, both in this Bill and the Commonwealth Prohibition of Human Cloning Act 2002. The constitutional jurisdiction issues underpinning the national scheme mean that the facts of a case will determine whether an alleged offence is prosecuted under the Commonwealth Act or the Queensland Act. An alleged offence will not be prosecuted under both. If an alleged offence is prosecuted under Commonwealth jurisdiction, a court may at its discretion supplement the imprisonment term with a monetary penalty or convert the imprisonment term to a monetary penalty of up to $495,000 for a corporation and $99,000 for an individual. If an alleged offence is prosecuted under Queensland jurisdiction, the equivalent financial penalty for an individual convicted in the District Court is restricted to a maximum of approximately $313,125 (4,175 penalty units). The Supreme Court may issue an unlimited financial penalty.\textsuperscript{33}

\textbf{No Defence that human embryo clone could not survive}

\textbf{Clause 9} [s12 Cth Prohibition of Human Cloning Act] provides that any human embryo clone that is intentionally created or implanted does not have to survive to the point of live birth in order for an offence to be established under Clause 7 [Cth s 9].

\textsuperscript{32} Explanatory Notes, Research Involving Human Embryos and Prohibition of Human Cloning Bill 2003, (Qld), p 10.

Placing a human embryo clone in the human body or the body of an animal

Clause 8 [s10 Cth Prohibition of Human Cloning Act 2002] makes it an offence to intentionally place into the body of a human or an animal, a human embryo that is a genetic copy of another living or dead human (ie. a human embryo clone). The maximum penalty that may be applied for placing a human embryo clone in the human body or the body of an animal is 15 years’ imprisonment both in this Bill and in the corresponding Commonwealth Act. The potential for financial penalties to be incurred is the same as noted for clause 7.  

The Senate Community Affairs Legislation Committee’s Inquiry

The Queensland Bioethics Centre submitted to the Senate Inquiry, in relation to the equivalent Commonwealth provision, that this offence should be couched in much broader terms to instead prohibit all uses of a human embryo clone.  

No Defence that human embryo clone could not survive

Clause 9 [s12 Cth Prohibition of Human Cloning Act] provides that any human embryo clone that is intentionally created or implanted does not have to survive to the point of live birth in order for an offence to be established under Clause 8 [Cth s s 10].

Importing or exporting a human embryo clone

Section 11 of the Commonwealth Prohibition of Human Cloning Act makes it an offence to intentionally import a human embryo clone into Australia or intentionally export a human embryo clone from Australia. This ensures that all avenues for obtaining a human embryo clone in Australia are unlawful, while ensuring that a person cannot export a human embryo clone that has been illegally created or obtained. No clause has been included in the Qld Bill as it is beyond the constitutional competence of the State to create import and export offences. The maximum penalty that may be applied for importing or exporting a human embryo clone under the Commonwealth Act is 15 years’ imprisonment. The potential for

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financial penalties to be incurred is outlined under the Explanatory Notes to clause 7.³⁶

Creating a human embryo other than by fertilisation, or developing such an embryo

Clause 10 [s13 Cth Prohibition of Human Cloning Act] makes it an offence to create a human embryo other than by fertilisation, or to develop such an embryo. This clause is intended to ensure that a human embryo is not intentionally created outside the body of a woman by any means other than by the fertilisation of a human egg by human sperm. The maximum penalty that may be applied for creating a human embryo other than by fertilisation of a human egg by human sperm is 10 years’ imprisonment under both this Bill and the corresponding Commonwealth Act. If an alleged offence is prosecuted under Commonwealth jurisdiction, a court may at its discretion supplement the imprisonment term with a monetary penalty or convert the imprisonment term to a monetary penalty of up to $330,000 for a corporation and $66,000 for an individual. If an alleged offence is prosecuted under Queensland jurisdiction, the equivalent financial penalty for an individual convicted in the District Court is restricted to a maximum of approximately $313,125 (4,175 penalty units). The Supreme Court may issue an unlimited financial penalty.³⁷

Creating a human embryo for a purpose other than achieving pregnancy in a woman

Clause 11 [s14 Cth Prohibition of Human Cloning Act] states that it is an offence to create a human embryo for a purpose other than achieving pregnancy in a woman. Sub-clause 11(1) [ss14(1) Cth Prohibition of Human Cloning Act] provides that a person can only create a human embryo outside the body of a woman if it is intended, at the time of creation, to attempt to achieve pregnancy in a particular woman. Thus, it will be an offence to create human embryos specifically for other purposes such as research or to derive embryonic stem cells. However, as the Explanatory Notes explain, this clause is not intended to prohibit certain uses of human embryos that are carried out as a part of attempting to achieve pregnancy in a woman in ART clinical practice, such as carrying out diagnostic procedures or undertaking therapeutic procedures on the embryo. Further, the Explanatory Notes also explain that it is not intended that this clause restrict the number of embryos


that may be created for the purposes of achieving pregnancy in a particular woman or prevent the circumstance whereby a human embryo created in an ART clinic, originally intended for implantation into a woman, may be found to be unsuitable for implantation, or may at some point not be required by the woman for whom it was originally created. In these situations, it is possible that such embryos could become excess ART embryos and at that point they may be used for purposes other than to attempt to achieve pregnancy in a woman subject to the system of regulatory oversight described in Part 3 of the Bill.

The maximum penalty that may be applied for creating a human embryo for a purpose other than achieving pregnancy in a woman is 10 years’ imprisonment under this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under the Explanatory Notes to clause 10.\(^{38}\)

Clause 11(2) of the Bill clarifies that the prosecution (rather than the defendant) bears the evidential burden in relation to an offence under Clause 11(1).

Creating or developing a human embryo containing genetic material provided by more than two persons

Clause 12 [s15 Cth Prohibition of Human Cloning Act] makes it an offence to intentionally create or develop a human embryo containing genetic material provided by more than two persons. One of the effects of this clause is to ban a relatively new ART technique of cytoplasmic transfer. Cytoplasmic transfer involves the injection of some of the cytoplasm (the part of the cell outside the nucleus) from a healthy donor egg into a recipient patient’s egg, with the aim of overcoming problems in achieving pregnancy related to the cytoplasm. As acknowledged by the Explanatory Notes, it has been reported that this procedure may be particularly valuable in achieving pregnancy in older women. However, both safety and ethical concerns have been raised about cytoplasmic transfer.\(^{39}\)

The Senate Community Affairs Legislation Committee’s Inquiry

In relation to the equivalent Commonwealth provision, Professor Robert Jansen, of Sydney IVF, submitted to the Senate Community Affairs Legislation Committee that, while the efficacy of the procedure (cytoplasmic transfer) has not yet been


\(^{39}\) Explanatory Notes, Research Involving Human Embryos And Prohibition Of Human Cloning Bill 2003, (Qld), pp 16-17.
proven, it should be further investigated and that the provision constituted “a significant set-back for improving the fertility of women over 35”.

In response, the NHMRC commented that:

_Cytoplasmic transfer is a relatively new and controversial technique, which involves the injection of cytoplasm from a healthy donor egg into a recipient patient’s egg. Because of the presence in the cytoplasm of mitochondria, which contains small amounts of DNA, embryos created through cytoplasmic transfer will have DNA from three separate people. The clinical safety and efficacy of this practice has not, to date, been established and therefore the impact of the third party mitochondrial DNA is not known._

_The Bill implements the cautious approach adopted by COAG by banning the creation of an embryo that contains genetic material from more than two persons. This is subject to review within three years when more may be known about the safety and efficacy of this technique._

The maximum penalty that may be applied for creating or developing a human embryo containing genetic material by more than two persons is 10 years' imprisonment under both the Qld Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under the Explanatory Notes to clause 10.

**Developing a human embryo outside the body of a woman for more than 14 days**

_Clause 13 [s16 Cth Prohibition of Human Cloning Act] makes it an offence to intentionally develop a human embryo outside the body of a woman for more than 14 days, (not including any time that the embryo’s development is suspended whilst frozen in storage). In practice, this means that human embryos created by assisted reproductive technology must be implanted, stored or allowed to succumb (if unsuitable for implantation or excess to the needs of the couple for whom the embryo was created) before the 14th day of their development. It is standard ART clinical practice for embryos to be implanted when they have reached between three and seven days of development. Reading this clause with clause 10 (which bans the creation of a human embryo by a means other than the fertilisation of human egg by human sperm), it means that a human embryo created by asexual_
means, such as by parthenogenesis, embryo splitting or somatic cell nuclear transfer, cannot be created or developed to any stage.

The Senate Community Affairs Legislation Committee’s Inquiry

In its submission to the inquiry conducted by the Senate Community Affairs Legislation Committee, the NHMRC advised, in relation to the equivalent provision in the Commonwealth legislation, that the 14-day limit is based on a clear policy direction in the COAG Communiqué and is consistent with Australian and international standards, including the:

- NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996);
- Reproductive Technology Accreditation Committee (RTAC) Guidelines;
- South Australian legislation (*Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995*);
- Western Australian legislation (*Human Reproductive Technology Act 1991*); and the
- United Kingdom legislation (*Human Fertilisation and Embryology Act 1990*).\(^43\)

Clause 13 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, under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under the Explanatory Notes to Clause 10.\(^44\)

**Commercial trading in human eggs, human sperm or human embryos**

**Clause 20** [s23 Cth Prohibition of Human Cloning Act] makes it an offence to trade commercially in human eggs, sperm and embryos. Both the person who sells the egg, sperm or embryo, and the person who purchases the egg, sperm or embryo, would commit an offence. The only consideration that 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. The maximum penalty for trading in human embryos, sperm or eggs is 10 years’ imprisonment, under both this Bill and the corresponding


Commonwealth Act. The potential for financial penalties to be incurred is outlined under the Explanatory Notes to clause 10.45

The Senate Community Affairs Legislation Committee’s Inquiry

The Senate Committee heard evidence that excessive handling fees had been offered in the US to escape provisions equivalent to those referred to above. In response to this the NHMRC advised the Committee that:

_The legislation prohibits the giving or receiving of valuable consideration for the supply of a human egg, human sperm or human ovum. Valuable consideration is further defined to include any inducement, discount or priority in provision of a service, and it is intended that this would include such things as a handling fee._46

6.1.3 Other Prohibited Practices

Other offences contained in Part 2 of the Qld Bill are:

- using precursor cells from a human embryo or a human foetus to create or develop a human embryo: **Clause 14** [s17 Cth Prohibition of Human Cloning Act] A precursor cell is defined in the Schedule to the Qld Bill as “a cell that has the potential to develop into a human egg or human sperm”. The practice is prohibited, as it would result in the birth of children who have had no living genetic parent.47
- manipulating a human genome that is intended to be heritable (ie. able to be passed on to subsequent generations of humans): **Clause 15** [s18 Cth Prohibition of Human Cloning Act]. This clause is intended to ban what is commonly referred to as germ line gene therapy.48
- removing a viable human embryo from the body of a woman after fertilisation has taken place in vivo **Clause 16** [s19 Cth Prohibition of


46 Committee Hansard, 26.09.02, p246 (Dr Morris); see also Submission 23, Additional information received 16.10.02, p6 (NHMRC) as quoted in Senate Community Affairs Legislation Committee, p 76.


Human Cloning Act]. This clause is intended to prohibit a practice sometimes referred to as embryo flushing.\(^{49}\)

- intentionally creating a chimeric or a hybrid embryo **Clause 17** [s20 Cth Prohibition of Human Cloning Act]. These terms are defined in the Schedule to the Bill.

- placing a human embryo into an animal or into the body of a human (other than a woman’s reproductive tract) or an animal embryo into a human for any period of gestation: **Clause 18** [s21 Cth Prohibition of Human Cloning Act].

- intentionally placing any embryo prohibited by clauses 10 to 17 inclusive, in the body of a woman: **Clause 19** [s22 Cth Prohibition of Human Cloning Act]. Section 22 of the Commonwealth Prohibition of Human Cloning Act 2002 includes both this prohibition on placement and an additional prohibition on importation of these same prohibited embryos. This is to remove the possibility that one person would be able to import a prohibited embryo and give it to another person to be implanted in a woman. In this case, both people would be in breach of the legislation forming the national regulatory scheme.\(^{50}\)

### 6.2 REGULATING THE USE OF EXCESS ASSISTED REPRODUCTIVE TECHNOLOGY EMBRYOS

**Part 3** of the 2003 Queensland Bill regulates the permitted uses of excess assisted reproductive technology embryos.

#### 6.2.1 Definitions

**Meaning of excess ART embryo**

**Sub-clause 22(1)** [s9(1) Cth Research Involving Human Embryos Act 2002] defines what is meant by an “excess ART embryo”, which are those embryos which may be available for research. To be excess it is necessary that –

- the embryo was created by assisted reproductive technology for use in the treatment of a woman; and


\(^{50}\) Explanatory Notes, Research Involving Human Embryos And Prohibition Of Human Cloning Bill 2003, (Qld), p 20.
• the embryo is excess to the needs of the woman for whom it was created and her spouse (if she had one at the time the embryo was created).

Sub-clause 22(2) [ss9(2) Cth Research Involving Human Embryos Act 2002] additionally provides that a human embryo is an “excess ART embryo”, if –

• there is a determination in writing from the woman for whom the embryo was created (and her spouse, if any) that the embryo is excess to their needs; or
• the woman for whom the embryo was created (and her spouse, if any) have provided authority, in writing, for the embryo to be used for a purpose other than achieving pregnancy (for example, research or training purposes).51

6.2.2 Offences

Using an excess ART embryo

Sub-clause 23(1) [s10 Research Involving Human Embryos Act 2002] essentially describes the scope of the regulatory scheme for excess ART embryos. It creates an offence to intentionally use an excess ART embryo without a licence. All uses of an excess ART embryo are required to be licensed by the NHMRC Licensing Committee unless such uses are “exempt uses” (eg storage, transportation) in accordance with sub-clause 23(2) [ss10(2) Research Involving Human Embryos Act 2002]. Other exempt uses include allowing the excess ART embryo to succumb, donating the excess ART embryo to another woman for the purpose of achieving pregnancy in that other woman, or doing diagnostic investigations using excess ART embryos that are unsuitable for implantation (for example, chromosomally abnormal embryos) provided that the investigations are specifically related to achieving pregnancy in the woman for whom the embryo was created. All other uses of an excess ART embryo are required to be licensed by the NHMRC Licensing Committee. This includes, for example, using excess ART embryos for research, to train clinical and laboratory staff in ART techniques, for quality assurance testing to ensure that pre-implantation diagnostic tests give accurate results and to examine the effectiveness of new culture media.52

The effect of sub-clause 23(1) [s10] is to make it an offence to intentionally use an excess ART embryo unless the use is authorised by a licence or is one of the


exempt uses detailed above. The maximum penalty that may be applied for use of
an excess ART embryo without a licence, or without that use being an exempt use,
is 5 years’ imprisonment, under both this Bill and the Commonwealth Research
Involving Human Embryos Act 2002. If an alleged offence is prosecuted under
Commonwealth jurisdiction, a court may, at its discretion, supplement the
imprisonment term with a monetary penalty or convert the imprisonment term to a
monetary penalty of up to $165,000 for a corporation and $33,000 for an
individual. If an alleged offence is prosecuted under Queensland jurisdiction, the
equivalent financial penalty for an individual convicted in the District Court is
restricted to a maximum of approximately $313,125 (4,175 penalty units). The
Supreme Court may issue an unlimited financial penalty.53

Using an embryo that is not an excess embryo

Clause 24 [s11 Cth Research Involving Human Embryos Act 2002] makes it an
offence to intentionally use a non-excess ART embryo unless the use is part of
assisted reproductive technology treatment carried out by an accredited ART clinic.
For example, it would be illegal to use an ART embryo that has not been declared
“excess” in the training of ART technicians or to derive embryonic stem cells. The
maximum penalty for an offence under this clause is 5 years’ imprisonment, under
both this Bill and the corresponding Commonwealth Act. The potential for
financial penalties to be incurred is the same as for clause 23.54

Breaching a licence condition

Under Clause 25 [s12 Cth Research Involving Human Embryos Act 2002] it is an
offence to intentionally or recklessly breach a licence condition. The maximum
penalty for breaching a condition of licence is 5 years’ imprisonment, under both
the proposed Qld Act and the corresponding Commonwealth Act. The potential for
financial penalties to be incurred is as outlined in this Brief for clause 23.55

53  Explanatory Notes, Research Involving Human Embryos And Prohibition Of Human Cloning
Bill 2003, (Qld), pp 24-25.

54  Explanatory Notes, Research Involving Human Embryos And Prohibition Of Human Cloning
Bill 2003, (Qld), p 25.

55  Explanatory Notes, Research Involving Human Embryos And Prohibition Of Human Cloning
6.2.3 The Embryo Research Licensing Committee

Part 3, Division 3 [s13] provides for the functions and powers of the Embryo Research Licensing Committee of the NHMRC. Section 13 of the Commonwealth Research Involving Human Embryos Act 2002 establishes the NHMRC Embryo Research Licensing Committee (the NHMRC Licensing Committee) as a Principal Committee of the NHMRC. The NHMRC Licensing Committee will be tasked with considering licence applications under this Bill and the Commonwealth Act in relation to the use of excess ART embryos.56

Functions of the Committee

Clause 26 [s14 Cth Research Involving Human Embryos Act 2002] lists the functions of the NHMRC Licensing Committee as being to:

- consider licence applications
- refuse or grant licences
- notify relevant parties of the Committee’s decision on a licence application
- vary, suspend or cancel licences as necessary
- establish and maintain a publicly available database containing information about activity involving excess ART embryos that has been licensed by the Committee
- monitor compliance with the legislation and take any necessary enforcement action; and
- provide information about the Committee’s functions for inclusion in the NHMRC annual report and reporting to Parliament.57

Powers and Membership of the Committee

Clause 27 [s15 Cth Research Involving Human Embryos Act 2002] gives the NHMRC Licensing Committee the power necessary to carry out the functions and duties assigned to the Committee under the Qld Bill. The Commonwealth Research Involving Human Embryos Act 2002 prescribes members to be appointed to the NHMRC Licensing Committee. Section 16 of that Commonwealth Act provides that the NHMRC Licensing Committee will comprise nine members as follows –

a) a member of AHEC;


b) a person with expertise in research ethics;
c) a person with expertise in a relevant area of research;
d) a person with expertise in assisted reproductive technology;
e) a person with expertise in a relevant area of law;
f) a person with expertise in consumer health issues as they relate to disability and disease;
g) a person with expertise in consumer issues relating to assisted reproductive technology;
h) a person with expertise in the regulation of assisted reproductive technology; and
i) a person with expertise in embryology.

In appointing members to the NHMRC Licensing Committee, the Commonwealth Act also requires the Commonwealth Minister (who appoints the members: see s 16(2) of the Cth Act) to have regard to the desirability of ensuring that the Committee as a whole comprises members from different States and Territories: s 16(6).

Despite this and other safeguards (eg the Minister must seek nominations from all the States and Territories, consult the States and Territories on proposed appointments and have regard to their views: ss s16(3)(a) and (b) of the Cth Act, several submissions to the Senate Inquiry into this Commonwealth provision expressed concern that the membership of the Licensing Committee might be unrepresentative. For example, the Catholic Archdiocese of Melbourne commented:

_The membership of the Licensing Committee could easily be stacked with those who have a particular interest in the embryo industry. There is no attempt to minimise this conflict of interest. Nor is there any attempt to ensure a broad spectrum of opinion or representation. Even with the inclusion of positions (b), (f), (h) and (i) there is no representative of the churches and no provision for a member with expertise in philosophical ethics, women’s issues or other social issues._

The Australian Catholic Bishops Conference commented that:

_The Bill provides nothing with respect to ‘conflict of interest’. Only in the Explanatory Memorandum is one referred to certain sections of the National Health and Medical Research Council Act 1992 (Cth) which summarily states (s.38 (b)(vi)) that it is the Council which determines ‘the disclosure of members’ interests in matters being considered by the Committee’. Given the vast sums of money at stake in embryo research, conflict of interest of researchers, decision-makers and_

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58 Catholic Archdiocese of Melbourne, Submission 876, p.12, quoted in Senate. Community Affairs Legislation Committee, p 86.
commercial interests with respect to licences must be dealt with comprehensively in the legislation.59

In the Senate, the Commonwealth provision was amended by adding the additional requirement (s 16(3)(c)) that before appointing a member of the NHMRC Licensing Committee, the Minister must:

be satisfied upon receipt of a written declaration by the member proposed to be appointed that the member proposed does not have a direct or indirect pecuniary interest in a body that undertakes uses of excess ART embryos, being an interest of a kind that could conflict with the proper performance of the member’s functions.

6.2.4 Licensing System

Part 3, Division 4 of the 2003 Qld Bill provides for a licensing system.

Applications for a licence

Clause 28 [s20 Cth Research Involving Human Embryos Act 2002] provides that a person may apply to the NHMRC Licensing Committee for a licence under this Act. Clause 29 [s21 Cth Research Involving Human Embryos Act 2002] describes the matters that must be considered by the NHMRC Licensing Committee when deciding whether or not to issue a licence. Sub-clause 29(3) 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 and to ensure that, where the couple for whom the embryo was created have specified any restrictions on the use of an embryo, these restrictions will be observed;

• if the proposed use of the excess ART embryo may damage or destroy the embryo, that appropriate protocols are in place to ensure that the excess ART embryos used in the activity (should the licence be approved) have been created before 5 April 2002; and

• the proposed research has been considered and assessed by a Human Research Ethics Committee (HREC) that is constituted in accordance with, and acting in compliance with, the National Statement on Ethical Conduct in Research Involving Humans (1999) issued by the NHMRC (or such other document that may replace the National Statement).60


**Determination of application by Committee**

**Sub-clause 29(4) [ss21(4) Research Involving Human Embryos Act 2002]** lists the matters the NHMRC Licensing Committee must have regard to in deciding whether to issue a licence –

- restricting the number of excess ART embryos to that likely to be necessary to achieve the goals of the activity or project proposed in the application;
- the likelihood of significant advance in knowledge, or improvement in technologies as a result of the use of excess ART embryos proposed in the application which could not reasonably be achieved by other means;
- any relevant guidelines, or parts of guidelines issued by the NHMRC, under the NHMRC Act and prescribed under a regulation;
- the HREC assessment of the application; and
- any additional matters prescribed by a regulation.61

In relation to the corresponding Commonwealth provision, several submissions commented that the provisions were somewhat indeterminate. The National Civic Council (WA) for instance commented that there was no specification of the kinds of “knowledge” that might be advanced or the type of “technologies for treatment” that might be improved. In response to these concerns, the NHMRC advised that:

> The Australian Health Ethics Committee (AHEC) is currently reviewing the NHMRC Ethical Guidelines on ART and a consultation draft of these revised guidelines is likely to be released shortly. It is anticipated that these guidelines will include information about the types of matters that should be considered in order to establish that certain uses of excess ART embryos are likely to result in a significant advance in knowledge, or improvement in technologies for treatment as a result of the use of excess ART embryos.62

**Notification of decision**

**Clause 30 [s22 Research Involving Human Embryos Act 2002]** requires the NHMRC Licensing Committee to notify its decision on an application to the applicant, the HREC that considered the application and the relevant State body (as notified by the State Government). In addition, if the NHMRC Licensing

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Committee issues a licence to the applicant, a copy of the licence must also be provided to the HREC and to the relevant State body.63

**Licence is subject to conditions**

**Sub-clauses 32(1), (2) and (3) [s24 Research Involving Human Embryos Act 2002]** describe the conditions with which all licence holders must comply. Before a person can commence using an excess ART embryo under a licence issued by the NHMRC Licensing Committee, the licence holder must provide written notice to that Committee:

- that consent has been obtained for the use of all the embryos
- of any restrictions on the use of the embryos
- for uses that may damage or destroy the embryos, that the embryos were created before 5 April 2002.64

**Power to suspend or revoke a licence**

**Clause 34** [s26 Research Involving Human Embryos Act 2002] confers power on the NHMRC Licensing Committee to suspend or revoke a licence that has been issued if they believe, on reasonable grounds, that a condition of the licence issued under the proposed Research Involving Human Embryos and Prohibition of Human Cloning Act has been breached. The NHMRC Licensing Committee must also revoke each licence held by a licence holder convicted of an offence under the proposed Act.65

**6.2.5 Licensing Committee to make certain information publicly available**

**Clause 37** [s29 Research Involving Human Embryos Act 2002] provides that the NHMRC Licensing Committee must establish and maintain a comprehensive, publicly available database containing information about licences that have been issued under this Act. The clause allows for the database information under this Act to be kept as part of a broader national database: cl 37(5). Information kept on the database would include the name of the licence holder, the period of the

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64 Explanatory Notes, Research Involving Human Embryos And Prohibition Of Human Cloning Bill 2003, (Qld), p 33.

licence’s validity, the nature of the authorised uses of the embryos (eg. whether the
embryos are proposed to be used for the derivation of stem cells, for use for testing
culture medium, for training of technicians etc), the conditions of the licence, and
the number of embryos proposed to be used. At the time that a licence is granted,
one of the conditions would describe the maximum number of embryos permitted
to be used in the project. Another condition of licence would describe requirements
to report on the number of embryos actually used and when they were used.66

This national regulatory scheme means that anyone wishing to undertake work
using excess ART embryos (other than exempt uses), would need to apply for a
licence from the NHMRC Licensing Committee.

6.2.6 Review of Operation of Act

Sub-clause 49(1) provides that the Queensland Minister responsible for this Act
must cause a review of this Act to start two years after this section is commenced.
Sub-clause 49(2) describes the nature and scope of the review, particularly taking
into account developments in assisted reproductive technology, scientific and
research developments, the potential therapeutic applications of any research and
community standards. The review must also take into account the applicability of
establishing a National Stem Cell Bank, an additional requirement inserted in each
of the two Cth Acts as a result of amendments made during the course of the debate
in the Senate. Sub-clause 49(3) provides that a review of this Act may be
undertaken as part of the reviews of the Commonwealth Research Involving
Human Embryos Act 2002 and the Commonwealth Prohibition on Human Cloning
Act 2002. This clause of the Bill has been drafted to take into account the
importance of national consistency and allow for the Queensland Act to be
reviewed in conjunction with the Commonwealth Acts as part of a consistent
national regulatory regime.67

7 A CONSCIENCE VOTE

In a Media Interview on 4 April 2002, the Prime Minister announced:

It is our proposal and our intention to legislate both the ban on human cloning, and
also the conditions attaching and governing the use of embryos for research
purposes that we should legislate that nationally. We will ask the states and the

66 Explanatory Notes, Research Involving Human Embryos And Prohibition Of Human Cloning
Bill 2003, (Qld), p 34.

67 Explanatory Notes, Research Involving Human Embryos And Prohibition Of Human Cloning
Bill 2003, (Qld), p 40.
territories to mirror that legislation at a State and Territory level so that we have a comprehensive national legislative framework governing aspects of this.

Members of Government parties will be allowed a free vote on this issue. I understand the Australian Labor Party has decided on a free vote. I think it is appropriate that on issues of this kind there be a free vote and that free vote will extend to Cabinet Ministers as well as to members of the backbench. I should also note of course that in the currency of debate on the legislation it would be open to anybody to put forward an amendment or even sponsor a private members bill and conditions of free vote would apply in relation to those as well. …

This is not an easy issue and there are genuinely held views on various sides of the debate. I believe that the conclusion that we have reached and the way that we intend to handle it is one that strikes the right balance between a careful regard for ethical considerations but also a belief that no stone should be unreasonably left unturned to provide an avenue for the relief of human suffering. This country has a remarkable capacity in the area of medical research. We have been at the forefront of many areas of medical research and I believe the potential in this area is very great. That is not the only consideration. It has to occur under very strictly defined conditions and I think what we are proposing will be seen by the broader community as striking that correct balance. But because it does involve issues of human life, considerations of when life begins, the circumstances in which it may end and the circumstances importantly in which it is lived and enjoyed or endured as sadly is the case with many people who suffer debilitating diseases, it’s only right that people have a free vote. 68

Voting on the (originally singular) Research Involving Embryos and Prohibition of Human Cloning Bills 2002 in the Commonwealth House of Representatives was, as had been presaged above, by way of conscience vote. Introducing that Bill, the Prime Minister, Mr John Howard MP said:

It is because the bill traverses areas involving complex moral and ethical judgments, where inevitably Australians will take a variety of attitudes, that senators and members of the Liberal and National parties will exercise a free vote on the bill as a whole and on all of its provisions 69.

A conscience vote will also be provided on the Queensland Bill, with the Premier, Hon P Beattie MP, stating:

It is inevitable that people will have varied and strong views on these issues, especially in areas involving excess assisted reproductive technology embryos. For

68 Transcript of the Prime Minister the Hon John Howard MP, Press Conference, Parliament House, 4 April 2002.

that reason, the government will provide a conscience vote on the bill as a whole and on all of its provisions.\textsuperscript{70}

Leader of the Opposition, Mr Springborg MP, is also reported to have said his MPs would have a conscience vote on the laws.\textsuperscript{71}

In the Queensland Parliament, the last full conscience vote (all parties) on a Bill was the Pregnancy Termination Control Bill on 21 May 1980.\textsuperscript{72}

\section*{8\hspace{1em} ONE BILL OR TWO}

\subsection*{8.1\hspace{1em} AT THE FEDERAL LEVEL}

Of the decision whether to split the Bill in two, in federal Parliament, the Prime Minister also allowed this to be a conscience vote, stating as follows:

\begin{quote}
Some members have argued that the bill should be split into two. In their mind, one would prohibit human cloning and other ethically unacceptable practices, which most members would support; the other bill would deal with research involving excess IVF embryos, which obviously would be more controversial.

The government has decided to introduce the bill in a consolidated form; but, out of respect for the views to which I have just referred, the government itself will not oppose any move in the House to split the bill. It will, however, be up to members in a free vote to decide whether or not this should occur.\textsuperscript{73}
\end{quote}

\subsection*{8.2\hspace{1em} QUEENSLAND}

The Queensland Government provided a detailed submission to the Senate Community Affairs Legislation Committee Inquiry into the Research Involving Embryos and Prohibition of Human Cloning Bill 2002. That submission contained


\textsuperscript{73} Hon J Howard (PM), Second Reading Speech, 27 June 2002, p 4542.
the following comments with regard to the issue of splitting the Commonwealth Bill:

*The Queensland Government does not support the splitting of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 into two separate statutory instruments. While recognising the necessity for providing an opportunity for a conscience vote on these complex and sensitive issues, Queensland has a number of concerns with the movement away from the provisions as originally drafted, which has occurred as an outcome of the House of Representatives’ decision on 29 August to split the Bill. The splitting of the original Bill requires the subject matter of the Bills to be considered separately when in fact the issues are closely related. The Queensland perspective is that this represents a departure from the cooperative drafting of the legislation. The Queensland Government encourages the Senate to consider and commence the Bills jointly and to reconsider the review provisions contained in the original Research Involving Embryos and Prohibition of Human Cloning Bill 2002.*

Introducing the Research Involving Human Embryos and Prohibition of Human Cloning Bill 2003 (Queensland), Premier Beattie said:

*A single Commonwealth Bill was introduced to the House of Representatives, then split during debate and passed as two acts. The Queensland Bill is presented as a single bill. I believe the prohibition of human cloning and certain reproductive technology practices and the regulation of research on excess embryos are all issues requiring equal moral and ethical consideration and can be dealt with effectively in one bill. That allows people to state their position on the particular clauses and to have on the parliamentary record their views on the different aspects of the various parts of the bill.*

*One single bill incorporates COAG agreements in a clear and unambiguous way. The national regime agreed by COAG addresses sensitive and difficult ethical and scientific issues.*

Most recently, it has been reported that the Government has announced that the Queensland Bill will be split.*

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76 ‘Bill to be split’, *Courier Mail*, 10 March 2003, p 5.
Leader of the Opposition, Mr Lawrence Springborg, MP is reported as stating that he was not opposed to splitting the Bill although he personally supported both parts.\footnote{Rodgers and Wardill, ‘MPs move to split cell research Bill’, \textit{The Courier Mail}, February 28, 2003, p 6.}

\section*{9 RECENT INTERNATIONAL DEVELOPMENTS}

Since the introduction of the Queensland Bill into the Legislative Assembly on 25 February 2003, the US House of Representatives (on 27 February 2003) passed the \textit{Human Cloning Prohibition Bill 2003} by 241 to 155 votes to impose a total ban on human cloning. All human cloning, to create a pregnancy or for medical research, is prohibited and it is also unlawful to import a cloned human embryo or any product derived from one. Any violation of the law will attract fines as high as $1$m and 10 year prison sentences. The argument by some legislators for an exception to allow human cloning research for cures for diseases such as Parkinson’s was rejected.\footnote{‘US House of Representatives passes Bill banning human cloning’, \textit{Canadian Press Online}, 27 February 2003.} Scientific research in human stem cells or cloning techniques to produce molecules, DNA or cells from embryos, tissues or organs from plants or animals other than humans would be allowed.\footnote{‘US House of Representatives approves total cloning ban,’ \textit{Sydney Morning Herald Online}, 1 March 2003.} The Bill will now be debated in the Senate.

Similar laws passed the House during the last legislative session but did not get taken up in the Senate. The laws reflect the Bush administration’s opposition to the cloning of humans, for reproduction or research, and President George Bush strongly supports efforts to ban all human cloning.\footnote{‘US House of Representatives approves total cloning ban’.}
APPENDIX A – MINISTERIAL MEDIA STATEMENTS

Hon Peter Beattie MP, Premier and Minister for Trade
25 February 2003
New Stem cell law will give scientists freedom to save lives

Premier Peter Beattie said today strict controls on human embryonic stem cell research will set clear limits for Queensland scientists seeking breakthroughs that could save and enhance lives.

Mr Beattie will today introduce into Queensland Parliament an integrated bill that bans human cloning and regulates research involving human embryos.

Mr Beattie said the Research Involving Human Embryos and Prohibition of Human Cloning Bill 2003 "strikes a sensible balance in regulating research involving human embryos".

"One of humanity's defining characteristics is our continuing quest to overcome diseases and injuries that diminish quality of life," he said.

"There is a strong scientific view that human embryonic stem cell research could lead to treatments that have so far eluded medical technology.

"I do not want to shut down inquiry into this potential medical application in Australia.

"To do so would shut down humane possibilities for the thousands of Australians whose lives are shortened and made painful by diseases and injuries such as: juvenile diabetes, Alzheimers, Parkinsons, liver and other organ failure, a variety of cancers, spinal cord injury, inherited conditions such as cystic fibrosis and nerve cell damage caused by stroke and heart disease," Mr Beattie said.

The Bill is part of a national approach agreed to by Prime Minister John Howard and State and Territory leaders at a Council of Australian Governments (COAG) meeting in April 2002.

It complements legislation introduced into the Commonwealth Parliament by Prime Minister John Howard, and passed with the support of Opposition Leader Simon Crean in December 2002.

Mr Beattie said the national approach will prevent loopholes.

Human cloning will carry a maximum penalty of 15 years in jail. Attempting to clone a human will also carry a maximum penalty of 15 years imprisonment.

Consistent with Commonwealth laws, any research which may damage or destroy an embryo is limited to the excess assisted reproductive technology
(ART) embryos which existed as at 5 April 2002 and for which donor consent has been given.

COAG will review the need to retain the ban on research on embryos created after 5 April 2002, after receiving a report from an ethics committee.

Mr Beattie said excess ART embryos are currently disposed of, largely through exposure to room temperature.

"I want to be quite clear on this: the source of the excess embryos capable of donation for stem cell research is the IVF program," Mr Beattie said.

"As a result of this bill, not a single extra embryo will be created, nor will a single further embryo die.

"I would much rather that early-stage embryos, which would otherwise be allowed to succumb, are used in research that might advance lifesaving and life-enhancing therapies.

"Promoting innovation that advances quality of life is a fundamental quality of the Smart State."

Queensland’s Bill supports the creation of a licensing committee within the National Health and Medical Research Council.

The licensing committee will examine each application to conduct research using excess ART embryos.

It will ensure that each use is fully justified and that embryos are donated with informed consent.

Labor Members of Parliament will have a conscience vote on the Bill.

Media inquiries: Fiona Kennedy 07 3224 4500
Joint Statement from Premiers of NSW, Victoria and Qld on stem cell research

On the eve of the Federal Parliament debate about embryonic stem cell research, the Premiers of New South Wales, Victoria, and Queensland have written to Prime Minister John Howard, urging him to stand firm and oppose any moves to split the legislation.

The Premiers were pleased Mr Howard's public comments have supported embryonic and adult stem cell research.

And they were happy he restated his commitment to the Council of Australian Governments' (COAG) Communiqué, including to:

- report within 12 months on protocols to preclude the creation of embryos specifically for research;
- review the need for the April 5 2002 restriction on the use of excess IVF embryos for research; and
- have the NHMRC assess the adequacy of supply of excess IVF embryos for research.

The Premiers, however, have expressed concern about possible attempts to split the Research Involving Embryos and Prohibition of Human Cloning Bill 2002.

"It was with some concern that we noted you (Mr Howard) will not oppose any move in the House to split the legislation into a Bill to prohibit human cloning and other unacceptable practices and a separate Bill to regulate research involving embryos," the Premiers said.

"This is not consistent with the spirit of our agreement at COAG. It will place at risk the nationally consistent scheme that we have been working towards.

"We would also like to stress that substantial changes to the Bill which extend the scope of the legislation, limit research opportunities, or prevent a meaningful review of the legislation within three years, will not be supported by our Governments," they said.

Media Contact: Steve Bishop 07 3224 4500
APPENDIX B – COUNCIL OF AUSTRALIAN GOVERNMENTS - COMMUNIQUE

INTRODUCTION

The Council of Australian Governments (COAG) today held its 11th meeting in Canberra. The Council, comprising the Prime Minister, Premiers and Chief Ministers and the President of the Australian Local Government Association (ALGA), had wide ranging discussions on important areas of national interest.

This Communique sets out the agreed outcomes of the discussions.

HUMAN CLONING, ASSISTED REPRODUCTIVE TECHNOLOGY (ART) AND RELATED MATTERS

The Council agreed that the Commonwealth, States and Territories would introduce nationally-consistent legislation to ban human cloning and other unacceptable practices. The Council noted the Commonwealth intends to introduce legislation by June 2002.

The Council agreed that research involving the use of excess assisted reproductive technology (ART) embryos that would otherwise have been destroyed is a difficult area of public policy, involving complex and sensitive ethical and scientific issues. Having noted the range of views across the community, including concerns that such research could lead to embryos being created specifically for research purposes, the Council agreed that research be allowed only on existing excess ART embryos, that would otherwise have been destroyed, under a strict regulatory regime, including requirements for the consent of donors and that the embryos were in existence at 5 April 2002. Donors will be able to specify restrictions, if they wish, on the research uses of such embryos.

The regulation restricting the use of embryos created after 5 April 2002 will cease to have effect in three years, unless an earlier time is agreed by the Council. The Council also agreed to establish an Ethics Committee with membership jointly agreed by the Council to report to the Council within 12 months on protocols to preclude the creation of embryos specifically for research purposes, with a view to reviewing the necessity for retaining the restriction on embryos created on or after 5 April 2002. The Council also agreed to request the National Health and Medical Research Council (NHMRC) to report within 12 months on the adequacy of supply and distribution for research of excess ART embryos which would otherwise have been destroyed.

The Council agreed that research involving the destruction of existing excess ART embryos be permitted under a strict regulatory regime to enable Australia to remain at the forefront of research which may lead to medical breakthroughs in the treatment of disease. It was further agreed that the regulatory regime governing the use of excess ART embryos that would
otherwise have been destroyed will be reviewed within three years. Research would need to have approval from an ethics committee and be in accordance with NHMRC and Australian Health Ethics Committee guidelines. This arrangement will be administered by the NHMRC as the national regulatory and licensing body.

Details of the agreed arrangements on the bans on human cloning and other unacceptable practices and the regulatory regime governing research involving the destructive use of existing excess ART embryos are attached.

ATTACHMENT

ARRANGEMENTS FOR NATIONALLY-CONSISTENT BANS ON HUMAN CLONING AND OTHER UNACCEPTABLE PRACTICES, AND USE OF EXCESS ASSISTED REPRODUCTIVE TECHNOLOGY (ART) EMBRYOS

The Council agreed that the Commonwealth, States and Territories would introduce nationally-consistent legislation to ban human cloning and other unacceptable practices. The Council noted the Commonwealth intends to introduce legislation by June 2002.

It is also intended that this legislation establish a national regulatory regime in relation to the use of excess ART embryos. Given the pace of scientific developments in this area, the Council also agreed that arrangements for research using excess ART embryos will be reviewed within three years.

The arrangements agreed by the Council are as follows.

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

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

   1.1 A person must not:

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

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

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

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

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

1.3 It is not a defence that the human clone or human embryo clone did not or could not survive.
“Human clone” means a human that is a genetic copy of another living or dead human.

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

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

**Nationally-consistent regulation of certain unacceptable practices**

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

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

a) for purposes other than assisted reproduction; or

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

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

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

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

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

2.6 A person must not conduct embryo flushing.

3. A person must not:

a) create or develop a hybrid embryo; or

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

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

3.2 A person must not:

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

b) place an animal embryo in a human for any period of gestation.
3.3 A person must not give or offer valuable consideration to any person for donation of gametes or embryos of that person or of any other person.

“Valuable consideration” includes a discount or priority in the provision of a service but does not include the disbursement of any reasonable expense incurred by a person in connection with a donation of his or her reproductive material.

4. The prohibited practices will be comprehensively reviewed within three years of nationally consistent legislation taking effect, taking into account changes in technology, the potential therapeutic uses for such technology and any changes in community standards.

A nationally-consistent approach to research involving human embryos

5. Research involving human embryos should be regulated through nationally-consistent legislation.

6. The following principles should underpin nationally-consistent legislation:

6.1 legislation should ensure appropriate ethical oversight of research involving embryos based on nationally-consistent standards;

6.2 the nationally-consistent standards should be clear, detailed and describe the ethical issues to be taken into account, research which may be permitted and the conditions upon which it may be permitted (that is, the “rules” to be observed by researchers undertaking work with embryos) and should be based on National Health and Medical Research Council (NHMRC) guidelines as devised by the Australian Health Ethics Committee (AHEC);

6.3 these national standards should be applied consistently throughout Australia, recognising that jurisdictions may use different mechanisms to establish that proposals comply with the national standards;

6.4 the system should provide for public reporting of research involving embryos so as to improve transparency and accountability to the public; and

6.5 the system should enable appropriate monitoring of compliance with the national standards and provide legislated penalties for non-compliance.

7. There is a range of legislative options that could meet these principles including systems of accreditation, licensing or mandating of compliance with the revised AHEC guidelines.

A nationally-consistent approach to the development and/or use of embryos for the derivation of stem cells

8. Research with existing stem cell lines will be permitted to continue in Australia subject to observance of conditions set by NHMRC/AHEC.

9. Research and possible therapeutic applications which involve the destruction of existing excess ART embryos (or which may otherwise not
leave the embryo in an implantable condition) will be permitted in accordance with the regulatory regime at Appendix 1.

10. The ban on the development of embryos for purposes other than for assisted reproduction will be maintained and reviewed within three years taking into account the implications for therapeutic use of embryonic stem cells (as detailed in the Health Ministers’ report, Chapter 4).

A nationally-consistent approach to ART

11. Accreditation by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia should provide the basis for a nationally-consistent approach to the oversight of ART clinical practice in Australia, noting that compliance with the NHMRC/AHEC Ethical Guidelines on ART is a key requirement of RTAC accreditation.

12. Individual jurisdictions may choose to mandate RTAC accreditation in legislation or supplement requirements for RTAC accreditation with an additional layer of oversight (for example, through a system of licensing or accreditation of ART service providers).

13. Non-legislative measures should be implemented to improve clarity regarding the role of Human Research Ethics Committees in relation to innovative practice and to increase public reporting of research and innovative practice (as detailed in the Health Ministers’ report, Chapter 5).

APPENDIX 1

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

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

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

• the embryo had been created prior 5 April 2002.

These regulations will be reviewed within three years.

The regulation restricting the use of embryos created after 5 April 2002 will cease to have effect in three years, unless an earlier time is agreed by the Council.

The Council also agreed to establish an Ethics Committee with membership jointly agreed by the Council to report to the Council within 12 months on protocols to preclude the creation of embryos specifically for research purposes, with a view to reviewing the necessity for retaining the restriction on embryos created on or after 5 April 2002.

The Council also agreed to request the NHMRC to report within 12 months on the adequacy of supply and distribution for research of excess ART embryos which would otherwise have been destroyed.

5 April 2002
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