The Senate

Standing Committee on Community Affairs

Legislative responses to recommendations of the Lockhart Review

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Senator Ruth Webber	ALP, Western Australia

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CHAPTER 1

INTRODUCTION

Terms of reference

On 14 September 2006 the Senate, on the motion of Senator the Hon Kay Patterson, agreed to the following resolution:

(1) That the following matter be referred to the Community Affairs Committee for inquiry and report by 27 October 2006:

Legislative responses to recommendations of the reports of the Legislation Review Committee on the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* (the Lockhart review).

(2) That in undertaking this inquiry the committee may consider any relevant bill or draft bill based on the Lockhart review introduced or tabled in the Senate or presented to the President by a Senator when the Senate is not sitting.

1.1 In accordance with part 2 of the resolution, the Committee considered the Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006 exposure draft tabled by Senators Stott Despoja and Webber on 14 September and the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 presented initially to the President by Senator Patterson on 26 September and introduced in the Senate on 19 October.[1]

Conduct of the Inquiry

1.2 The inquiry was advertised in *The Australian* on 28 August and 11 September 2002 and through the Internet. Submissions were also invited from a large range of groups and individuals. Due to the tight timeframe for the inquiry, the closing date for submissions was 4 October 2006, although the Committee continued to receive submissions throughout the course of the inquiry.

1.3 The Committee received 494 public submissions, together with a large amount of additional material from witnesses at hearings and in response to questions on notice. The list of submissions and other written material received by the Committee and for which publication was authorised is at Appendix 1. A large volume of correspondence was received providing general comments. While this correspondence has been processed as submissions it was not possible to acknowledge them all individually. Public hearings were held in Canberra on 20 October, Sydney

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

on 23 October and Melbourne on 24 October. A list of witnesses who appeared at the public hearings is included at Appendix 2. Submissions authorised for publication and the *Hansard* record of the public hearings may be accessed through the Committee's website at www.aph.gov.au/senate_ca

1.4 This inquiry has been undertaken in circumstances where the political parties have given their Senators a 'free vote' on the legislation 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 legislative responses to the Lockhart Review.

1.5 The report has been structured in the following fashion. This introductory chapter refers to recent inquiries, reports and debate that have resulted in the preparation of the two Bills. Chapter 2 provides the recommendations of the Lockhart Review that form the basis of the terms of reference and are addressed in the respective Bills. Chapter 3 outlines the issues and arguments raised in evidence by those groups and individuals supporting the Lockhart recommendations and the proposed Bills; while Chapter 4 outlines the issues and arguments of those opposing the recommendations and proposed Bills. A number of Senators have attached additional comments to the report.

Background history and chronology

1.6 In 1998 scientific advances in cloning prompted legislatures around the world to consider the ramifications of this work.

1.7 In the same year, the Minister for Health and Aged Care, Dr. Michael Wooldridge, asked the Australian Health Ethics Committee (AHEC) to report to him on the scientific, ethical and regulatory considerations relevant to cloning of human beings.

1.8 In its report,[2] AHEC made a number of recommendations including that the Minister should encourage informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques.

1.9 In 1999, Minister Wooldridge asked the House of Representatives Standing Committee on Legal and Constitutional Affairs to review the AHEC 1998 Report. In its 2001 report *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*, the majority of the Committee recommended:

- the enactment of legislation to regulate human cloning and stem cell research;

2 *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings,* Australian Health Ethics Committee, 1998.

- that such legislation should include a ban on cloning for reproductive purposes combined with criminal penalties and loss of an individual's research licence; and
- The establishment of a national licensing body empowered to issue licences for research involving the isolation, creating and use of embryonic stem cells.

1.10 In addition the Committee said 'there should be a moratorium on the creation of embryos by means of somatic cell nuclear transfer techniques for three years, at which point the issue should be re-examined. During the next three years the progress of research should be continually monitored by AHEC and it should provide regular reports to the Council of Australian Governments through the Commonwealth Minister for Health and Aged Care.'

1.11 Australian Health Ministers and the Council of Australian Governments (COAG) had been considering the issue of human cloning and research involving excess ART embryos from the late 1990s. At a 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 unacceptable practices and 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. A draft bill was prepared and after consultations undertaken by the NHMRC in each State and Territory the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 was introduced in Parliament on 27 June 2002.

1.12 After the Bill's introduction, its provisions were referred to the Community Affairs Legislation Committee which received evidence from a wide range of stakeholders in the community to inform the Senate in its deliberations on the Bill. As is the situation with the current legislation, Senators were given a 'free vote' when the Bill was debated in the Senate.

Committee's Report on the Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002

1.13 The Committee's report into the Bill debated by the Parliament in 2002, that was subsequently divided to be passed as the two Acts subject to the Lockhart Review, was tabled in October 2002[3]. The report provided background to the previous inquiries, reports and deliberations that ultimately led to the passage of the two Acts and the legislative review undertaken by the Lockhart Committee.

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3 Senate Community Affairs Legislation Committee, *Report on the Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002*, October 2002, pp.2-8. http://www.aph.gov.au/senate/committee/clac_ctte/completed_inquiries/2002-04/emb_cloning/index.htm

1.14 The report gave an overview of the scientific aspects of the debate, including defining stem cells, outlining the properties of cells and cloning technologies and discussing the potential applications of stem cell research. The report also considered the philosophical arguments over the ethics of embryonic stem cell research. These arguments covered issues such as the moral status of the human embryo, utilitarian arguments, conceptual loss and the slippery slope.

1.15 A description of the provisions of the Bill, subsequently split to become the RIHE Act and the PHC Act, and a brief discussion of international comparisons as they stood at the time, was also provided.

1.16 Attached to the report were a number of supplementary reports and qualifying comments by Senators providing their respective views on the Bill and evidence received by the Committee.

1.17 The Committee has not, as part of this inquiry, replicated the lengthy analysis of the issues raised in 2002 that remain relevant to the current debate. The 2002 report provides useful background on many of these issues, both scientific and ethical.

1.18 The Bill was extensively debated in the House and the Senate, divided into two Bills and finally enacted as the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*. Following the passage of these Commonwealth Acts, each State and Territory enacted complementary legislation.

Legislative Review Committee

1.19 The *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* each contain a provision that an independent review of the operation of the Act must be undertaken two years after the Act received Royal Assent by persons chosen by the Minister with the agreement of each State. In June 2005 the Legislative Review Committee chaired by former Federal Court judge, the Hon John Lockhart AO, was appointed to consider and report on the scope and operation of each of the Acts. The report of the Lockhart Review was presented to the Minister for Ageing on 19 December 2005. The recommendations are reproduced in Chapter 2.

1.20 On 23 June 2006 the Prime Minister, the Hon John Howard, provided the Government's response to the recommendations of the Lockhart Review:

> After careful reflection, the Government is not disposed to make any changes to the existing national legislative framework for research involving human embryos, agreed in 2002.
>
> Recognising, however, the range of issues and views, there will be a detailed discussion on this issue within the Government parties when Parliament resumes for the Spring sitting…
>
> The Lockhart Review also recommended some administrative improvements that will help reduce red tape in the licensing process and provide further support to the regulatory scheme by enhancing the National Health and Medical Research Council guidelines. Taking into account

> experience since the enactment of the legislation in 2002, the Government is supportive of these recommendations.
>
> The Government also supports further exploring the establishment of a national register of donated excess embryos created originally for ART purposes and a national stem cell bank.[4]

1.21 COAG considered the Lockhart Review at a meeting on 14 July 2006 and stated in a communiqué:

> COAG noted that agreement had not yet been reached across jurisdictions on all the 54 recommendations of the Lockhart Review Committee Report. However, COAG agreed that officials would continue to work on those Lockhart Review recommendations of an administrative nature on which there is agreement and report back to COAG by December 2006.
>
> While COAG restated its preference for nationally consistent arrangements, in the absence of national agreement some states and territories reserved the right to alter the legislation within their own jurisdictions to the extent that is within their power.[5]

1.22 On 31 August the Prime Minister released a report prepared by mpconsulting that had been commissioned by the Department of the Prime Minister and Cabinet titled 'Analysis of advice on developments in assisted reproductive technology and related medical and scientific research'.

1.23 It was also announced in August that the members of the Coalition parties and the Australian Labor Party would be allowed a free vote if legislation came before the parliament. The tabling of the exposure draft bill by Senators Stott Despoja and Webber and the subsequent introduction of the bill by Senator Patterson has now placed legislation to enact the Lockhart Review recommendations before the parliament.

Senators' Bills seeking to give effect to Lockhart recommendations

1.24 Both Senator Patterson's bill and Senators Stott Despoja and Webber's exposure draft bill reflect the Lockhart Review's recommendations in a legislative form.

1.25 Senator Stott Despoja informed the Senate that the exposure draft bill was intended to create a starting point for discussion of the issues raised by the Lockhart Review, of which this inquiry is a part. All the Lockhart Review recommendations were incorporated into the draft bill. In an accompanying speech, Senator Stott Despoja stated:

> This bill enshrines the scientific recommendations of the Lockhart Review that require legislative change to the original Acts.

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4 Prime Minister of Australia, Media Release, Lockhart Review, 23 June 2006.

5 Council of Australian Government's meeting 14 July 2006, Communiqué p.13

> The inclusion of all the Lockhart recommendations gives the Parliament the opportunity to accept, reject, or amend them, but, at least, debate them. I am not cherry-picking recommendations – it should be for the Parliament to decide which ones become law.[6]

1.26 Senator Patterson released the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 (the Patterson bill) on 26 September and subsequently introduced the bill on 19 October 2006. This bill also seeks to implement each of the Lockhart Review's recommendations where a legislative response is required. When introducing the bill, Senator Patterson advised the Senate:

> In 2002, when I was the Minister for Health and Ageing, I had the responsibility of taking the Prohibition of Human Cloning Bill and the Research Involving Human Embryo Bill through the Senate on behalf of the Government.
>
> As I have said, the Acts required that they be reviewed, and one of the terms of reference required that the "reports must contain recommendations about amendments, if any, that should be made to the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos 2002, whichever is applicable".
>
> In 2002 I said in the debate on the Bills, "If the review gives rise to possible amendments to the legislation, any such amendments must come before parliament, and at that time, whoever is here will have the opportunity to consider in detail any proposed changes to the legislation".
>
> This bill provides that opportunity.[7]

1.27 A table showing how the Lockhart Review recommendations are addressed in the Patterson bill is at Appendix 3.

6 Senator Stott Despoja, *Draft Second Reading Speech*, p. 1.

7 Senator Patterson, Second Reading Speech, *Senate Hansard*, 19 October 2006, p.14.

CHAPTER 2

THE LOCKHART REVIEW RECOMMENDATIONS

2.1 The Legislation Review Committee, chaired by the late the Hon John Lockhart AO QC, was appointed in June 2005 and reported on 19 December 2005.[1] The recommendations made by the Review Committee are listed in this chapter followed by a brief profile of each of the Review Committee members.

Recommendations

National legislation

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.

Reproductive cloning

2 Reproductive cloning should continue to be prohibited.

Prohibitions on developing and implanting embryos

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.

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.

5 Implantation into the reproductive tract of a woman of a human–animal hybrid or chimeric embryo should continue be prohibited.

6 Development of a human–animal hybrid or chimeric embryo should continue to be prohibited, except as indicated in Recommendation 17.

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.

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.

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1 The complete report of the Legislation Review Committee may be accessed at http://www.lockhartreview.com.au/index.html See also Appendix 5.

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.

10 Implantation into the reproductive tract of a woman of an embryo carrying heritable alterations to the genome should continue to prohibited.

11 Collection of a viable human embryo from the body of a woman should continue to be prohibited.

Creation of human embryos by fertilisation

12 Creation of human embryos by fertilisation of human eggs by human sperm should remain restricted to ART treatment for the purposes of reproduction.

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.

Use of excess ART embryos in research

14 Use of excess ART embryos in research should continue to be permitted, under licence, as under current legislation.

ART clinical practice and ART research

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.

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.

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.

18 The Licensing Committee should develop a simple proforma application for licences to undertake training and quality assurance activities for ART clinics.

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.

Use of fresh ART embryos

20 An expert body should formulate objective criteria to define those embryos that are unsuitable for implantation.

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.

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.

Use of human embryos created by somatic cell nuclear transfer

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.

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.

Use of human embryos created by activation methods not involving fertilisation of a human egg by a human sperm or somatic cell nuclear transfer

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.

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.

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.

Definition of a human embryo

28 The definition of a 'human embryo' in both Acts should be 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.'

Consent arrangements for the donation of embryos

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.

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).

Egg donation

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.

32 The NHMRC should develop guidelines for egg donation.

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.

Licensing arrangements

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.

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).

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.

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.

Monitoring powers

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.

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.

Oversight of ART clinical practice and research

40 There should be a continuation of the role of the Reproductive Technology Accreditation Committee in the regulation of ART.

Import and export of human reproductive materials for personal use

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.

Trade and international exchange of human reproductive materials and stem cells

42 The import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority.

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.

Biotechnology and commercialisation

44 Trade in human gametes or embryos, or any commodification of these items, should continue to be prohibited.

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.

46 The development of biotechnology and pharmaceutical products arising from stem cell research should be supported.

National stem cell bank

47 A national stem cell bank should be established.

48 Consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem cell bank.

49 A national register of donated excess ART embryos should be established.

Regulatory approach to legislation

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.

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.

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.

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.

Public education

54 There should be ongoing public education and consultation programs in the areas of science that are relevant to the Acts.

Committee members

2.2 A brief profile of the members of the Legislative Review Committee follows.[2] The Hon John Lockhart passed away in January 2006, shortly after the presentation of the Review Committee's report.

The Hon John S Lockhart AO QC (Chair)

The Honourable John Lockhart is a highly regarded member of the international legal community. He was a Justice of the Federal Court of Australia from 1978 until 1999. He has been a member of the Appellate Body of the World Trade Organization, Geneva, Switzerland since 2002 and was appointed as the Deputy Chair of the International Legal Services Advisory Council in 2004. Mr Lockhart has highly relevant experience in chairing high level committees that deliberate on contentious issues.

Associate Professor Ian Kerridge (New South Wales)

Associate Professor Kerridge is a highly regarded clinical ethicist and specialist haematologist. He is Associate Professor in Bioethics and Director of the Centre for Values, Ethics and Law in Medicine at the University of Sydney and Staff Haematologist/Bone Marrow Transplant Physician at Westmead Hospital, Sydney. Associate Professor Kerridge has highly relevant skills and expertise demonstrated through his work and publications in the fields of health ethics.

Professor Barry Marshall (Western Australia)

Professor Marshall is Research Professor of Microbiology at the University of Western Australia and also brings generalist scientific expertise in addition to his abilities in community representation. He is a highly awarded scientist of international renown who is also a successful community advocate both in Australia and overseas. He is a specialist gastroenterologist who is noted for his discovery of the link between the bacteria Helicobacter pylori and gastric ulcers. Professor Marshall and a colleague won the 2005 Nobel Prize in Physiology or Medicine for this discovery.

2 These profiles are reproduced from Legislation Review, Appendix 1, p.188.

Associate Professor Pamela McCombe (Queensland)

Associate Professor McCombe is a Consultant Neurologist and a Visiting Medical Officer at the Royal Brisbane Hospital and holds the position of Associate Professor, Department of Medicine at the University of Queensland. She is Chair of the Wesley Research Institute Research Committee and Chair of the Scientific Program Committee of the Australian Association of Neurologists.

Professor Peter Schofield (New South Wales)

Professor Schofield is a renowned neuroscientist. He is Executive Director and Chief Executive Officer of the Prince of Wales Medical Research Institute, Senior Principal Research Fellow at the Garvan Institute of Medical Research and Conjoint Professor at the Faculty of Science and Faculty of Medicine at the University of New South Wales. Professor Schofield's skills and expertise are in a highly relevant scientific discipline to the review subject matter.

Professor Loane Skene (Victoria)

Professor Skene is a renowned lawyer, ethicist and academic. She is Pro Vice-Chancellor, Professor of Law in the Law Faculty and an Adjunct Professor of Law in the Faculty of Medicine, Dentistry and Health Sciences at the University of Melbourne. Professor Skene has highly relevant skills and expertise demonstrated through her work and publications in the fields of health law and ethics.

CHAPTER 3

THE MAJORITY REPORT

THE CASE FOR THE LOCKHART RECOMMENDATIONS

Introduction

3.1 The Committee was divided on acceptance of the two bills, which were based on the Lockhart Recommendations. However a majority of the committee agreed emphatically to support, and to recommend that Senators vote for, the Patterson Bill. The majority of the Committee also acknowledge the excellent contribution to the deliberations from Senators Stott Despoja and Webber through their draft exposure bill.

3.2 This chapter provides a brief scientific overview of the issues involved in the Lockhart Recommendations and the arguments provided in evidence which supported the Lockhart Recommendations, and the two bills prepared in response to the recommendations.

Overview of the science relevant to this Bill

A. Assisted Reproductive Technology:

3.3 Assisted Reproductive Technology (ART) is the application of laboratory or clinical technology to gametes and/or embryos for the purposes of reproduction. ART services are overseen by the NHMRC. Further information about ART and the NHMRC's role can be found on the NHMRC website www.nhmrc.gov.au.

3.4 The information given on the NHMRC website is written in the context of the current legislation.

B. Stem Cell Science:

3.5 There are many explanations of stem cell science available in scientific literature, lay press and online. Some sources communicate the science in a clear non-emotive fashion; others are biased, confusing or simply wrong. Rather than adding to the array of information already available, the Committee has decided to write a brief overview and defer to the NHMRC online educational resource for detailed information on the matter. This can be found in hard copy in Appendix 4 or online as "Stem Cells, cloning and related issues" at
http://www.nhmrc.gov.au/embryos/stemcells/index.htm

3.6 The information given on the NHMRC website is written in the context of the current legislation.

3.7 The Lockhart Committee also gives a description of the science which can be found on pages 39 – 40 as 5.1 'Background to Stem Cell Sciences' www.lockhartreview.com.au

3.8 Stem cells are ‘unspecialised’ cells that have the unique potential to develop into ‘specialised’ cell types in the body (for example blood cells, muscle cells or nerve cells). This can be either for growth and development, or for replenishment and repair. They occur at all stages of human development, from embryo to adult—but their versatility and numbers tend to decrease with age. Given the right conditions in the body or the laboratory, stem cells (unlike muscle cells, nerve cells and or blood cells) can replicate themselves many times over. When a stem cell replicates, the resulting cells can either remain as stem cells or can become specialised cells.

3.9 Stem cells are commonly described as 'adult' and 'embryonic' because of the tissue from which they are derived but they can also be defined by their potential as 'totipotent', 'pluripotent' and 'multipotent'. Totipotent cells are those stem cells which have the capacity to become any cell of the body as well as the capacity to form a whole being. These are only found in the first days of embryo development before the differentiation process begins.

3.10 Pluripotent cells have the potential to become any cell in the body but have no capacity to form a whole being. Under the current legislation human embryonic stem cells may only be obtained from donated surplus IVF embryos, and then only under special licence. These are what we commonly refer to as embryonic stem cells.

3.11 Multipotent stem cells are those that have entered a more specialised stage and can only develop into a certain range of cell types. Human adult stem cells, which generally fall into this category, are donated by people who have given informed consent for their use in research.

3.12 Another source of human embryonic stem cells could be Somatic Cell Nuclear Transfer (SCNT). This is a process commonly called cloning. It is important to remember that the word cloning is used to describe replication of single cells, genetic material as well as whole beings. It is vital that the different outcomes are clearly acknowledged. The SCNT process is where the nucleus of an egg is removed and replaced by one taken from a donor adult cell eg. a skin cell. This is then stimulated and it behaves like an embryo produced by sperm and egg. While the basic SCNT technique is the same as that used to clone whole animals, this cannot happen in humans for several reasons:

1) There has been and shall remain, if the Patterson Bill is passed, a strict prohibition on SCNT embryos being implanted in the body of an animal or human.

2) They are also prohibited from developing beyond 14 days.

3) Under the proposed legislation attempting to do either of these things whether with intent or otherwise will attract a penalty of up to 15 years imprisonment for the person or persons who tried to do it.

4) Scientists believe that the current indications are that the chances of these SCNT embryos developing beyond the blastocyst stage are very remote.

3.13 The representatives of Do No Harm tabled at the hearing on Tuesday 25th November an Editorial from Nature which says 'Whether taken from a fertility clinic or made through cloning, a blastocyst embryo has the potential to become a full functional organism'.[1] This is exactly what the Lockhart Committee addressed in ensuring that an embryo created by SCNT is encompassed by the definition of embryo.

3.14 This technique is widely used in animal research but is currently prohibited in Australia using human cells. However it is not illegal in, for example, the United Kingdom, USA, Singapore, and Sweden. As yet, researchers have not been able to successfully produce human embryonic stem cells using SCNT however this technique is less than 10 years old.

3.15 SCNT requires a source of ova. The bills propose these can be donated human ova or animal ova. Concern has been raised about the potential for exploitation of women as egg donors and also the ethics of using animal eggs in the research. It is important to stress that both bills prohibit the commercialisation of human egg donation and insertion of any cloned human embryo into the body of an animal or human. The notion of informed consent is an integral part of any medical procedure.

3.16 There is research that has pointed to the possibility that some multipotent cells possess plasticity and may be able to develop into more than one cell type making them more like pluripotent cells.[2] Other research has recently shown that it is possible to re-program specialised cells to behave like pluripotent cells.[3] This is promising new research, as if proven it could remove the need to use human ova. However SCNT research using ova remains pivotal to advancing this new research which winds back the cellular clock because we need to understand what it is in the cytoplasm of the egg that causes the donor nucleus in SCNT to behave like that of an embryo formed by sperm and egg.

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1 Nature, Vol 436, 7th July, 2005

2 Multipotent stem cells from adult olfactory mucosa. Murrell et al Dev Dyn 2005 Jun;233(2):496-515.

3 Takahashi and Yamanaka (2006). Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors. Cell 126: 663-676.

The Lockhart Review Committee

The Lockhart Committee Membership

3.17 The Lockhart Committee was appointed by the then Minister for Ageing, the Hon. Julie Bishop, and the membership was agreed to by the States and Territories.

3.18 The membership comprised a group of six eminent Australians. It was chaired by the late Hon. John Lockhart and included Professor Barry Marshall whose work, undertaken with Dr Warren, discovering the link between the bacteria Helicobactor pylori and gastric ulcers, was recognised in October 2005 when they shared the Nobel Prize in Physiology or Medicine.

3.19 The Committee in the Reports and in the Executive Summary detail the process of the extensive Review they undertook.

3.20 It was of concern to the majority of the Committee that a description such as 'a poorly outfitted group'[4] was used by those opposed to the recommendations of the Review to describe the members of the Lockhart review and their work.

3.21 Professor Sherley's attack on the credibility of the members was rejected outright by the majority of witnesses appearing before the Committee. The members of the Lockhart Committee also rejected this unwarranted criticism.

3.22 In his evidence to the Melbourne Inquiry, Professor Graham Jenkin from Monash Immunology and Stem Cell Laboratories cited an interview with Bob Klein, Chairman, California Institute for Regenerative Medicine:

> The American Medical Association, the California Medical Association and a group of 80 Nobel Laureates each independently reviewed the potential stem cell science and reached similar conclusions. What is more, these independent reviewers fully agreed with the Lockhart Committee's key position.[5]

What did the Lockhart Committee consider?

3.23 The Terms of Reference for the Lockhart Review were prescribed in the the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*. They were that the persons undertaking the review must consider and report on the scope and operation of these Acts taking into account the following:

1) developments in technology in relation to assisted reproductive technology;

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4 Professor James Sherley, *Submission 181*, p. 2.

5 'Inquirer', *Weekend Australian*, October 21-22 2006, p.28.

2) developments in medical research and scientific research and the potential therapeutic applications of such research;

3) community standards; and

4) the applicability of establishing a National Stem Cell Bank.

3.24 The Acts required that the Lockhart Committee report must contain recommendations about amendments that should be made to this Act, having regard to the matters mentioned above.

3.25 They also required that the Lockhart Committee must consult:

(a) the Commonwealth and the States; and

(b) a broad range of persons with expertise in or experience of relevant disciplines; and the views of the Commonwealth, the States and the persons mentioned in paragraph (b) must be set out in the report to the extent that it is reasonably practicable to do so.

What impact do the Lockhart recommendations as proposed in the Patterson Bill have on the application of the existing legislation?

3.26 The Lockhart recommendations and explanations for these can be found on pages 162-183 of the Lockhart Report and are in Appendix 5.

3.27 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 for the purposes of research;
    - 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.

3.28 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.

3.29 The Patterson Bill gives effect to the recommendations of the Lockhart Committee by either maintaining recommended prohibitions or making alterations to the legislation where needed to reflect the recommendations.

The science

3.30 It is important to note that the main area of controversy is not the merits or otherwise of embryonic stem cell research. This research has been legal and widely accepted in Australia since the 2002 using donated surplus human IVF embryos. The

major disagreement is the permitting of SCNT as a potential additional source of human embryonic stem cells. Many of those who argued against this aspect of the recommendations object to using any stem cells derived from an embryo that is destroyed in the process. That is, their objections go beyond SCNT to procedures that are already lawful.

3.31 Overwhelmingly Lockhart members, contributors and the majority members of this committee in favour of the Patterson Bill acknowledged that an SCNT embryo is defined as a human embryo. While respecting the individual's right to see the SCNT embryo as equal in status to that of an embryo produced by egg and sperm, it is intrinsic in the recommendations of Lockhart and the Patterson Bill that the continued prohibition of the creation of an embryo by egg and sperm for any purpose other than ART demonstrates the difference in the intrinsic value of the egg and sperm embryo.

3.32 Those in favour of the Patterson Bill argued that the central issue to consider is whether the value of the SCNT embryo outweighs the potential that SCNT research may offer living and future people for the prevention and treatments of disease.

3.33 Most evidence the committee received in support of the Lockhart Review and related bills focussed on the need and benefits of permitting somatic cell nuclear transfer (SCNT) to produce embryonic stem cells. People in favour of this bill were sensitive to those who believe that the intrinsic value of the SCNT embryo is equal to that of an embryo created through natural fertilization using egg and sperm. However they did not think that this belief should outweigh the potential to help living people with the possible understanding of disease process, therapies or drug testing the resultant SCNT ES cells may be used in finding.

3.34 In the lead up and during the course of these hearings some people accused scientists of 'peddling hope to vulnerable people' and misleading people using 'hype' by promising cures. The majority of the committee found those in favour of this research to be measured and candid about the uncertainty of the outcome of the research.

3.35 Interestingly upon perusal of a previous committee report on this same issue it appears that a simular view point was expressed by one of our colleagues in the House of Representatives. In 2001 the Standing Committee on Legal and Constitutional Affairs reported to the House of Representatives through its chair The Hon Kevin Andrews that:

> …the Committee has heard from many people. Scientists have shared their excitement about the discovery of techniques that could open future possibilities of cures for life threatening conditions. Families of people with disabilities have welcomed the prospect that some day relatives with Parkinson's or Alzheimer's disease might be restored to health. Yet researchers have cautioned also that such treatments remain speculative, and warned against raising hopes prematurely. In the case of Alzheimer's, the disease process has not even been identified.

3.36 It is the opinion of the majority of this committee that the claim that reputable scientists are hyping the potential of this research is inappropriate.

3.37 An overwhelming number of scientific contributors stressed that before we could expect to develop therapies we needed to understand how cells develop and differentiate and how disease processes occur at a cellular level. They also argued while this research remained prohibited any hope of finding therapies would be delayed and that stem cells derived by this technique would assist in our understanding of cell biology and in developing therapies for genetic disease. Many also argued that this knowledge would also provide greater potential for identifying adult stem cell treatments.

3.38 Supporters also suggested variously that:

- Existing legislation was being overtaken by scientific development;
- Legislative differences over SCNT amongst jurisdictions were causing leading researchers to leave Australia and was hampering collaborative work with overseas institutions;
- The proposed amendments reflect a plurality of views; and
- The current regulatory framework is inconsistent by allowing embryos created for ART to be used for stem cell research, but prohibits creating cloned embryos from being created for the same purpose.

3.39 The Lockhart Review sought to establish the equivalence of these two activities, saying in their report that:

> ...the production and destruction of such embryos is not dissimilar to the production and destruction of excess ART embryos, which is permitted by the legislation and widely accepted by society. Thus, to permit one (production and destruction of ART embryos) but not the other (production and destruction of nuclear transfer and other bioengineered embryos) is inconsistent and appears to attach more importance to the treatment of infertility than to the treatment of other serious diseases and conditions that could be helped as a result of this activity.[6]

3.40 Dr Paul Brock indicated that the implementation of the Lockhart recommendations would address legislative inconsistencies between the two acts:

> The Lockhart Review put the focus on a current anomaly which the proposed Bill will redress. The 2002 Australian legislation allowed for the creation of human embryonic stem cell lines from fertilised human eggs that have become surplus to the needs of IVF implantation – which means that they would never be implanted into the woman's uterus. But the 2002 legislation currently does not allow creation of such human embryonic stem cell lines derived from an unfertilised human egg in the SCNT process,

6 *Legislation Review*, p. 170.

> which would also never be implanted into the woman's uterus. This is a logically and ethically inconsistent situation.[7]

3.41 SpinalCure Australia also emphasised that allowing SCNT would be comparable with the current treatment of excess ART embryos:

> This type of embryo is not intended to be implanted, so the production and destruction of such an embryo is not dissimilar to the production and destruction of excess IVF embryos, which is permitted by legislation and accepted by society. Therefore denying SCNT but allowing IVF research implicitly values infertility treatment more than potential cures to chronic diseases.[8]

3.42 Likewise, Professor Melissa Little indicated that, in the context of already allowing research on excess ART embryos, the Lockhart Review's recommendation to allow SCNT presented the same ethical questions as those addressed in 2002. Referring to the current legislative arrangement, she stated:

> This acknowledges that, while not the opinion of all in our country, our society does not regard the blastocyst as having equivalent rights to an implanted embryo, fetus or a postnatal human being. A blastocyst is a ball of undifferentiated cells with no capacity to self-sustain or to differentiate without successful implantation into a womb. It is a seed. It has potential and no more. We condone the discard of such tissues as a part of IVF, hence there is no additional ethical dilemma in using these cells for some other purpose...
>
> The Lockhart committee reaffirms the acceptability of our existing legislation with respect to the regulated derivation of new human ES cell lines.[9]

The case for SCNT Research

3.43 While the obvious argument in favour of allowing human SCNT research to take place in Australia is the potential medical benefits human embryonic stem cells in general may bring, we are reminded that as yet no human ES cells been derived from this process. Scientists point out the catch-22 that until the ban is lifted research cannot progress in Australia. Many scientists who contributed to the debate pointed out that SCNT research in animals has shown that this technique has specific value over and above that of ES cell research using egg and sperm derived embryos.

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7 Dr Paul Brock, *Submission 2*, p. 6.

8 SpinalCure Australia, *Submission 29*, p. 2.

9 Professor Melissa Little, *Submission 167*, p. 2.

Creation of Disease-Specific Embryonic Stem Cell Lines

3.44 Because SCNT techniques involve cloning of donated adult cells we would have the opportunity to seek donations of cells from people with identified diseases. This could allow targeted research into particular diseases.

> …if we wish to generate pluripotent cell lines in order to gain insights into certain complex diseases, there is currently no alternative to the generation of disease-specific embryonic stem cell line [other than] via SCNT.[10]

3.45 These disease-specific stem cells lines would allow scientists in multiple laboratories to work on cells known to have genetic problems at the same time. These cloned cells could be used to gain better understanding of those disease processes at a cellular level, test drugs and hopefully derive therapies.

3.46 Professor Jack Martin, one of the few respected scientists who objected to this research, based his argument on the notion that there have been no therapies derived from ES cells and there was no 'proof of concept' to justify lifting the prohibition on SCNT. Other scientists disagreed, as well illustrated by Professor Martin Pera's comment to the committee where he stated:

> …with respect to the statement that there are no [human] therapies from cloned embryonic stem cells, of course there are not because research has not been done on a human yet that would enable it. However, there is proof of concept in animal studies that you can treat disease with such an approach.[11]

Better understanding of ageing process and cancer

3.47 It is known that as we age our genetic material deteriorates and SCNT technology allows exploration of the cellular ageing process which could lead to a better understanding of conditions such as cancer.

Understanding de-differentiation

3.48 Concern has been raised about the need to use donated human eggs in order to perform SCNT research. It has been pointed out that promising new research uses insertion of certain proteins into an adult cell to stimulate it to regress to a pluripotent stem cell-like state. This could mean that the need for human eggs may be reduced or even eliminated if this research can be replicated. However scientists point out that SCNT research is vital in advancing this new research as de-differentiation of the adult cell is an intrinsic part of the SCNT process and so SCNT research allows the ideal arena to further our understanding of de-differentiation.

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10 Professor Andrew Elafanty, *Committee Hansard*, 24 October 2006, p. 68.

11 *Committee Hansard*, 24 October 2006, p. 13.

3.49 Sir Gustav Nossal encapsulated the argument in support of lifting the prohibition on SCNT. He wrote:

> Embryonic stem cell research is rich in promise. It has already demonstrated its potential in the study of disease causation, in development of new diagnostic methods and in basic research. In the longer term, the possibility of new therapies for serious diseases is real, though this will be the work of decades rather than of years…
>
> Stem cell science has advanced to the point where it is pushing against the boundaries of current legislation. It is time for the next step.[12]

3.50 The Monash Immunology and Stem Cell Senior Researchers (The Monash Researchers) supported permitting SCNT on the basis of its potential to treat a number of incurable diseases:

> Access to somatic cell nuclear transfer (SCNT) technology is critical to study the causation and treatment of many common, yet complex human diseases, including many types of cancers and neurodegenerative diseases such as Motor Neurone Disease (Lou Gehrig's Disease or AML), Parkinson's Disease, Alzheimer's Disease, Multiple Sclerosis, Muscular Dystrophies, and numerous other debilitating conditions... It is important to emphasise that neither embryonic nor adult stem cells (as opposed to SCNT derived stem cells) are able to provide an adequate research platform for study of disease processes such as those listed above, neither are diseased cells derived from the lesions able to be expanded sufficiently in vitro for detailed analysis. The advent of SCNT circumvents these issues and provides a unique opportunity to examine such disease states.[13]

3.51 A number of disability support groups argued similarly with Kidney Health Australia submitting that:

> Embryonic stem cells offer great hope to patients with kidney disease, because potentially they can be induced to form any cell type of the human body, including any type of kidney cell. So if a cell type in the kidney (of which there are approximately 30 different types) is being lost due to disease, or parts of the kidney have been damaged or destroyed by disease, embryonic stem cells offer the promise of replacing these lost cell populations and/or repairing regions of the kidney.[14]

3.52 Professor Melissa Little, in discussing the potential for therapeutic applications, suggested that improvements in understanding cell biology and drug screening would constitute the main benefits. Professor Little is researching treatments for kidney disease at the University of Queensland and wrote:

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12 *Submission 74*, p. 1.

13 The Monash Researchers, *Submission 73*, p. 2.

14 Kidney Health Australia, *Submission 56*, p. 1.

> While the long-term objective is obviously some advancement in medical science, it is possibly more likely that research into stem cells will not lead to the cures that we currently imagine. I would argue that there is likely to be two often undiscussed outcomes of this research that may well have far greater implications for human health and a much greater chance of being delivered. The first of these is increased biological understanding. Our fundamental understanding of how a cell is directed to become a specific type of cell remains vague. The fact that there is an ability to change the fate of a cell such that it takes on another form is only just becoming accepted in cell biology and this has come out of recent advances in stem cell science. How and when and why this happens during normal processes of response to injury or disease can start to be addressed by investigating processes such as how a nucleus is reprogrammed during somatic cell nuclear transfer. This will have very broad implications for our understanding of biology and medicine. It may also ultimately allow us to avoid the derivation of a blastocyst at all, which would be a position morally acceptable to all. The second outcome of stem cell research that is often overlooked is the development of such cells as screening tools. To have a supply of potentially patient-specific human cells to screen compounds in development for human use is very likely to revolutionise the pharmaceutical and biotechnology industries and lead to increased safety in new products.[15]

3.53 The Australian Stem Cell Centre also stated that SCNT would assist in greater understanding of genetic diseases:

> SCNT offers a unique approach to the study of genetic disorders in humans. The availability of such cell lines would enable the study of the cellular basis of disease susceptibility, an understanding of the evolution or trigger for the emergence of a genetic disease in the very early human and the testing of hypotheses concerning the involvement of specific genes for patients suffering from a number of serious diseases. [16]

Adult and embryonic stem cell complementarity

3.54 There was no witness or submission where support for embryonic stem cell research was expressed that was not also in favour of concurrent adult stem cell research. These supporters spoke of the importance of both arms of stem cell research.

3.55 Many opponents of SCNT have argued that there is little justification for crossing ethical barriers to develop embryonic stem cells when adult stem cells offer greater therapeutic promise. However this is not an argument against SCNT per se but rather objection to the general notion of embryonic stem cell research.

3.56 Conversely, submitters supportive of the Lockhart recommendations argued that research on embryonic and adult stem cells should be undertaken

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15 Professor Melissa Little, *Submission 167*, pp. 1-2.

16 Australian Stem Cell Centre, *Submission 63*, p. 5.

contemporaneously, thereby improving the overall understanding of stem cell differentiation and the potential applications of stem cell therapies, from both adult and embryonic stem cells.[17]

3.57 Senator Stott Despoja emphasised this issue in her tabling speech:

> We should be wary of advocating one type of research over the other. Each has its strengths and weaknesses – such as the pluripotency (ability to differentiate into any body cell) of embryonic stem cells versus the more limited multipotency (restricted to certain cell types) of adult stem cells – although new research is challenging this idea. Embryonic stem cells also have the unlimited capacity to keep dividing.
>
> Most scientists agree that both forms of research must be pursued in the quest for knowledge of diseases and conditions and potentially treatments; that neither area of research can single-handedly provide all treatments.[18]

3.58 The Monash Researchers noted the complementary nature of research in this field commenting that: 'Knowledge about one or other cell type will in all probability enhance the breadth and efficacy of the applications of the other'.[19] Similarly, Professor Tuch and Dr Sidhu stated: 'only by encouraging research with all forms of stem cells will benefits result to the community, both of a scientific and therapeutic nature'.[20]

3.59 The Federation of Australian Scientific and Technological Societies also suggested that it would be 'premature' to give preference to one aspect of stem cell research over another:

> ...the rapidity and intensity of the field means that results in both adult and embryonic stem cell research in Australia and internationally, have, in many cases, not been replicated or confirmed (and this is to be expected given the time frames involved). Thus it is premature to make definitive statements about the efficacy of different research or potential clinical techniques. Indeed, the scientific evidence suggests it is highly desirable that a variety of techniques both within and across adult and embryonic stem cell research and other tissue regeneration research programs are supported.[21]

3.60 Professor Barry Rolfe argued that comparisons between the two types are needed to progress adult stem cell therapy:

> The advances being made in research into adult stem cells should in no way preclude research using embryonic stem cells. I am studying the concept of

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17 See for example Kidney Health Australia, *Submission 56*, p. 2.

18 Senator Stott Despoja, *Tabling speech*, 14 September 2006, p.5.

19 The Monash Researchers, *Submission 73*, p. 1.

20 Tuch and Sidhu, *Submission 1*, p. 2.

21 Federation of Australian Scientific and Technological Societies, *Submission 72*, p. 2.

> stem cell reprogramming and it is clear from the research to date that we need as many comparisons as possible to work out how to go forward from a totipotent stem cell to a defined pluripotent stem cell type and how one might progress "backwards" from a pluripotent cell to a true totipotent cell. Resolution of this question could help to bypass all the future fuss over embryonic stem cells. We cannot possibly know what such research may lead to, so a comparison is very valuable.[22]

3.61 Professor Bob Williamson from the Australian Academy of Science and who works with adult stem cells explained the need to research both embryonic and adult stem cells:

> We believe that stem cell science represents a real opportunity for better clinical care. I actually work exclusively with adult stem cells, and perhaps I will make the point around that: why do I as an adult stem cell scientist believe that somatic cell nuclear transfer and embryonic stem cell research is important? Embryonic stem cells have two very important properties that are positive. One is that they can differentiate; they can give any cell type in the body. Adult stem cells cannot transdifferentiate in general and, as you get older, they become less and less likely to transdifferentiate. So, although it is possible to get liver cells from an adult to form more liver cells, and bone marrow cells to form bone marrow cells, we cannot get those cells to form heart muscle, neurones and so on. Only embryonic stem cells can do that.
>
> Only embryonic stem cells have the capacity to grow and grow and grow indefinitely—their second important property. Adult stem cells stop growing after 15, 20 or 25 generations. Because we need to understand these properties, we need to use research in ES cells to teach us how to use adult stem cells. Adult stem cells have two great advantages: one is that they are safe and the second is that they will not be immunologically rejected.
>
> My personal view as an adult stem cell scientist is that we need to encourage this kind of research.[23]

3.62 Professor Phil Waite from UNSW stated that it was too early to predict the potential of embryonic stem cells as 'research on human embryonic cells has been underway for just 8 years, compared with 50 years for adult cells' and emphasised the need to better understand both types of stem cells:

> ...it is clear that adult and embryonic stem cells are fundamentally different. We need to understand the basic science of these cells and their differences before we can determine which would be most useful for the many disorders we seek to treat...Clearly we should not shut the door on any one type before we know its potential.[24]

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22 Professor Barry Rolfe, *Submission 6*, p. 4.

23 *Committee Hansard*, 20 October 2006, p.39.

24 Professor Phil Waite, *Submission 93*, p. 1.

3.63 Stem Cell Sciences Ltd contended that the focus should be on appropriate regulation, rather than the merits of adult over embryonic stem cells:

> As a Company actively exploring the therapeutic potential of different stem cell types, including both adult and embryonic stem cells, we believe that it is not yet clear which stem cell type will be of most value in certain therapeutic indications and that both must be pursued in order to deliver the most effective and safest medical outcomes. The debate surrounding the Lockhart Review recommendations should not be about which type of stem cell is superior but about how to regulate valuable and necessary research to advance regenerative medicine in Australia.[25]

3.64 The Australian Stem Cell Centre submitted that allowing SCNT research could improve adult stem cell therapies such that many of the ethical dilemmas central to this debate could be overcome:

> SCNT should be viewed as an important tool for reprogramming an adult cell genome in an experimental environment and not as a procedure related to reproductive biology to achieve a live birth.
>
> Understanding the reprogramming of an adult cell nucleus to achieve a more flexible or plastic state would have far-reaching beneficial implications for biology and medicine. Ultimately, SCNT may deliver an understanding of those unidentified factors within an egg cell that can reprogram the behaviour of a mature cell, these findings might eventually obviate the need to use eggs or produce embryos at all, because it could be applied directly to the reprogramming of adult cells. In addition, understanding reprogramming would also increase our knowledge of adult tissue stem cell plasticity (the conversion of one type of tissue stem cell into cells of another tissue). This important area of SCNT is currently entirely closed to Australian researchers.[26]

What has changed since 2002

3.65 Opponents of the Lockhart recommendations claim that nothing has changed to justify relaxing of the current legislation. Some scientists who gave evidence supported this view for example Professor James Sherley and Emeritus Professor John Martin. However the overwhelming majority of scientists who provided evidence to the inquiry refuted this claim. They provided a significant number of peer reviewed journal articles clearly demonstrating that the claim is baseless. In addition opponents referred to the report commissioned by the government by MP consulting. However this document has attracted controversy over the narrow terms of reference given to the consulting firm. It has been claimed that the scope was so limited that the findings were predictably in favour of the premise that there was little change in 'the state of play':

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25 Stem Cell Sciences Ltd, *Submission 104*, p. 1.

26 Australian Stem Cell Centre, *Submission 63*, p. 5.

> I have read the MP Consulting document...I genuinely do not believe that the MP Consulting document has any credibility. I say that first because the MP Consulting document was prepared in private, without taking any evidence, without inviting any evidence, without allowing any rebuttal; whereas Lockhart took evidence in public debate.[27]
>
> I understand that the MP Consulting document had a much narrower range and brief and they were asked to assess the state of play. I was a little concerned that the state of play was almost to look at public announcements and commentary and not necessarily the scientific merit and justification.[28]
>
> Stem cell science is pushing up against the boundaries of the current legislation.[29]

3.66 Advocates of SCNT described the limitations of what can be achieved using stem cells derived from ART embryos, which usually do not have specific disease characteristics. Evidence was provided that there had been advances in embryonic stem cell research since the passage of the Acts, which give weight to the contention that the legislation was being overtaken by developments in the field.

3.67 The Victorian Government provided the Committee with a report titled 'Key Recent Advances in Human Embryonic Stem Cell Research: A Review of scientific literature commissioned by the Department of Innovation, Industry and Regional Development, Government of Victoria'. The Australian Academy of Science also referred to this review and provided a commentary prepared by Sir Gustav Nossal and Dr Graham Mitchell on technological developments over the past few years in the field of human stem cells in regenerative medicine. They concluded:

> In the opinion of these reviewers and in the current and appropriate cautious and regulated environment, a broad SCNT approach is required for stem-cell based regenerative medicine to achieve its undoubted promise. On the specific question of whether the field has actually progressed in a technological sense, we can respond unequivocally in the affirmative. Formidable challenges confronting the field have been addressed particularly around the generation of clinically-acceptable human ES cells and production of medically-relevant tissue cells from human ES cells (tested in animal systems). SCNT appears to be the best current approach to address the fundamental issue of rejection by the recipient of transplanted cells. Finally, very obvious progress has been made in the use of ES cells and their progeny in cell-based screening for new drugs, for toxicology assays, and for the identification of molecules involved in ES cell renewal and, conversely, differentiation into tissue cells.[30]

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27 Professor Williamson, Committee Hansard, 20 October 2006, p. 46.

28 Dr Munsie, Committee Hansard, 24 October 2006, p. 27.

29 Sir Gustav Nossal, *Submission 74*.

30 'Progress in Stem Cell R&D', GJV Nossal and GF Mitchell, 12 September 2006.

3.68 A Literature Review 'Human embryos, stem cells and cloning – developments in research and regulations since 2001' prepared for the Department of Health and Ageing in August 2005 noted that:

> Research on the growth and differentiation of stem cells for scientific investigations, development of cellular therapies and investigation of disease development has increased rapidly since 2001. Most work has focused on rodent, nonhuman primate and human embryonic and adult stem cells. The literature in this area is vast and we have only been able to include the most general reviews and summarise the main issues relating to embryonic and adult cell types.[31]

3.69 Professor Phil Waite, who is comparing embryonic stem cells, adult bone marrow stem cells and olfactory stem cells in spinal cord injury, listed the following recent advancements:

> ...research in the last few years has demonstrated that:
>
> - Human embryonic stem cells can be differentiated into myelin producing precursor cells and made in sufficient numbers and purity for human use.
> - Human embryonic stem cells can repair demyelinating lesions in mice.
> - Human embryonic stem cells can improve locomotor function in a rat model of spinal cord injury.
> - Adult stem cells migrated less well in the spinal cord and mature glial cells would not remyelinate.
> - Complications such as excessive growth of teratomas were never seen.[32]

3.70 Advocates of SCNT stressed that the benefits that may occur through SCNT were not available through excess ART embryos. According to Professor Little, having access to disease-specific embryonic stem cells is significant:

> ...the derivation of hES cell lines [by SCNT] will enable us to increase our understanding of normal development, abnormal development, nuclear activity and our ability to reprogram one cell type into another. This understanding will be of great importance to the development of new treatment techniques and the manipulation of cell type during disease. To be able to develop a human ES cell from a patient with a disease of development is likely to give us significant insight into what has gone wrong in embryonic patterning. Such understanding can never be gained by simply harvesting existing hES cells from an IVF blastocyst.[33]

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31 Human embryos, stem cells and cloning – developments in research and regulations since 2001: Literature Review, prepared for the Department of Health and Ageing by Biotext PL, August 2005, p.xvii.

32 Professor Phil Waite, *Submission 93*, p. 2.

33 Professor Melissa Little, *Submission 167*, p. 3.

3.71 Stem Cell Sciences Pty Ltd state in their submission that 'since 2002 there have been several major publications that demonstrate the advances in human embryonic stem cell research'.[34] These include:

1. Improvements in the quality of embryonic stem cell lines towards generation of cells that could be used for a clinical application;[35]
2. Numerous examples of differentiation and engraftment of cells derived from human and animal embryonic stem cells in animal models;[36]
3. Correction of genetic abnormalities in mouse embryonic stem cells;[37]
4. Value of embryonic stem cells in drug screening and toxicology;[38]
5. Demonstration that stem cells generated from SCNT share the same characteristics as those derived from a fertilised blastocyst in animal models;[39]

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34 *Submission 104*, Attachment, 'Advances in Human Embryonic stem cell research since 2002'.

35 Ludwig T et al (2006). Derivation of human embryonic stem cells in defined conditions. Nature Biotechnol. 24: 185 – 187; Liu Y et al (2006). A novel chemical-defined medium with bFGF and N2B27 supplements supports undifferentiated growth in human embryonic stem cells. Biochem. Biophys. Res. Comm. 346: 131 – 139; Ellerström et al (2006). Derivation of xeno-free human ES cell line. Stem Cells (published on-line June 1 2006).

36 Trounson (2006). The production and directed differentiation of human embryonic stem cells. Endocrine Rev 27: 208 – 219; Ben-Hur et al (2004). Transplantation of human embryonic stem cell-derived neural progenitors improves behavioural deficit in Parkinsonian rats. Stem Cells 22: 1246 – 1255; Takagi et al (2005). Dopaminergic neurons generated from monkey embryonic stem cells function in a Parkinson primate model. J Clin Invest 115: 102 – 109; Kehat et al (2004). Electromechanical integration of cardiomyocytes derived from human embryonic stem cells. Nature Biotech 22: 1282 – 1289; Faulkner and Keirstead (2005). Human embryonic stem cell-derived oligodendrocyte progenitors for the treatment of spinal cord injury. Transpl Immunol. 15: 131 – 142; Keirstead et al (2006). Human embryonic stem cell-derived oligodendrocyte progenitor cell transplants remyelinate and restore locomotion after spinal cord injury. J. Neurosci. 25 : 4694 – 4705; Fujikawa et al (2005). Teratoma formation leads to failure of treatment for type I diabetes using embryonic stem cell-derived insulin-producing cells. Am J Pathol 166: 1781 – 1791; Zheng et al (2006). Skeletal myogenesis by embryonic stem cells. Cell Res 16: 713 – 722.

37 Chang et al (2006). Correction of the sickle cell mutation in embryonic stem cells. Proc Natl Acad Sci USA 103: 1036 – 1040; Rideout et al (2002). Correction of a genetic defect by nuclear transplantation and combined cell and gene therapy. Cell 109: 17 - 27.

38 Gorba and Allsopp (2003). Pharmacological potential of embryonic stem cells. Pharmacol Res 47: 269 – 278; Davila et al (2004). Use and application of stem cells in toxicology. Toxicol Sci 79: 214 – 223; Gorba and Allsopp (2003). Pharmacological potential of embryonic stem cells. Pharmacol Res 47: 269 – 278; Kulkarni and Khanna (2006). Functional hepatocyte-like cells derived from mouse embryonic stem cells: a novel in vitro hepatotoxicity model for drug screening. Toxicology In Vitro 20: 1014 – 1022.

39 Brambrink et al (2006). ES cells derived from cloned and fertilized blastocysts are transcriptionally and functionally indistinguishable. Proc. Natl. Acad. Sci. USA 103: 933 – 938; Wakayama et al (2006). Equivalency of nuclear transfer-derived embryonic stem cells to those derived from fertilized mouse blastocysts. Stem Cells 24: 2023 – 2033.

6. Basic proof-of-concept that stem cells generated by SCNT could partially restore function in animal models;[40] and

7. Value of SCNT to investigate epigenetic factors including cancer characteristics in animal models.[41]

3.72 Monash Immunology submitted that recent advances in stem cell research provide unparalleled opportunities to explore cell and tissue development, to enable tissue repair, and to lead to new treatments and drug discoveries that could limit or ameliorate degenerative diseases. Research involving both adult and embryonic stem cells should be pursued with rigor and intensity to determine the efficacy and safety of new medical treatments based on cell therapy and associated discoveries.[42]

3.73 They cited many of the same publications that Stem Cell Sciences Pty Ltd did as the key publications on transplantation of human/primate embryonic stem cells into preclinical animal models of human disease and injury and also:

- Banin E, et al. 2006. Retinal incorporation and differentiation of neural precursors derived from human embryonic stem cells. Stem Cells 24(2):246-257; and
- Lund RD, et al. 2006. Human embryonic stem cell-derived cells rescue visual function in dystrophic RCS rats. Cloning and Stem Cells 8(3): 189-199, 2006

3.74 At the Melbourne Hearing they tabled another highly relevant article that had been published since the hearing commenced which highlighted the speed at which this research is moving forward:

- D'Amour et al, Production of pancreatic hormone-expressing endocrine cells from human embryonic stem cells. Nat Biotechnol. 2006 Oct 19; [Epub ahead of print] Jurisdictional implications for Australian research.

40 Rideout et al (2002). Correction of a genetic defect by nuclear transplantation and combined cell and gene therapy. Cell 109: 17 – 27; Barberi et al (2003). Neural subtype specification of fertilization and nuclear transfer embryonic stem cells and application in parkinsonian mice. Nature Biotech 21: 1200 – 1207.

41 Blelloch et al (2004). Nuclear cloning of embryonal carcinoma cells. Proc Natl Acad Sci USA 39: 13985 – 13990; Hochedlinger et al (2004). Reprogramming of a melanoma genome by nuclear transplantation. Genes and Dev 18: 1875 – 1885.

42 *Submission 73*.

Jurisdictional discrepancies

3.75 Somatic cell nuclear transfer is currently legal in the following countries: Belgium, China, Japan, Mexico, New Zealand, South Korea, Singapore, South Africa, Sweden, Thailand, United Kingdom and United States of America.[43]

3.76 The committee was warned of the implications of legislative differences on SCNT between Australia and these countries. First, Australian scientists working in the area of embryonic stem cell research would leave Australia, usually for the United States, to pursue their research. Secondly, a more restrictive regime in Australia would adversely affect collaborative projects being undertaken with overseas institutions operating in jurisdictions where the practice is legal.

3.77 The Coalition for the Advancement of Medical Research in Australia (CAMRA) argued that prohibiting SCNT was encouraging leading stem cell researchers to move overseas:

> Australia has been a leader in stem cell research. Earlier this year we lost our top human embryonic stem cell scientist, A/Professor Martin Pera, to California. Last month we lost one of our top adult stem cell scientists, A/Professor Paul Simmons, to Texas. This will continue.[44]

3.78 The Australian Stem Cell Centre confirmed this trend:

> Without the ability to perform SCNT, elite researchers remaining in Australia will always be behind the lead of the top researchers in the United States, United Kingdom and other countries where SCNT is lawful. Inevitably, without the ability to perform SCNT and collaborate on SCNT projects, the strategy and outlook for the Centre will also be hindered. A number of key senior scientists have this year left Australia for the United States where SCNT is permitted and considerable funds are available. The length of time the legislative review has taken to date and the uncertainty in the outcome is a significant deterrent to the Centre being able to attract leading scientists, from this field, to come to Australia. It is also a significant risk to the stability of the Australian scientists working in this field at present.[45]

3.79 Legislative differences between different jurisdictions where stem cell research is carried out also have implications for collaborative research. The

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43 There is no federal legislation covering this area of research in the U.S., though the federal government does not provide funding for research involving the destruction of embryos. Some states have legislated to allow SCNT. See Biotext Pty Ltd, *Human embryos, stem cells and cloning – developments in research and regulations since 2001: Literature review*, August 2005, http://www.lockhartreview.com.au/_files/Literature%20Review%20(Biotext).pdf, (accessed 17 October 2006).

44 CAMRA, *Submission 21*, p. 2. Also *Committee Hansard* 20.10.06, p.45 (Australian Academy of Science).

45 Australian Stem Cell Centre, *Submission 63*, p. 5.

Australian Stem Cell Centre indicated that unless the Lockhart recommendations were implemented, it would be impeded in:

> ...establish[ing] important scientific collaborations with highly regarded research groups in jurisdictions that allow activities that are not currently allowed in Australia under Australian law (particularly key groups in the UK and the US).[46]

Reflecting plurality in legislation

3.80 Another argument in support of the Lockhart Review and the bills was that a vociferous minority should not be able to force the prohibition of activities supported by a significant proportion of the community. This view holds that in a liberal society with a wide diversity of views, the moral and ethical opinions of one section of the community should not be imposed on another.

3.81 The Lockhart Committee contended that the arguments used to oppose embryo research and SCNT did not justify its legal prohibition:

> The Committee was acutely aware of the special moral status attached to embryos and the concerns that many groups, particularly Christian churches, had regarding their destruction. But the Committee also recognised that not all communities in Australia attach the same significance to the embryo, and that other concerns, such as the need to care for the sick and vulnerable and respect the wishes of individuals, are also morally important.[47]

3.82 Dr Paul Brock, who has motor neurone disease, agreed that in a pluralist society no one view should dictate ethical standards:

> In any multi-cultural, multi-faithed and non-faithed secular democratic society such as ours, the formulation of principles of ethical standards cannot be based exclusively upon any or only one religious creed, or denomination, or sub-denominations.[48]

Evidence supporting other specific Lockhart Recommendations

Amending the definition of an embryo

3.83 Presently, the Acts define a ***human embryo*** as 'a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.'[49] The definition proposed in both the Patterson Bill and Stott Despoja and Webber exposure draft bill is as follows:

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46 Australian Stem Cell Centre, *Submission 63*, p. 2.

47 Lockhart Review Committee, *Submission 20*, p. 3.

48 Dr Paul Brock, *Submission 2*, p. 2. Dr Brock's PhD is in English.

49 Section 7 of the RIHE Act; s. 8 of the PHC Act.

> ***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.

3.84 The Lockhart Committee advised Senators Patterson and Stott Despoja that it was their intention that this definition be consistent with the NHMRC discussion paper titled 'Human Embryo – A Biological Definition',[50] which was being prepared at the same time as the Lockhart Report was being finalised for publication. This is reflected in both bills.

3.85 The Lockhart Committee noted that while the 2002 legislation enabled scientists to continue ART research, the choice of definition for a 'human embryo' in the Acts:

> Has had the apparently unintended consequence of impeding valuable research and clinical practice in ART clinics. In particular, the legislation has stopped research on culture and maturation of immature eggs (called 'in vitro maturation of oocytes', or IVM), storage of frozen eggs, various aspects of IVF, and gamete (egg and sperm) development. Research on maturation of eggs has been further prevented by the prohibition on oocyte activation (also called 'parthenogenesis'). The ability to produce mature eggs in culture provides a way of reducing the treatment of woman with follicle stimulating hormone, which would benefit many women undergoing ART. It may also allow production of mature eggs from frozen ovarian tissue, thus allowing women who have undergone chemotherapy or other treatments that reduce ovarian function to have their own genetic children.[51]

3.86 Any attempt to define 'human embryo' will always be contentious. In their report the Lockhart Committee clearly explain their reasons for recommending change to the existing definition in the Acts. Professor Wendy Rogers emphasised the importance of achieving legislative clarity by referring to an observable marker:

> As fertilisation is a process which occurs over time, rather than a discrete event, any definition relating to embryos created by fertilisation of an egg by a sperm will be somewhat arbitrary in the sense that it selects one moment in the process as the marker to define when a human embryo begins to exist. The NHMRC definition uses a biologically observable

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50 The second part of the definition, part (b), proposed in the Lockhart Review refers to development up to fourteen days, rather than the primitive streak.

51 *Legislation Revie*w, Executive Summary, pp.xiv-xv.

> feature (first mitotic division) to anchor their definition for an embryo created for reproductive purposes, thereby clarifying what is and is not a human embryo in ways that can be verified, as opposed to using syngamy which is not as easily observable.[52]

3.87 With regard to the definition's treatment of embryos created by means other than fertilisation of an egg by a sperm, she commented:

> For entities created in other ways, the potential to develop to the point of appearance of the primitive streak indicates that a human being might ensue from the process, whilst excluding other entities that have no potential to develop into a human being. Recognition of potential is one of reasons often cited for giving moral regard to embryos, so that recognising this in the definition is consistent with widespread moral views.[53]

3.88 Professor Susan Dodds suggested that the legal definition of an embryo should seek to provide legal clarity, rather than resolve ethical differences. This, she stated, was achieved by the proposed definition:

> The ethical differences that exist in the community regarding the moral status of embryos cannot be resolved by legal artifice, and laws that depend on a particular ethical perspective for their interpretation are likely to be found to be unjustified. For that reason one of the most important features of both Bills is that they offer a noncircular definition of the human embryo that uses objective, observable, scientific features of the development of fertilised oocytes into embryos to establish the scope of the legal provisions... Researchers ought to be confident (at least so long as the science supports first mitotic division and development of the primitive streak as clear identifiers) that they can predict when and whether the laws apply to their research.[54]

3.89 Support for the proposed definition was provided by the Fertility Society of Australia which recognised the scientific justification for the proposed new definition:

> The inclusion of the revised definition of an embryo is useful in acknowledging that fertilisation is a dynamic process and cannot be defined until a physiological marker is observed.[55]

Obtaining fresh embryos for research

3.90 Lockhart Recommendations 20-22 and Schedule 2, Items 4 and 24 of the Patterson Bill seek to enable prior consent to be granted for the use of fresh embryos, regarded as 'unsuitable for implantation', for research. This unsuitability would be determined by being either diagnosed with a genetic abnormality prior to

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52 Professor Wendy Rogers, *Submission 67*, p. 1.

53 Professor Wendy Rogers, *Submission 67*, p. 1.

54 Professor Susan Dodds, *Submission 84*, p. 2.

55 Fertility Society of Australia, *Submission 40*, p. 1.

implantation, or by being deemed otherwise unsuitable against objective criteria. Support for allowing these categories of embryos to be obtained in a fresh state for research purposes focused mainly on the benefits of studying embryonic stem cells carrying known genetic deficiencies.

3.91 The Australian Stem Cell Centre wrote of the potential advances possible should this activity be permitted:

> Currently, scientists are unable to obtain IVF created embryos (created for the purpose of reproduction) affected by an inherited genetic disease, deemed unsuitable for implantation. ... The potential benefits for the study of disease by developing disease-affected stem cell lines, with appropriate consent from the donors, could have many uses from understanding the genetic triggers and processes during the onset of disease to using the cells for the development of new drugs and treatments for such diseases.

3.92 The Monash Researchers stressed the importance of creating stem cell lines with known genetic abnormalities:

> ...new embryonic stem cell lines need to be established from embryos with diagnosed genetic abnormality and inheritable genetic disease (eg. Huntington's Disease, Cystic Fibrosis, Thalassaemia, Muscular Dystrophy), donated by couples having IVF and preimplantation genetic diagnosis of such serious genetic disease. Collectively these will generate research tools that will be a new and unique resource for gaining improved understanding of these serious disease conditions and for development of potential new treatment strategies.[56]

3.93 Professor Wendy Rogers, a specialist in medical ethics and health law from Flinders University, expressed support for Lockhart's recommendation on unsuitable embryos identified through pre-implantation genetic diagnosis (PIGD). She wrote:

> I believe that couples can give informed consent to research with these embryos without the 2 week cooling off period on the grounds that they have spent considerable time and effort in reaching the point of PIGD, and are aware of the possibility of some of the embryos being unsuitable for implantation. In these circumstances, it is not wrong to allow discussion of the fate of the embryos that will not be used for attempting pregnancy prior to the results of tests which will identify any such embryos. Allowing donation of unsuitable embryos for research allows the donating couple to retrieve some good from the process, and also allows them to express agency in ways that we usually recognise in Australia. Other couples with ART embryos that are not required for reproductive purposes have the opportunity to donate their embryos for research if they so wish; making this change in the legislation will accord couples with PIGD-identified unsuitable embryos the same options.[57]

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56 The Monash Researchers, *Submission 73*, pp. 1-2.

57 Professor Wendy Rogers, *Submission 67*, p. 3.

3.94 Her support for the use of fresh ART embryos was, however, limited to those identified through PIGD. Professor Rogers submitted that identifying other embryos as 'unsuitable', by objective criteria, was more problematic:

> The process of judging the quality of embryos when choosing which to implant is a very inexact science, and any embryos judged as "less vigorous" on clinical grounds alone should not be considered for use in research when fresh if there is any chance that they might be considered for implantation at a later stage.[58]

3.95 The Authors of this Chapter noted that recommendation 32 calls for the NHMRC to develop guidelines for egg donation and considers that Professor Rogers' comments should be referred to the NHMRC to be considered when developing the guidelines.

Allowing the international exchange of genetic material

3.96 Lockhart Recommendation 41, Schedule 4 of the Patterson Bill and division 2, clause 19 of the Stott Despoja and Webber exposure draft bill seek to enable the import or export of a patient's reproductive material, including ART embryos, subject to quarantine regulation. ACCESS supported this measure to remove 'previously burdensome requirements for people needing to import or export embryos to continue their ART treatment in another country'.[59]

3.97 Also, Recommendation 42 of the Lockhart Review, Clause 23C of the Patterson Bill, and division 2, clause 18 of the Stott Despoja and Webber exposure draft bill would enable researchers to access embryonic stem cell lines from overseas provided they were derived in a manner consistent with Australian legislative requirements. The Monash Researchers submitted that the international exchange of stem cell resources should indeed be facilitated:

> It is a global research priority to derive pluripotent stem cells with a broad range of diseases for scientific study. Collaborations for this endeavour will minimize the duplication of effort and resources needed to derive these important cell lines.[60]

3.98 The Australian Stem Cell Centre also supported a relaxation of the regulations on exchanging such material. It suggested that this would improve collaboration and enable donated eggs to be used more efficiently:

> The Centre supports an amendment to the *Customs (Prohibited Imports) Regulations 1956* to allow Australian researchers access to stem cells and stem cell lines derived from SCNT embryos developed overseas. If SCNT becomes lawful in Australia as a result of this inquiry, co-extensive

58 Professor Wendy Rogers, *Submission 67*, p. 3.

59 ACCESS, *Submission 176*, p. 1.

60 The Monash Researchers, *Submission 73*, p. 8.

> amendments must be made to allow importation of SCNT-derived cell lines in order for researchers in Australia to effectively use this technology and collaborate with other international scientific groups. This would also ensure no duplication of unnecessary stem cell lines, effectively minimising the number of nuclear transfer embryos created and the number of human eggs used to create those cell lines.[61]

National stem cell bank

3.99 The legislation does not expressly deal with the question of establishing a national stem cell bank, as recommended by the Lockhart Review. Senator Stott Despoja commented:

> In this draft bill, I have not legislated for a national stem cell bank. This is partly because a stem cell bank does not necessarily require legislation. In fact, the UK has a national stem cell bank which does not have a legislative basis. There are options for such a framework including the possibility of establishing a stem cell bank along similar lines to that of blood bank.
>
> This bill requires the Attorney-General's Department and the Department of Health and Ageing to examine in some detail the issues surrounding a stem cell bank. The terms of reference are more detailed than those under which the Lockhart Review was operating.[62]

3.100 In the Patterson Bill the proposed clause of 47b of the RIHE Act requires the Minister to report to Parliament (within 6 months) regarding the establishment of a National Stem Cell Centre and a national register of donated excess ART embryos.

3.101 A number of submitters commented on this issue. Professor Tuch and Dr Sidhu suggested that the new stem cell bank should operate across several cities, using existing facilities, and perform the following functions:

- Storing stem cell lines;
- Distributing stem cell lines; and
- Acting as an official site to deposit cell lines.

3.102 They further suggested that a central steering committee could be established to maintain a registry of stem cell lines and make other decisions, such as on storage and IP issues.[63]

3.103 The Australian Stem Cell Centre suggested that it, in conjunction with the Major National Research Facility, is 'the logical organisation to oversee a national stem cell bank as it has an existing cell storage facility and trained staff'. Its submission outlined the following benefits of such a facility:

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61 Australian Stem Cell Centre, *Submission 63*, p. 6.

62 Senator Stott Despoja, tabling speech, 14 September 2006, p.7.

63 Tuch and Sidhu, *Submission 1*, p. 2.

> The formal implementation of an Australian stem cell bank would enhance Australia's reputation as a leading producer of high quality cell lines. A national stem cell bank would have many positive features including:
>
> 1. ensuring regulatory and ethical compliance of all cell lines deposited;
> 2. standardising the quality of all cell lines;
> 3. providing consistent complementary information and service advice with all cell lines;
> 4. conserving embryos; the Bank would reduce duplication of research to produce specific cell lines;
> 5. being a national (and eventually international) resource by requiring compulsory deposition of all Australian derived cell lines;
> 6. providing an independent assessment of the quality and standard of cell lines;
> 7. being a database of historical records of production and distribution of all cell lines;
> 8. monitoring the import and export of cell lines; and
> 9. providing a central body for the independent reporting requirement to licensing bodies.[64]

3.104 Professor Wendy Rogers insisted that stem cell resources remain in public hands:

> ...there is a serious ethical issue of equity that arises when tissues donated by Australians for the benefit of the Australian community (including both researchers and patients) are then used to develop commercial products for private enterprise. The products and profits from the research involving SCNT and the development of stem cell lines including a stem cell bank (should they proceed in Australia) should remain in public control, and equally available within the public healthcare system. The current climate of competition between the states for commercial biotechnology investment raises concerns that there will not be public ownership of many resources donated by Australian women for stem cell research. It is appropriate that any legislation recognises the interest of those groups who provide the basic resources for the development of potential therapeutic treatments in having access to those treatments.[65]

64 Australian Stem Cell Centre, *Submission 63*, p. 7.

65 Professor Wendy Rogers, *Submission 67*, p. 3.

Community Standards

3.105 Some of those opposed to the recommendations suggested the Lockhart Committee had not adequately taken into account community standards in making their recommendations. The majority of the Senate Committee are of the opinion that this is not a valid criticism of them. The Lockhart Committee undertook extensive consultation involving 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.

3.106 Witnesses referred to the number of surveys relating to community opinions on this research and questioned the independence of some, noting that the use of particular wording, without appropriate context or background information, could provide misleading results. Ms Joanna Knott from the Coalition for the Advancement of Medical Research in Australia questioned the independence of these surveys:

> I am aware of quite a lot of research that has come out, but I think that the Roy Morgan and ACNielsen research is truly independent. I am not convinced that some of the other research is as convincing, because it is not necessarily as independent.[66]

3.107 The majority of independent polls found consistently strong support for research. Professor John McNeil also considered that the Morgan and ACNielsen polls were more indicative of informed community opinion:

> Of the four Australian studies that have been published, two of them—the ACNielsen poll and the Morgan poll—have been conducted to what I would regard as a good scientific standard through random telephone dialling. They have come to quite remarkably similar conclusions.
>
> The key issue is that the percentage of individuals who have expressed opposition to the concept of stem cell research is roughly 11, 12 or 13 per cent—males and females—and the number that support research in these studies has been in the majority: over 50 and usually 60 per cent. Quite a few have not been able to offer an opinion.
>
> There have been somewhat contrary results provided by the Sexton Marketing study. But it is important to point out that it is recognised that in an area like this, where there is a large degree of community ignorance, the way a question is asked can have an enormous impact on the response that is given. For example, a simple bald question like, 'Do you support or oppose the cloning of human embryos as a source of stem cells?' would be regarded by me as a rather emotive way of putting a question. And it is not

66 CAMRA, *Committee Hansard*, 23 October 2006, p. 33.

> surprising that without a proper lead-in the results were somewhat different. The response to that poll suggested that 51 per cent opposed cloning.
>
> My attitude here is that without an introductory program that explains the context in which the word 'cloning' was used it is very unlikely that the majority of respondents actually understood what they were being asked about. Therefore, I would pay less attention to this result than I would to the ACNielsen and Morgan studies.[67]

Response to specific comments raised in opposition

3.108 This final section provides a response to some specific issues raised by those in opposition to the recommendations and bills that are discussed in the second part of this chapter.

Embryonic Stem cells and cancer risk

3.109 Concern was raised by some opponents of the bill that embryonic stem cells may, if injected into people, sometimes cause cancer, in particular teratoma. It is the opinion of the majority of the Committee that this concern, while important, does not require legislative change. These are the sorts of risks taken into consideration before any new clinical trial involving humans is permitted to proceed in this country. Also this issue applies to existing legal research and is adequately covered by standard risk benefit analysis for medical research and the current protocols under NHRMC and Therapeutic Goods Administration.

Slippery slope argument and future reviews

3.110 Opponents of the bills referred to the 'slippery slope' argument expressing scepticism that a line would be drawn at SCNT. The Lockhart Committee rejected the slippery slope view:

> Allowing SCNT under licence will not inevitably lead to reproductive cloning. The Australian community almost unanimously opposes it and it should remain prohibited. However, the best safeguard against reproductive cloning is restricting the degree to which embryos can be matured and prohibiting them being implanted [sic] into women. It is reassuring that there have been no instances of non-compliance with legislative and regulatory requirements in Australia (where embryo research is allowed under licence) or in the UK (where SCNT is allowed).[68]

3.111 Dr Paul Brock also rejected the proposition:

> ...the 'slippery slope' assertions of those claiming that embryonic stem cell research would lead to human reproductive cloning are as hollow as they are improperly alarmist. It's like saying that fertilizer production and

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67 Professor McNeil, *Committee Hansard,* 24 October 2006, p. 24

68 Lockhart Review Committee, *Submission 20*, p. 3.

> nuclear medical research should be banned because terrorists can use these processes and products to make bombs.[69]

3.112 Related to this argument were concerns that a future review of the Acts would create pressure for further concessions. The Monash researchers supported continuing legislative review to ensure that research developments were recognised:

> Since this field of research is developing rapidly, the Acts should remain under review from time to time (eg 3 yearly) to enable new unforeseen directions of research endeavour and benefits to be pursued for treatment of otherwise intractable pathologies and injuries. It is not always possible to predict the outcomes and direction of research and important new developments which could be severely hampered unintentionally by inflexible legislation.

3.113 Professor Susan Dodds also supported ongoing review of the Acts, but suggested the process needs refinement when assessing 'community standards':

> It is important that RIHE and PHC Acts and any amendments to them should be regularly reviewed in light of scientific developments, legal developments and evolving ethical attitudes (as is seen in the changes in attitudes towards IVF over the past 25 years), nonetheless any group responsible for such a review will need a tool or baseline or set of criteria to be able to assess "community standards", especially as it is accepted that the underlying ethical differences in attitude towards human embryos at various stages of development will very likely continue to exist.[70]
>
> The recommendations of the Review reflect that temporally compressed process and the critical reflection of the Review Committee on the expert advice it received, while clearly acknowledging that there does not exist a single set of community standards obtaining in these areas.[71]

3.114 Dr Megan Munsie from Stem Cell Sciences Ltd rejected the assertion that proponents of SCNT would seek to incrementally push the legislative boundaries each time a review occurs and explained that their position had not changed since the original legislation was passed:

> I think we are being consistent: three years ago we were asking for the same thing. Three years ago we were asking to do somatic cell nuclear transfer, and we have the bills we currently have. We have not changed our position.[72]

3.115 The Lockhart Committee submitted that they had sought middle ground in a highly polarised debate:

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69 Dr Paul Brock, *Submission 2*, p. 3.

70 Professor Susan Dodds, *Submission 84*, p. 3.

71 Professor Susan Dodds, *Submission 84*, p. 1.

72 Stem Cell Sciences Ltd, *Committee Hansard*, 24 October 2006, p. 23.

> The Committee found from its community consultations, conducted as part of the Review, that the views on this type of research are widely polarised and that they cannot always be reconciled. Our report and its recommendations proposed that a middle ground which reflected the values and priorities of the community would be supported by the majority of Australians, while recognising that some would consider that the recommendations went too far, and others would argue that they did not go far enough.[73]

Availability of ova

3.116 The Majority of the Committee was impressed by the high value placed on human ova by those working in the area of stem cell and ART research. They referred to the ova as 'precious' and conveyed to the committee a sense of responsibility in dealing with limited resource and the sensitivities surrounding their donation. They also indicated their commitment to develop techniques that could ultimately minimise the number required for research.

3.117 It should not be forgotten that any research must pass the vigorous scrutiny of an institute ethics committee and NHMRC licensing requirements and monitoring before it can take place. The Bill recommends guidelines for egg donation. The Majority of the Committee are comfortable, without minimising the significance of human ova, that the bill together with existing protocols for informed consent regarding medical procedures puts this type of donation on a par with any other human tissue donation.

3.118 There have been some exaggerated claims that thousands of eggs will be required to develop and provide treatment for disease using SCNT research. However these inflated figures were put in perspective by statements like those of Professor Marilyn Renfree from the Australian Academy of Science where she stated at the Canberra Hearing that it is hard to speculate on how many eggs would be needed to research Parkinson's disease, Alzheimer's disease and Motor Neurone disease because no-one has yet done it, particularly due to restrictions in Australia. However, Professor Renfree does state :

> ...that we can understand stem cell biology and cellular biology by using the surplus eggs from assisted reproductive technology treatments, because once you have a few of those you can make a stem cell bank. They are banks of stem cells that can, as Professor Williams said, be propagated indefinitely, so you can multiply them into as many as you wish and distribute them to various laboratories. Relatively few would be required.[74]

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73 Lockhart Committee, *Submission 20*, p. 2.

74 Senate Community Affairs Committee Inquiry into Legislative Responses to Recommendations of the Lockhart Review, Friday 20 October 2006, p. 41.

3.119 Claims were made that the demand for human eggs for use in SCNT research could lead to unethical sourcing and possible commodification of human eggs. Senator Stott Despoja refuted this idea in her tabling speech:

> Some opponents of SCNT have warned that legalisation of this technique may lead to the commodification of human eggs. It is important to note that this bill maintains the current prohibition of the sale of human eggs, sperm and embryos and clarifies "reasonable expenses" in relation to permitting reimbursement of expenses for the supply of human eggs, sperm and embryos.[75]

3.120 The Majority of the Committee notes that this is dealt with in a compatible way in the Patterson bill and is comfortable that this bill continues the strict prohibition of sale of eggs.

3.121 In his submission Emeritus Professor John Martin expresses concern that by permitting the use of animal eggs to be used in SCNT research as a means to conserve human eggs could lead to animal human hybrid clones being implanted in an animal.[76] This is absolutely not the case. He cites what he alleges as a deficiency in the bill with regard to the prohibition of implantation of this type of embryo into an animal or human body. With respect, Professor Martin has misinterpreted the intent and meaning of this bill. Notwithstanding the preposterous notion that any proposal for research of this nature would get approval from an institute ethics committee or be consistent with the stringent guidelines and protocols of the NHMRC, the bill clearly prohibits implantation of hybrid embryos into the body of human or animals.

3.122 The definition of a human embryo is defined in the bill under Schedule 1. Clause 3b includes:

> *any other process that initiates organised development of a biological entity of a human nuclear genome or altered human genome that has the potential to develop up to or beyond the stage at which the primitive streak appears.*

3.123 And if the Bill is passed the definition of a human embryo clone will remain consistent with the PHC Act in part 1 section 8 Definitions Clause (1)(2) where it states that:

> *For the purposes of establishing that a human embryo clone is a genetic copy of a living or dead human: (a) it is sufficient to establish that the set of genes in the nuclei of the cells of the living or dead human has been copied; and (b) it is not necessary to establish that the copy is an identical genetic copy.*

3.124 And so it follows that Part 2 division 1, 9 of the Bill applies to hybrid embryos where it is clearly stated that it is an offence to place *'a human embryo clone*

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75 Senator Stott Despoja, Tabling speech, 14 September 2006, p.4.

76 Submission 35, section 3(ii).

in the human body or body of an animal'. Such activity would attract a maximum 15 years in prison.

3.125 The majority of the Committee hopes that Emeritus Professor Martin is comfortable with this explanation as it is certainly the intent of the Committee that no such embryo clone should be placed in the body of a human or animal.

3.126 Some opponents of the bill have cited Dr Peacock, Chief Scientist of Australia as calling for the continued ban on using animal eggs in SCNT research. Dr Peacock made the following statement in a stem cell briefing session on 13 September 2006:

> In the Lockhart Review it was suggested that animal eggs could be used for some of the research so that fewer human eggs would be required. Many scientists think that using a nucleus and egg cell from different species complicates the research. Most scientists regard this particular recommendation to be of little importance.

3.127 Dr Peacock's statement is not about banning but about safety which is adequately covered by research and clinical protocols overseen by the NHMRC.

Conclusion

3.128 Australia has always enjoyed a leading role in biotechnology. We have been at the forefront of in vitro fertilization since the first break throughs in the 1970's. Australian researchers were amongst the first to isolate human embryonic stem cells in the late 1990s and the first to publish proof-of-principle of somatic cell nuclear transfer (SCNT) in the mouse in 2000.

3.129 The 2002 legislation enacted the three year moratorium on SCNT research as recommended by the 2001 report of the House of Representatives Standing Committee on Legal and Constitutional Affairs (Human Cloning: scientific ethical and regulatory aspects of human cloning and stem cell research) by prescribing the legislative review which has come to be known as the Lockhart review. It is the opinion of the majority of this committee that the Lockhart Committee discharged their duties with sensitivity and honesty as they carefully considered the risks and benefits to the Australian community as a whole. They consulted appropriately and were thoughtful and fair in their recommendation. They clearly explained every decision they made in language understandable to all.

3.130 Kevin Andrews who chaired the 2001 committee concluded the foreword of that report stating:

> These are not matters to be decided behind closed doors by scientists or lawyers, however expert and sincere, without widespread community consultation. Nor are they matters that can be resolved by doing nothing. As a society we are confronted with profound issues that require ongoing attention and discussion.

3.131 The new legislation, if enacted will require that a similar review be undertaken in a further three years in order to maintain appropriate public and parliamentary scrutiny of this very important and sensitive research area.

3.132 It is the opinion of the majority of this committee that the overwhelming weight of evidence presented before us must lead to the acceptance of the recommendations of the Lockhart Committee.

Senator the Hon Kay Patterson
LP, Victoria

Senator Natasha Stott Despoja
AD, South Australia

Senator Ruth Webber
ALP, Western Australia

Senator Claire Moore
ALP, Queensland

Senator Carol Brown
ALP, Tasmania

Senator Kerry Nettle
AG, New South Wales

Senator Judith Adams
LP, Western Australia

Senator Jeannie Ferris
LP, South Australia

CHAPTER 4

THE CASE AGAINST

Arguments opposed

Summary

4.1 The arguments presented in submissions and in oral evidence to the Committee against the Lockhart Review's recommendations, and the Bills that seek to implement them, are summarised below:

- The lack of scientific evidence, including lack of `proof of concept' and lack of any clinical trials, regarding the potential benefits of human embryonic stem cell research.
- The dangers (such as cancer formation) inherent in the research and clinical application of human embryonic stem cells.
- The work of Korean researchers (Professor Hwang) that promoted cloning, relied upon by the Lockhart Review, exposed as fraudulent.
- The significant number of clinical trials already underway around the world in relation to adult stem cells.
- The small number of licences (9) granted by the Licensing Committee since the establishment of the current regulatory regime, and the even smaller number of licences granted for research into human disease. The majority of licences issued (5) relate to artificial reproductive technology research. If human embryonic stem cells are so efficacious and safe, why so few licences, and why even fewer specifically for research into disease? The NHMRC has confirmed that only 1 licence, issued to IVF Australia, has been issued that aims at treating a specific condition.
- The ethical boundary, long-recognised in medical research codes, that would be crossed in legislating to allow **the creation of cloned human life exclusively for the purpose of it being destroyed** in the pursuit of knowledge.
- The health risks to women in egg harvesting, as well as the risk of exploitation of women to gain access to more human eggs.
- The conclusion of the independent *mpconsulting report*, prepared for the Department of Prime Minister and Cabinet and released by the Prime Minister on 31st August 2006, which found: 'On each of these issues [the definition of human embryo; the creation and use of embryos for ART research; and the creation of embryos for stem cell research] … there has not been any significant change in the state of play since 2002'.

- The risk that, just as those in the current debate have changed their mind from opposing therapeutic cloning in 2002 to promoting it in 2006, the current ban against reproductive cloning could, equally in a few short years, be lifted because sections of the scientific community, using the same arguments advanced today, argue that it would facilitate the pursuit and accumulation of knowledge.
- The complexity of issues, the speed of examination, and the highly contested case (medically and ethically) that promotes change, is not an adequate foundation to alter the current legislative framework.

Insufficient scientific merit of SCNT

4.2 Many participants in this inquiry said there needed to be overwhelming evidence of the benefits of creating cloned embryos for embryonic stem cell research to justify changing the current legislative regime. They argued that the onus was on its proponents to prove the case for allowing SCNT to a standard that acknowledges the moral and ethical questions the practice raises. It was asserted that this had not been achieved for the following reasons:

- New breakthroughs had not been demonstrated to warrant a change to the position adopted by legislators in 2002;
- There were inherent limitations of and dangers in the potential application of embryonic stem cell technology;
- Adult stem cells continue to provide ethical and scientific advances; and
- The number of human eggs required for SCNT would, in the absence of unethical practices, and in the risks to women, make the technology impractical.

Embryonic stem cell research has not justified allowing SCNT

4.3 It was argued that the scientific benefits advocated by supporters of SCNT were unproved and unlikely, and do not justify crossing the ethical boundary previously established by the parliament when the PHC Act was passed in 2002.

4.4 Professor John Martin of Melbourne University submitted that:

> Any move towards the deliberate manufacture of human embryos for research purposes constitutes a major elevation in the ethical barrier, and the standard of proof required for a positive outcome of that research becomes all the higher.[1]

1 Professor Martin, *Submission 35*, p. 1.

Professor Martin quoted the Lockhart Report itself, which states that '…at this stage, ES cell research has not reached the stage needed to start clinical trials (ie proof of principle of a safe and efficacious treatment in animal models)'.[2]

4.5 The Southern Cross Bioethics Institute also queried the imperatives for change:

> At the time of the 2002 debate about stem cells and cloning, the opposition to any form of cloning was unanimous and held on ethical grounds. The reasons for any change would need to be extremely compelling. Yet neither scientific advance nor change in community standards have been anywhere near compelling.[3]

4.6 For Professor Alan Mackay-Sim, the ethical barrier crossed by allowing therapeutic cloning is tacit support for its inevitable successor, human reproductive cloning. He contended that legislative approval for developing the techniques for reproductive cloning needed to be justified by 'extra evidence' of their benefits. In his view, this had not been demonstrated.[4]

4.7 In this respect, the Lockhart Review was criticised for proposing to allow SCNT when animal studies have not yet established proof of concept for deriving human embryonic stem cells lines by this method. Professor Martin said in a Parliamentary Library Lecture that, in order to demonstrate proof of concept for this activity, proponents had to 'establish prolonged efficacy and safety in appropriate animal models of disease'.[5] Indeed, the Lockhart Review itself observed that 'ES cell research has not reached the stage needed to start clinical trials (ie proof of principle of a safe and efficacious treatment in animal models)'.[6]

4.8 Evidence to the Committee highlighted medical ethical guidelines such as the Nuremburg Code and Declaration of Helsinki's requirements with regards to

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2 *Legislation Review*, p.42. See also Dr Monique Baldwin, *Submission 57*, p.2; Gene Ethics, *Submission 106*, p.2; Professor Mackay-Sim, *Submission 178*; Dr Silburn, *Submission 180*; Associate Professor Sherley, *Submission 181*.

3 Southern Cross Bioethics Institute, Submission 16, p. 2. See also evidence of Dr van Gend (Do No Harm) Senate Committee *Hansard* 24 October 2006, pp.97-98.

4 Professor Alan Mackay-Sim, *Submission 178*, pp. 1-3. See also Submission 105 & evidence of Dr van Gend (Do No Harm) *Committee Hansard*, 24 October 2006, pp.97-98 citing publications of Professor Savulescu "Should we clone human beings? Cloning as a source of tissue for transplantation," (1999) 25 *Journal of Medical Ethics* 87, and D. Elsner, "Just another reproductive right? The Ethics of human reproductive cloning as an experimental medical procedure," (2006) 32 *Journal of Medical Ethics* 596. Elsner is from the University of Melbourne.

5 Professor John Martin, *Parliamentary Library Lecture*, 10 October 2006.

6 *Legislation Review*, p.42.

experimentation involving human subjects.[7] The Declaration of Helsinki, issued by the World Medical Association, stipulates that:

> Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.
>
> In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.[8]

4.9 Other evidence referred to and cited sections of the United States President's Council on Bioethics 2002 Report, *Human Cloning and Human Dignity*. That Report stated:

> The technical description of the cloning method (that is SCNT) omits reference not only to cloning but also to the immediate product of the activity. This obscurity enables some to argue that the immediate product of SCNT is not an 'embryo' but rather 'an egg' or 'an unfertilised egg' or 'an activated egg', and that the subsequent stages of development should not be called embryos but 'clumps of cells' or 'activated cells.' …we insist on making the effort to describe the product of SCNT as accurately and as fairly as we can.[9]

4.10 Members of the Lockhart Review gave evidence to the Committee and were asked about the inclusion of the Indian Council of Medical Research (2004) draft guidelines for stem cell research/regulation, and the omission of reference to any of the three reports (2002, 2004 & 2005) of the United States President's Council on Bioethics relating to cloning, stem cell research and alternative sources of human Pluripotent stem cells. Professor Loane Skene said:

> We had six months for our deliberations. …We did not have time to do a very extensive investigation of what was happening in other parts of the world.[10]

4.11 It was argued that these requirements, especially for proven clinical results in animal trials, had not been satisfied.[11] Professor Martin commented that the only

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7 See for example Professor John Martin, *Submission 35*, p. 2; Dr Monique Baldwin, *Submission 57*, p. 2; Catholic Archdiocese of Sydney, *Submission 100*, p. 6; Evidence of Mr Campbell (Queensland Bioethics Centre) Senate Committee *Hansard* 24 October 2006, p.98.

8 World Medical Association Declaration of Helsinki, http://www.wma.net/e/policy/b3.htm, (accessed 11 October 2006). The Nuremberg Code provides that "the experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random or unnecessary in nature."

9 Catholic Health Australia, *Submission 26*, p.4. The citation from the President's Council on Bioethics 2002 report, *Human Cloning and Human Dignity*, is from p.49.

10 *Committee Hansard*, 20 October 2006, p.6.

11 See for example Professor Alan Mackay-Sim, *Submission 178*, p. 2 & Catholic Archdiocese of Adelaide, *Submission 78*, p. 9.

scientific evidence the Lockhart Review was impressed by was that of South Korea's Dr Hwang Woo Suk.[12] Dr Hwang's claims that he succeeded in deriving stem cell lines from SCNT were later revealed to be fraudulent, including the number of eggs used in his cloning experiments. It was also later revealed that junior researchers from his laboratory were 'encouraged' to donate their eggs.

4.12 Dr Nicholas Tonti-Filippini argued that the case for SCNT had actually deteriorated since 2002:

> Nothing has changed scientifically to support some kind of new argument of necessity to use SCNT embryonic stem cells. If anything, the possibility of developing therapies involving cultured embryonic stem cell transplant has become more remote as more has become known about the difficulties.[13]

4.13 He suggested that the status quo be maintained at least until more is understood about embryonic stem cells:

> In the future, there may be some greater benefit to be obtained from using embryos, but as a matter of science it is not clear that they will be of benefit. There seems to be little reason to overturn the existing compromise supported last time by the NHMRC and by a large majority in the Parliaments. A balanced approach may be to maintain the status quo allowing access to excess IVF embryos only and then address the question of deliberately creating them for research purposes at some time if the future if and when animal models show some evidence that benefit is to be obtained from them.[14]

The limitations of embryonic stem cells

4.14 The problems experienced by researchers investigating ES cells were raised, though many of these were acknowledged by proponents as issues that needed to be resolved before tangible benefits would be seen. However, while their view was that these problems would be overcome, others saw them as being more intractable.

4.15 Many opposing the bills argued that there were scientific impediments limiting the effectiveness of embryonic stem cells generally, and those derived from SCNT more specifically.

Embryonic stem cells cause cancer

4.16 The problem of tumour formations caused by transplanted embryonic stem cells was frequently referred to in submissions from opponents of the Lockhart

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12 Professor John Martin, *Parliamentary Library Lecture*, 10 October 2006. See also Australian Family Association, *Submission 97*, p. 20.

13 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 7.

14 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 8.

Review's recommendations.[15] Embryonic stem cells' capacity to differentiate easily - pluripotency - is seen to be one of their promising characteristics by advocates of ES cell research. However, it was highlighted as a significant problem.

4.17 Professor John Martin discussed the extent of this difficulty:

> Whatever the origin of ES cells, animal or human, whenever they are transplanted into an animal, they have up to a 25% incidence of growth of a particular type of cancer, a teratoma. No substantial progress has been made towards resolving this problem of cancer development with ES cells. This problem is sufficient by itself to exclude any possibility of using ES cells in therapy for human disease, even if there were strong indications of likely efficacy on other grounds.[16]

Stem cell lines from SCNT are genetically unstable

4.18 Genetic abnormalities have been a major impediment to bringing cloned animals to birth and enjoying a full life span. Dr Nicholas Tonti-Filippini described this difficulty:

> A disadvantage of SCNT embryos is that they are epigenetically compromised. That is to say, because they have been formed using the nucleus of a somatic cell, many of the gene functions that would normally be available in an embryo are not available. The latter explains the problems of immune system diseases in cloned animals such as Dolly the sheep. (Dolly was euthanased.) It may also explain why it has proved to be so difficult to clone some animals, including humans.[17]

4.19 Clinical neurologist, Dr Silburn, stated in evidence to the Committee:

> …[embryonic stem] cells are genetically and epigenetically unstable and the resources are not there in either human or other.[18]

4.20 Professor Martin indicated that the abnormalities in gene expression that have plagued efforts to clone animals to birth would affect ES cell lines also derived from SCNT.[19]

Embryonic stem cells are difficult to control

4.21 Because of their pluripotent character, ES cells present the difficulty of being difficult to maintain in any given differentiated state. Professor Martin described this

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15 See for example, Catholic Archdiocese of Sydney, *Submission 100*, p. 7.

16 Professor John Martin, *Submission 35*, p. 2.

17 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 6.

18 *Committee Hansard*, 20 October 2006, p.25.

19 Professor John Martin, *Submission 35*, p. 3.

phenomenon succinctly: 'they want to become other cells'.[20] Dr Joe Santamaria submitted:

> It is known that cell lines established from such embryonic stem cells tend to undergo genetic drift or changes as successive populations are generated from the original cloned cell.[21]

Adult stem cells provide greater hope

4.22 Another common argument against allowing SCNT is best expressed as a rhetorical question: why would we cross this ethical line when adult stem cells promise so much hope for curing a number of diseases? This view held that there is no need to pursue 'unethical' avenues of research when adult stem cells are already used in clinical treatments and are continuing to offer a number of breakthroughs.

4.23 Those in favour of pursuing adult stem cell research *instead* of, rather than in conjunction with, embryonic stem cells highlighted that adult stem cells were not as erratic and unpredictable and therefore did not pose the same difficulties as those discussed above.

4.24 Professor Alan Mackay-Sim, a molecular biologist from Griffith University, rejected claims that adult stem cells lacked sufficient plasticity. He described their benefits as follows:

> Adult stem cells from numerous sources (e.g. bone marrow, olfactory mucosa, skin, hair follicles, muscle, fat) have been shown in numerous independent laboratories to develop into cells not normally found in the originating tissues and, despite the rhetoric to the contrary, some develop into most cell types of the body. Adult stem cells are currently used in human therapies and there are numerous animal studies demonstrating their efficacy in a variety of animal models of disease and injury such as spinal cord injury, stroke, Parkinson's disease and cardiac ischemia. The scientific evidence for the therapeutic potential of adult stem cells in currently incurable diseases is as strong for adult stem cells as it is for embryonic stem cells with two major differences. Adult stem cells do not form teratomas and they can avoid immune rejection when derived from and transplanted into the same person.[22]

4.25 He added that adult stem cells were also much easier to access for research:

> A justification for therapeutic cloning is that is will provide cellular models of incurable diseases such as motor neuron disease. It certainly has this potential but the potential is limited compared to adult stem cells. Adult stem cells are available in all adults and are much easier to propagate than embryonic stem cells. Even if therapeutic cloning were possible the

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20 Professor John Martin, *Parliamentary Library Lecture*, 10 October 2006.

21 Dr Joe Santamaria, *Submission 25*, p. 4.

22 Professor Alan Mackay-Sim, *Submission 178*, pp. 2-3.

> logistics of producing cloned cells would preclude making cells lines from many patients. This will limit the utility of this approach in discovering causes common to all persons with the disease. The ease of adult stem cell production obviates this problem.[23]

Dr Silburn stated:

> One of the specific areas to mention is that people seem to have the notion that adult stem cells are not capable of generating many different cell types and that it is necessary to clone to generate different cell types. This is incorrect.
>
> …If you have a galloping horse like adult stem cells, why not pursue that? I cannot see the big argument with the necessity for cloning. Why I am here is to say that cloning is not necessary …[24]

4.26 Associate Professor of Biological Engineering at the Massachusetts Institute of Technology, Professor James Sherley, described the different roles of the two cell types and how this affects their capacity to be used to develop cellular therapies. He wrote:

> Mature functional cells are short-lived. Within days to weeks, they die and are lost from the tissue. Therefore, they must be continuously replenished or "renewed" without the tissue losing the instructions for their elaboration. Adult stem cells accomplish this function by a process called asymmetric self renewal. When an adult stem cell divides to make two cells, one cell is a "worker" cell that multiplies to become the short-lived mature functional cells. The other cell is a new adult stem cell that retains the gene instructions for how to elaborate more worker cells.
>
> For success, any proposed approach to disease therapies for tissues in children and adults must be able to sustain the essential renewal process of adult tissues. Only adult stem cells can accomplish this feat. Embryonic stem cells cannot, because they lack the property of asymmetric self-renewal.[25]

4.27 Some evidence framed the argument in terms of allocating resources in the most efficient manner:

> In a society where research funding is limited, it makes more public policy sense to allocate scarce resources to those areas of research that hold the best promise and have evidence to justify funding. Adult stem cell research is by far the most appropriate field to support.[26]

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23 Professor Alan Mackay-Sim, *Submission 178*, p. 3.

24 *Committee Hansard*, 20 October 2006, pp.24- 25.

25 Professor James Sherley, *Submission 181*, p. 4.

26 Catholic Health Australia, *Submission 26*, p. 9. See also Professor James Sherley, *Submission 181*, p. 4, and the testimony of Dr Silburn, Senate Committee *Hansard*, 20 October 2006, pp.25 & 26.

4.28 Reference was made to a Japanese clinical trial in which induced adult mouse cells can be reprogrammed into pluripotent stem cells by introducing four specific genes.[27] A number of submitters highlighted this as a breakthrough that could circumvent the need for SCNT.[28] Professor Martin described it as 'an exciting proof of concept that a pluripotent cell could be generated from an adult cell without cloning'. If able to be refined to the point where the results could be replicated in human cells, he suggested this reprogramming technique could potentially obviate the problems, ethical and logistical, associated with SCNT-derived stem cells.[29] In discussing the Japanese study, Dr Silburn commented: 'We are talking about cloning. Do we need to clone to get adult cells to try and treat disease? No, we do not'.[30]

The egg supply problem

4.29 Finally, objections to SCNT were raised because the supply of human eggs would simply not be sufficient to undertake research on ES derived in this way. They articulated concerns that the subsequent new demand for human eggs, without accompanying health benefits to the donor, would lead to the unethical sourcing of eggs from vulnerable women including the possible commodification of human eggs.

4.30 The Lockhart Review's approach to this supply problem, which they acknowledged, was to permit the use of animal eggs as a replacement. This was criticised by some respondents, who questioned either the morality or usefulness of allowing such a procedure. Evidence to the Committee confirmed that researchers could not quantify how many eggs would be required for research. For example, in answer to a question '…do you think there are enough eggs to do all the potential research that you want to do?' Professor Jenkin from Monash Immunology and Stem Cell Laboratories said 'No'. Associate Professor Elefanty, from the same laboratory, said:

> That is not a question which is easy to answer, simply because there has not been the opportunity to actually determine what the requirements would be for this sort of research.[31]

4.31 Ms George, from Women's Forum Australia, stated in evidence:

> What we can see from overseas is that it is impossible to obtain near sufficient supplies of ova without offering women some sort of commercial incentive. …If cloning is opened up in this country, it then creates demand

27 Takahashi and Yamanaka, Induction of Pluripotent Stem Cells from Mouse Embryonic and adult Fibroblast Cultures by Defined Factors, *Cell*, 126, pp. 663-676, 25 August 2006.

28 See for example Dr Monique Baldwin, *Submission 57*, p. 1; Caroline Chisholm Centre for Health Ethics, *Submission 68*, p. 4.

29 Professor John Martin, *Submission 35*, p. 3.

30 *Committee Hansard*, 20 October 2006, p.27.

31 *Committee Hansard* 24 October 2006, p.72.

> for ova and, as I said, overseas experience would suggest that that can only be satisfied by paying women to undertake these risks.[32]

Egg donation risks

4.32 The Women's Forum of Australia (WFA) said that SCNT should not be allowed while its proponents had failed to ensure the safety of egg donors:

> Since research cloning is impossible without access to thousands of women's ova, advocates of this research bear the onus of demonstrating that sufficient ova can be sourced without harm to women. They have failed to discharge this onus.[33]

4.33 The WFA submission described the unpleasant experience of donating eggs:

> Extracting sufficient ova can only be achieved with high doses of ovulation stimulating agents.
>
> Women describe the extraction process as invasive and uncomfortable, requiring several clinic visits and multiple injections of hormones. Often a dozen or more eggs are produced at a time, instead of the usual one or two per cycle.[34]

4.34 The Feminist International Network of Resistance to Reproductive and Genetic Engineering (FINRRAGE) submitted that it was unethical to harvest eggs from women with no associated health benefit.[35]

4.35 According to WFA, the process of stimulating the ovaries to produce large numbers of eggs at a time was in fact no longer best practice for IVF clinics:

> The proposal is...contrary to recent developments in fertility technology that are moving towards minimal stimulation IVF where only one ovum at a time is extracted. In this patient-friendly procedure only low doses of hormones are administered for only a few days causing few side effects. Retrieval of the egg is comparatively quick and easy and can be performed without analgesia…
>
> Hyper-stimulating IVF patients to produce extra eggs for research might benefit the researchers but it is against the best interests of the women patients when less intrusive techniques are now available.[36]

4.36 It was argued that the process was not only unbeneficial and unpleasant, but unsafe. WFA described short term symptoms ranging from pain, hot flushes, nausea and vomiting to more serious symptoms associated with ovarian hyper stimulation

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32 *Committee Hansard*, 24 October 2006, p.60.

33 Women's Forum of Australia, *Submission 80*, p. 2.

34 Women's Forum of Australia, *Submission 80*, p. 3.

35 FINRRAGE, Submission 32, p. 2.

36 WFA, *Submission 80*, p. 10.

syndrome that can require hospitalisation.[37] It was also claimed that the long-term risks of the drugs used to stimulate ovulation were unknown, and that some had been implicated in the development of cancer.[38]

Ensuring informed consent

4.37 Given the absence of health or fertility imperatives for donating eggs for SCNT research, the prospect that women may be improperly pressured to do so was raised. IVF patients, who already supply eggs for their own fertility treatment, were identified as being particularly susceptible.

4.38 Dr Sheryl de Lacey, from the Research Centre for Reproductive Health at the University of Adelaide, suggested that women in the general community were unlikely to volunteer to donate eggs. As such, women undergoing IVF treatment were vulnerable to 'recruitment strategies' for egg donation that may not serve their best interests. Dr de Lacey submitted:

> Research has so far relied on the donation of embryos that are excess or surplus to a patient's treatment. But there is no such thing as a 'surplus' egg. Every egg collected represents a potential embryo and a potential pregnancy for an infertile woman. Donating eggs to research during treatment is likely to reduce the woman donor's chance of success thereby increasing her risk of ongoing childlessness, her use of ART and elevating the costs involved, and thereby risking harm to her.[39]

4.39 Although supportive of permitting SCNT, Professor Wendy Rogers stressed the importance of the consent process ensuring donors were fully informed:

> Because of the potential risks to women, women donating oocytes or other tissues for research should be offered all relevant information about the likely use of their donation, including details about likelihood of production of patentable products and profits, and whether profits will accrue to the public or private sector. Women seeking fertility treatments may be unusually vulnerable in terms of feeling dependant upon staff and technology and therefore fell obliged to consider donating eggs if requested.[40]

4.40 FINRRAGE questioned whether informed consent was possible in the context of existing power imbalances and expressed concern that 'reimbursement' could in fact equate to 'payment' for poorer women:

> Although women may not be physically forced to 'donate' eggs, women's decisions take place in particular social contexts, in which there are often significant imbalances in power between women and a) the researchers who

37 WFA, *Submission 80*, pp. 3-4.

38 See for example Dr Con Pelanki, *Submission 49*, p. 2; WFA, *Submission 80*, pp. 4-5.

39 Dr Sheryl de Lacey, *Submission 27*, p. 3.

40 Professor Wendy Rogers, *Submission 67*, p. 2.

> want embryos to pursue their research; and, b) the companies looking to cash in on a biotechnology investment that may be worth millions, especially when they can 'patent' the products from women's eggs...
>
> Reimbursement of women's 'expenses' or 'inconvenience' for 'donating' ova may not seem profitable to the people considering this legislation, but it can represent a substantial sum of money to poorer women, particularly students and unskilled or unemployed women. These are women who may not otherwise be able to earn extra money in any other way.[41]

4.41 WFA commented that:

> Already, with cloning research only in its infancy, all indications are that this research is not practicable without the commercial sale of ova. In the UK extensive publicity campaigns have failed to recruit sperm and egg donors without commercial payment (Mc Laughlin 1998).[42]

4.42 The Sydney Diocese of the Anglican Church expressed the view that sidestepping the usual 14 day cooling off period to allow fresh embryos to be obtained for research could generate undue pressure to donate. The Diocese submitted:

> ...if consent for research were to be given immediately, it would be difficult to ensure that there was no coercion involved, given the time-pressure for decision-making. One would also want to be convinced that the persons responsible, at such an early stage of treatment when they will be extremely vulnerable and expecting treatment to be successful, were completely sure they have no further use for the embryos, especially considering the research mentioned above regarding the non-correlation of appearance and viability of embryos. Would the less-perfect embryos still be considered 'excess' if the implantation of apparently more suitable embryos proved unsuccessful? If prospective parents' choice was between a less perfect embryo and none at all, it is highly likely that some would deeply regret the relegation of these embryos to research. The decision is therefore too complex to make quickly and in advance of knowing the results of treatment.[43]

4.43 The proposed change to the consent regime to enable 'unsuitable' fresh ART embryos to be used for research is discussed later in the chapter.

Alternative egg sources

4.44 Recognising the difficulties of obtaining a sufficient supply of human eggs, the Lockhart Review recommended allowing SCNT using animal eggs. However, aside from the moral objections expressed by some submitters, others expressed doubt over the effectiveness of the practice, particularly when embryonic stem cells derived

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41 FINRRAGE, *Submission 32*, p. 7.

42 WFA, *Submission 80*, p. 12.

43 Anglican Church, Sydney Diocese, *Submission 41*, p. 5.

from an animal egg would contain animal DNA. This would, according to the objections raised, produce results that could be misleading and would certainly be unsuitable for any clinical treatment.

4.45 The Southern Cross Bioethics Institute wrote:

> So far the only alternative to the many thousands of human eggs required for even the most rudimentary cloning experiments is using animal eggs. Creating hybrid embryos is not only an ethical Pandora's box in its own right, but rests on a naïve assumption that inserting the human nuclear genome into an extraordinarily complex structure with very different cytoplasmic machinery to that in the human egg, will produce a comparable result. The level of scientific knowledge about the interaction between genes and their cytoplasmic environment is very preliminary. We can only guess at the possible result of transferring human nuclei and animal oocytes.[44]

4.46 Dr Peter McCullagh concurred: 'studies within one (non-human) species would be much more likely to provide interpretable data than those obtained in highly contrived inter-species hybrid experiments'.[45]

4.47 Dr Klein, from FINRRAGE, and Mr Phelps, from Gene Ethics Network, both expressed concerns about egg harvesting. Mr Phelps put it in slightly wider context, saying that 'We do bridle at the term 'therapeutic cloning'. There is no evidence that this is therapeutic. It seems designed to divert our attention from the broader activities and implications: egg harvesting, destructive experimentation and drug testing and development'.[46] The Catholic Archdiocese of Adelaide highlighted the egg supply dilemma faced by researchers in this field:

> While possessing the DNA from the somatic cell donor, the entity would also possess the animal DNA found in the mitochondria.
>
> This mixture of DNA would render any ESCs harvested as probably useless for therapeutic outcomes. Even though the majority DNA would be histocompatible, the introduction of non-human DNA could result in unforeseen consequences.
>
> It would seem, therefore, that any legislative outcome from Lockhart will find itself with a dilemma: For the sake of women's health, the harvesting of great numbers of human oocytes should be avoided; yet the alternative is problematic and probably unacceptable to the great majority of Australians.[47]

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44 Southern Cross Bioethics Institute, *Submission 16*, p. 3.

45 Dr Peter McCullagh, *Submission 85*, p. 5.

46 *Committee Hansard*, 24 October 2006, p.101 (Mr Phelps); pp.99-100 (Dr Klein).

47 Catholic Archdiocese of Adelaide, *Submission 78*, p. 10. See also Do No Harm, *Submission 105*, p. 13.

4.48 Despite being generally supportive of the Lockhart Review's recommendations, the Australian Stem Cell Centre offered only mixed support for the practice:

> The ASCC prefers the use of human eggs to animal eggs in SCNT experiments that involve a human nuclei (somatic cell). The Centre believes there is limited merit in inserting human nuclei into an animal egg. In addition, due to the scarcity of human eggs, the Centre believes that, ideally, preparatory training for scientists in the technique of SCNT should occur using animal eggs with animal nuclei until such time that a very high standard of technical capability has been achieved.[48]

4.49 Professor Bob Williamson, Chair of the National Committee for Medicine at the Australian Academy of Science, also suggested that the practice of using animal eggs would only be beneficial for training purposes, in order to ensure that human eggs are not wasted.[49]

The slippery slope

4.50 Opponents of these bills regularly argued that allowing SCNT would, after a period of time, lead to calls for more drastic research activities to be legalised. They were sceptical that a line would be drawn at SCNT, particularly after it was rejected by the Parliament in 2002.[50]

4.51 The Southern Cross Bioethics Institute claimed that the utilitarian nature of the arguments for change rendered further calls for destructive research on embryos likely:

> ...there is little reason why attempts will not be made to argue for more and more extreme practices to be justified on the grounds of possible benefit. That is precisely what is happening here, even though the potential benefit is as yet unproven.
>
> Second, what grounds does the community have for believing those who previously firmly stated their opposition to both therapeutic and reproductive cloning on ethical grounds, but who now state that one form, that is, therapeutic cloning, has become acceptable to them? If those same proponents now claim to be opposed to reproductive cloning on ethical grounds, the community could be forgiven for being sceptical. That is the nature of utilitarian ethics.[51]

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48 Australian Stem Cell Centre, *Submission 63*, p. 6.

49 Professor Bob Williamson, *Parliamentary Library Lecture*, 11 October 2006.

50 Medical law text books question how long legislative bans on reproductive cloning can be maintained. For example, see *Law and Medical Ethics*, Seventh Edition, (J.K. Mason; G.T. Laurie) (Oxford: Oxford University Press, 2006) p.252: "We suspect that the days of the outright prohibition on reproductive cloning are numbered."

51 Southern Cross Bioethics Institute, *Submission 16*, p. 2.

4.52 The Australian Family Association predicted that biotechnologists would seek to be allowed to develop cloned embryos beyond 14 days, or have them implanted into a woman.[52] Many feared that allowing SCNT would inevitably lead to reproductive cloning.[53] The Southern Cross Bioethics Institute was concerned that SCNT would give valuable practice to those wishing to create a living clone:

> Research on cloning human embryos is inextricably connected to bringing clones to birth. Regardless of the legislative restrictions on 'reproductive cloning', the groundwork will be laid for those in other settings who will implant cloned embryos for development to birth. If this legislation is passed, government funded research that results in the refinement of procedures for producing cloned human embryos will be taken up by others who are intent on producing born human clones. This needs to be acknowledged as a real consequence of such legislative permission.[54]

4.53 Some respondents predicted that another future review would create pressure for further concessions.[55] Among them was Festival of Light Australia:

> We are likely to be told then by some scientists that to get the full benefits from human cloning we need to allow clones to develop to the foetal stage in order to harvest their organs. We could be told that in order to get sufficient ova to bring about the potential benefits of human cloning we need to offer reimbursement to women for their time and compensation for the risks they must undergo.[56]

4.54 WFA focussed on what they saw as an emerging commercial market for human gametes. They asserted that the commodification of human eggs would occur due to an absence of willing, altruistic, donors.

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52 Australian Family Association, *Submission 97*, p. 22.

53 See for example Do No Harm, *Submission 105*, pp. 14-15. Evidence of Dr van Gend citing D. Elsner, "Just another reproductive technology? The ethics of human reproductive cloning as an experimental medical procedure," (24 October 2006) 32 *Journal of Medical Ethics* 596-600.

54 Southern Cross Bioethics Institute, Submission 16, p. 3. See also Anglican Church, Sydney Diocese, *Submission 41*, p. 8; Catholic Archdiocese of Melbourne, *Submission 108*, p. 4. Dr. McCullagh, *Submission* 85 quotes prominent philosopher and IVF advocate, Baroness Warnock, in relation to the "14 day marker" as indicating that it was at that time "that I became me." In 2002 she asked rhetorically "Would the cloning of humans be intrinsically wrong?" See Mary Warnock, *Making Babies: Is there a right to have children?* (Oxford: Oxford University Press, 2002) pp.102-108. Australian researchers have very recently pursued the same argument in favour of reproductive cloning. See D. Elsner, "Just another reproductive technology? The ethics of human reproductive cloning as an experimental medical procedure," (24 October 2006) 32 *Journal of Medical Ethics* 596-600. Elsner is from the University of Melbourne.

55 See for example Gene Ethics Network, *Submission 106*, p. 5.

56 Festival of Light Australia, *Submission 34*, p. 16.

Other changes opposed

4.55 Other proposed changes to the regulation of this area of research also received critical comment. They related to:

- The inappropriateness of the proposed new definition of a human embryo and its potentially adverse effect on regulating research on embryos; and
- The problems associated with attempting to define 'unsuitable' fresh embryos that could be donated for research.

Legislative definition of an embryo

4.56 The earlier discussion on the proposed new definition of an embryo related to claims that arbitrary legislative distinctions were being sought to confuse peoples' understanding of the nature of the activities, currently unlawful, proposed to be allowed. These arguments were based on the premise that the proposed definition bore no relationship to the reality of when an embryo starts; merely representing a legislative strategy to access certain research techniques.

4.57 There was significant conflict in evidence before the Committee, and among Committee members, regarding the definition of 'embryo' and 'cloning'. Some, such as the Coalition for the Advancement of Medical Research in Australia (CAMRA) (Submission 21) and SpinalCure Australia (Submission 29), both contend that 'SCNT is not cloning'. This is contrary to standard medical dictionaries, such as Stedmans and Dorlands. Some members of the Committee, such as Senator Ferris, suggested to witnesses that there was a fundamental difference between an embryo created by the fusion of sperm and ovum, on the one hand, and an embryo created by SCNT or therapeutic cloning. Such a distinction was denied as relevant by many witnesses.[57]

4.58 Professor Skene, Deputy Chair of the Lockhart, also did not accept this distinction, saying: 'We did not shy away from calling it an embryo because it is conceiveable, as happened with Dolly the sheep, that if that entity were put into a woman, after a lot of care, it could in fact develop into a foetus'.[58]

4.59 In addition to those complaints, it was argued that the scientific basis of the definition is flawed, that it was prematurely lifted from a working document and that it could have unintended consequences for the regulation of this research field.

The source of the definition

4.60 Firstly, the argument was made that it was inappropriate to use a definition that was still a work in progress as the definition of a human embryo in the legislation regulating this area of research. In its submission to this inquiry the NHMRC indicated that their 'discussion paper' definition had not been formally endorsed:

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57 Evidence of Dr van Gend, *Committee Hansard*, 24 October 2006, p.104; Dr Klein, p.105.

58 *Committee Hansard*, 20 October 2006, p.9.

> ...in December 2005 the National Health and Medical Research Council released the final report of the Biological Definition of Human Embryo Working Party as a discussion paper. The definition of "human embryo" provided in that discussion paper (Attachment B) was not endorsed by the NHMRC.[59]

4.61 Dr Nicholas Tonti-Filippini contended that it was premature for the Lockhart Review to rely on a definition that was mooted in a NHMRC discussion paper:

> ...the proposed biological definition has not been promulgated by the NHMRC but has only been made available as a discussion paper prepared by an NHMRC Working Party. As far as I am aware, the NHMRC has not altered the position taken on this matter in the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* developed by the Australian Health Ethics Committee. The guidelines were issued at the 154th Session of the NHMRC in 2004. The Australian Health Ethics Committee has statutory responsibility for developing ethical guidelines for medical research. The new proposed biological definition of the embryo has not been developed in a way that is consistent with the ethical guidelines. Its use in this way is thus premature and problematic for the existing guidelines.[60]

4.62 Dr Peter McCullagh commented on the lack of consultation that the discussion paper definition was intended to elicit. He said:

> The selected definition is derived from a discussion paper, 'Human Embryo' – A Biological Definition, released by the NHMRC in December, 2005. This paper presents considerable background information on the subject of embryological nomenclature with the intention, expressed in its Preface, of eliciting comment from a 'wider audience'. The incorporation of its definition in legislation in the apparent absence of any widespread debate to inform the Parliament of community attitudes on its specific features could be regarded as inappropriate.[61]

Part (a) of the definition

4.63 Another source of opposition to the proposed definition was disagreement over the starting point of an embryo created by fertilisation of a human egg by a human sperm. In the opinion of many, the embryo exists once the sperm and the egg are united, not at an arbitrarily defined point that occurs afterwards.[62] The Southern Cross Bioethics Institute's submission stated:

> Regardless of the terminology used, the new entity created by union of sperm and egg or by any other means is developmentally continuous in time

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59 NHMRC, *Submission 168*, p. 4.

60 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 2.

61 Dr Peter McCullagh, *Submission 85*, p. 1.

62 See for example Catholic Archdiocese of Melbourne, *Submission 108*, p. 2.

> and should not be treated differently because of an arbitrary selection of a time at which greater moral significance is said to arise.[63]

4.64 Dr Nicholas Tonti-Filippini agreed:

> The mitotic division is not the beginning of the new entity, but something that occurs in an entity which already has a completed human genome and which is already organised for further development.[64]

4.65 Dr Joe Santamaria submitted that the definition lacked scientific credibility:

> It bears no resemblance to any definition of the human embryo found in the standard textbooks on Human Embryology.[65]

4.66 The Sydney Diocese of Anglican Church queried the Lockhart Review's justification for choosing one identifiable marker over another, more logical one:

> We do not see evidence of why the completion of fertilisation, rather than its beginning, is used to define the starting point of fertilised embryonic life. The text of the Lockhart Report suggests that the primary purpose of this change is to allow recommencement of research during the early stage of fertilisation, rather than being based upon any biological criteria (see p.xv). However, precisely these restrictions on research were identified in the debate prior to the passing of the 2002 legislation, so it is unclear how they can now be seen as having 'apparently unintended consequence(s) of impeding valuable research and clinical practice in ART clinics'(p. xv).[66]

4.67 The Diocese further submitted that if research on fertilised eggs was to be permitted, then these activities should remain under the scrutiny of the Licensing Committee of the NHMRC.[67] Similarly, the Caroline Chisholm Centre for Health Ethics and the Catholic Archdioceses of Sydney and Melbourne expressed concern that fertilised eggs could be experimented on until the two-cell stage without regulatory oversight.[68]

4.68 Dr Peter McCullagh suggested that defining the embryo from the first observable marker after fertilisation has occurred would be overtaken by technological advancement, explaining that:

> ...the placement in time of any developmental point is entirely at the mercy of the technology which is available at the time to recognise when that

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63 Southern Cross Bioethics Institute, *Submission 16*, p. 3.

64 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 3.

65 Dr Joe Santamaria, *Submission 25*, p. 6.

66 Anglican Church, Sydney Diocese, *Submission 41*, p. 3.

67 Anglican Church, Sydney Diocese, *Submission 41*, p. 3.

68 Caroline Chisholm Centre for Health Ethics, *Submission 68*, p. 6; Catholic Archdiocese of Sydney, *Submission 100*, p. 8; Catholic Archdiocese of Melbourne, *Submission 108*, p. 2.

> point has been attained. Inevitably, the time of recognition will move closer to the actual time of occurrence of the event as science advances.

He thought that a more appropriate 'marker event' to demonstrate the existence of a new entity would be the release of Early Pregnancy Factor (EPF):

> This entails amplification of the message (I'm here) by a 'cascade' mechanism with resemblance to that responsible for blood coagulation. EPF is produced at the single cell stage of development and Morton has demonstrated its appearance within 6-24 hours of a fertile mating. I suggest that it is a much more sensitive indication of the appearance of a new entity (historically referred to as an embryo) than any other. It certainly represents a recognition signal which is observable much closer to the event it signifies than any other.[69]

Part (b) of the definition

4.69 Concerns were also raised about the possible consequences of the second part of the proposed new definition. The use of the phrase 'has the potential to develop up to, or beyond, the stage at which the primitive streak appears', has led some to believe that embryos created through SCNT could be placed outside the regulatory framework altogether.[70]

4.70 Dr Tonti-Filippini explained the significance of the word 'potential' in the context of creating embryos for destructive research:

> The definition is open to the interpretation that an embryo that is never to be transferred to the uterus of a woman lacks the potential to form a primitive streak. The formation of a primitive streak depends on implantation. Thus the second part of the definition would allow an interpretation that a cloned embryo was only an embryo if it is to be implanted. Thus it would be permissible, using this definition, to form embryos by cloning, as long as they were not to be transferred into an environment where it would be possible for implantation to occur and development to the stage of the formation of a primitive streak. Those unimplanted, cloned embryos would then be completely outside the regulatory framework established by the guidelines and by the proposed legislation.[71]

4.71 He, as well as the Catholic Archdiocese of Sydney, suggested the following:

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69 Dr Peter McCullagh, *Submission 85*, pp. 2-3.

70 See for example Queensland Bioethics Centre, *Submission 31*, p. 4; Catholic Archdiocese of Adelaide, *Submission 78*, p. 13.

71 Dr Nicholas Tonti-Filippini, *Submission 15*, pp. 3-4.

> The second part of the definition at least needs a qualifier such as adding the words "if placed in a suitable environment" after the words "potential to develop".[72]

4.72 In his submission, Dr Tonti-Filippini also speculated that researchers may intentionally disable the embryo such that it could not reach the primitive streak stage currently proposed in the bills. Accordingly, he suggested the point of distinction be moved to the blastocyst stage.

Fresh 'unsuitable' ART embryos

4.73 Argument in support of researchers accessing currently discarded fresh embryos is included earlier in the chapter. However, a number of submissions expressed doubt over the appropriateness of objectively defining embryos as 'unsuitable' for implantation, which could then be made freshly available for research.[73] In particular, concerns were raised over the practical difficulty of making such an assessment, as well as the potential for viable embryos to be donated contrary to the best interests of the patient's fertility treatment.

4.74 The Sydney Diocese of the Anglican Church commented:

> We are surprised that this category of embryo has been recommended for inclusion as according to research it does not exist. While there have been suggestions that there is some correlation between the external appearance of an embryo and its likelihood of implantation and successful development, research has previously shown that appearances can be misleading. Some unhealthy-looking embryos implant and develop successfully while some healthy-looking embryos fail to implant or have developmental problems. We are not aware of any method of embryo assessment that has been proven effective or valid in terms of predicting the viability of ART problems. If there are viable cells present, some clinicians would consider going ahead with uterine transfer, despite unfavourable morphology, considering this the only way to determine true viability.[74]

4.75 As a consequence of the difficulty of making such a judgment, the Southern Cross Bioethics Institute doubted the likely objectivity of such a process:

> In one of the Bills, the permission granted to use ART embryos deemed unfit for implantation amounts to the selective destruction of embryos on grounds that it is difficult to imagine would be entirely objective. If that is

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72 Dr Nicholas Tonti-Filippini, *Submission 15*, p. 4; Catholic Archdiocese of Sydney, *Submission 100*, p. 8. See also Pro-Life Victoria, *Submission 43*, p. 4.

73 Subject to proposed changes to the consent process, ie removing the 14 day cooling off period in some circumstances. See the committee's discussion of Lockhart Review recommendations 20-22.

74 Anglican Church, Sydney Diocese, *Submission 41*, p. 4.

> the case, then an element of subjectivity could be used to enhance the supply of embryos for programmes when the supply is failing.[75]

4.76 Dr Peter McCullagh offered an alternative suggestion:

> I disagree with this recommendation on the basis that to tamper with the general recommendation for an adequate 'cooling off' period in order to overcome one specific difficulty is a bad approach (the 'What never – well, hardly ever' solution). If the Senate believes that these 'unsuitable for implantation' embryos could advance research, it is preferable to arrange its legislation so that they may legitimately be declared as 'excess' so permitting their cryopreservation followed by incorporation of the regular incorporation of an appropriate 'cooling off' period before use.[76]

4.77 The NHMRC noted a lack of clarity over its potential responsibility in this regard. It submitted that while the Lockhart Review had recommended that they 'develop ethical guidelines for the use of embryos that are unsuitable for implantation',[77] the recommendations did not propose any NHMRC requirement to develop objective criteria upon which such an assessment of unsuitability would take place.[78] Recommendation 22 in the Lockhart Review suggests this be left to 'an expert body'. However, Senator Patterson's Bill stipulates that the criteria should be 'specified in guidelines issued by the CEO of the NHMRC'.[79]

4.78 Finally, fertility advocates expressed concerns that the implementation of this proposal could have implications for IVF treatment procedures. The Fertility Society of Australia suggested:

> The determination of objective criteria for "unsuitable for implantation" could have significance upon ART. The concern being that anything deemed not "unsuitable for implantation" by the objective criteria is suitable for implantation. What implications will this have to the person undertaking treatment?[80]

Number of excess IVF embryos and embryos from cadavers and aborted foetuses

4.79 The Lockhart Report addressed the problem of sourcing sufficient donated eggs for SCNT and related technologies. Reference was made to the harvesting of eggs from cadavers and aborted foetuses,[81] though these were not formal recommendations.

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75 Southern Cross Bioethics Institute, *Submission 16*, p. 4.

76 Dr Peter McCullagh, *Submission 85*, p. 6.

77 See Lockhart Review Recommendation 30.

78 NHMRC, Submission 168, p. 4.

79 Schedule 2, Item 4.

80 Fertility Society of Australia, *Submission 40*, p. 2. Also ACCESS, *Submission 176*, p. 2.

81 For example, *Legislation Review*, p.176.

4.80 A number of witnesses questioned both the ethics and medical safety of using eggs harvested from cadavers or aborted foetuses, as well as such suggestions being completely contrary to the Parliamentary debate and agreement in 2002. It appears no gauging of community reaction to such concepts was attempted by the Lockhart Review.

4.81 These practices are, however, permitted under the Patterson Bill.[82]

The Lockhart Review Committee's preconceived approach

4.82 Two main contentions emerged with regard to the composition and conduct of the Lockhart Review Committee. The first was that it was initially 'stacked' with members predisposed to supporting the legalisation of the activities their recommendations ultimately suggested be permitted. The second was that this inherent bias was confirmed by the way the Lockhart Committee approached its terms of reference, particularly with regards to changing community attitudes in this area and the scientific evidence that had emerged since the original Acts were passed.

Lockhart Committee 'stacked'

4.83 The Lockhart Review Committee was appointed in June 2005 by the then Minister for Ageing the Hon. Julie Bishop MP. The Lockhart Review stated that, in accordance with the Acts, these appointments were agreed to by each State and Territory. However, a number of submissions expressed the view that at least some of the Lockhart Review Committee held known, pre-conceived, views on the issues central to this debate. Many provided examples of quotes from Lockhart Review Committee members, articulated prior to the human cloning debate in 2002, and advocating the potential benefits of therapeutic cloning, or SCNT.[83]

3.162 The Queensland Bioethics Centre blamed the COAG selection process for a lack of diverse views on the Lockhart Review,[84] while the Australian Family Association viewed the Review's attitude to opponents of change as 'dismissive':

> ...the statement by the Chairman of the Review, Justice John Lockhart, that the Committee's task was "...to strike a balance between emotional reaction and rational progress" further compromised the neutrality of the Review. In reading the Review's Issues Paper and its Report, it becomes very apparent that the use of the words "emotional reaction" was indicative of a dismissive attitude at the outset to those in favour of the current legislative restrictions.[85]

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82 See the exchange between Senator Moore and Dr van Gend, *Committee Hansard*, 24 October 2006, pp.110-111.

83 See for example Family Council of Queensland Inc, *Submission 89*, p. 2; Do No Harm, *Submission 105*, p. 23; Coalition for the Defence of Human Life, *Submission 23*, p. 2.

84 Queensland Bioethics Centre, *Submission 31*, pp. 2-3.

85 Australian Family Association, *Submission 97*, p. 8.

4.84 Associate Professor of Biological Engineering at the Massachusetts Institute of Technology, James Sherley, queried the technical expertise of the Lockhart Committee:

> There was no one with stem cell science expertise on the Lockhart Committee. To external reviewers, it seems unthinkable that the Australian Parliament would have charged such a poorly outfitted group with the responsibility of rendering such a crucial document for the debate on human embryo cloning research. Although the Committee reports that it interviewed stem cell scientists, the absence of such official expertise on the Committee proper is such an unbelievable oversight that it calls into question the integrity of the selection process and the quality of the Report. Thus, the absence of stem cell expertise on the Lockhart Committee is viewed to be sufficient cause to disallow the recommendations of the Report in the current debate.[86]

Demonstrated bias

4.85 A number of submitters complained that the Lockhart Review cherry-picked the surveys they used to convey community attitudes on therapeutic cloning. Many also criticised the Lockhart Review for failing to highlight that a majority of submissions to their review expressed opposition to SCNT, or therapeutic cloning.

4.86 Opponents of the Lockhart recommendations claimed that two surveys in particular were ignored in the Lockhart report, while one that produced a favourable result for SCNT advocates, a Morgan telephone poll was quoted.[87] For instance, the Queensland Bioethics Centre submitted that:

> The Lockhart Committee's approach to community standards was novel and not scientifically based. A Swinburne University study published in 2004 clearly indicated that the majority of Australians were not comfortable with scientists cloning human embryos for research purposes. Although this research was available to the Lockhart Committee, no reference is made to it. A more recent study by the Sexton Marketing Group for the Southern Cross Bioethics Institute gave a similar result.
>
> There would appear to be no grounds for asserting that community standards have changed since 2002.[88]

4.87 Professor Martin stated that the premise of the Morgan Poll, that stem cells had in fact already been derived from SCNT, was false and misleading.[89] The Catholic Archdiocese of Melbourne criticised it for omitting particular key phrases:

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86 *Submission 181*, p. 2.

87 See for example Australian Family Association, *Submission 97*, p. 8.; Do No Harm, *Submission 105*, p. 27. The details of this survey can be found at http://www.roymorgan.com/news/polls/2006/4036/, (accessed 16 October 2006).

88 Queensland Bioethics Centre, *Submission 31*, p. 3.

89 Professor John Martin, *Submission 35*, p. 4.

> A recent Morgan Poll claimed 80% public support for the extracting of embryonic cells from human embryos. However such claims are unreliable, and misleading given that the public is told that embryonic stem cells are made by "merging an unfertilised egg with a skin cell, in which case no fertilisation and no merger of the egg and sperm takes places." No mention here of cloning or that a new human life has been manufactured. Certainly no mention of the word 'embryo'.[90]

4.88 The Caroline Chisholm Centre for Health Ethics contrasted this survey with the result of the Swinburne University study,[91] which was the outcome of a process that provided information to its participants prior to measuring their opinions:

> It is worth noting that this was a survey of people across Australia who had become informed by participating in focus discussion groups. Participants knew that therapeutic cloning involves the destruction of embryos, and, as I have mentioned above, not all surveys make that known. It is clear, properly informed Australians understand what 'therapeutic cloning' of embryos for research means, and they do not like it.[92]

4.89 The Australian Family Association claimed that 'curiously, not a single reference to promising developments in search of pluripotent stem cells without embryos appears in Lockhart's literature review'.[93]

4.90 Others noted the Lockhart Review's reference to the fraudulent claims by South Korean researcher Dr Hwang, the only evidence at the time of successfully deriving embryonic stem cells from cloned embryos. In evidence to the Committee, Professor Schofield of the Lockhart Review noted that '…there was no single linchpin study and in fact there were some rumours and machinations going on in the scientific community regarding the Korean work'.[94] Do No Harm criticised the Lockhart Review Committee for not amending their recommendations and report after the results of Dr Hwang were revealed to be fraudulent:

> The one allegedly significant scientific advance that Lockhart used to justify overturning our ban turned out, within days of tabling the Lockhart report (tabled Dec 19th 2005), to be a monumental fraud.
>
> The serious question is why, realising that their recommendations were almost exclusively based on what was now shown to be fraudulent science, the Review did not recall and amend their recommendations?

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90 Catholic Archdiocese of Melbourne, *Submission 108*, p. 3.

91 Critchley and Turney, 'Understanding Australians' Perceptions Of Controversial Scientific Research', Australian Journal of Emerging Technologies and Society, Vol. 2, No. 2, 2004, pp. 82-87, http://www.swin.edu.au/sbs/ajets/journal/V2N2/pdf/V2N2-2-Critchley.pdf, (accessed 16 October 2006).

92 Caroline Chisholm Centre for Health Ethics, *Submission 68*, p. 3.

93 Australian Family Association, *Submission 97*, p. 18.

94 *Committee Hansard*, 20 October 2006, p.6.

Senator Gary Humphries
Chair

October 2006

Senator Concetta Fierravanti-Wells
LP, New South Wales

Senator Helen Polley
ALP, Tasmania

Senator John Hogg
ALP, Queensland

Senator Steve Fielding
FFP, Victoria

Senator Guy Barnett
LP, Tasmania

Senator the Hon Ronald Boswell
NATS, Queensland

Senator Ursula Stephens
ALP, New South Wales

Additional Comments in Support of the Bill

1. We reject the assertion that supporting the Lockhart recommendations means compromising on ethics and human rights. While we acknowledge that an embryo is deserving of respect, the qualities that give humans their dignity and special status are not present in a 14 day old embryo (Sub. 2, Sub. 8, Sub. 20b, Sub. 74.)

2. Independent polls demonstrate broad community support for this research. While the views of minorities must always be respected, they should not override the views of the majority in such an important issue. This is not an instance of "enforcing" a majority view on all members of the community: those who object to the research are entitled to refuse to participate in it. (Sub. 20, Sub. 21, Sub. 65.)

3. The current law allows research to be performed on excess ART embryos. Thus the Lockhart recommendations do not mean a "quantum leap" in human ethics; the proposals only ensure that the most suitable stem cells are available for the specific research being performed. (Sub. 20b, Sub. 21, Sub. 73.)

4. Furthermore, the law already allows embryos to be created in the knowledge that some will be destroyed for the purposes of IVF. We reject the claim that the pursuit of life-saving cures is a less worthy goal than that of helping infertile couples conceive children. Both goals deserve our support. (Sub. 2, Sub. 29.)

5. There have been claims that the Lockhart recommendations, if accepted, will lead to women being exploited for their ova. Australia has very stringent guidelines that govern the donation of organs and tissue by living donors, and we see no reason that ova-donation should be treated any differently. The NHMRC is well-equipped to monitor and enforce guidelines to protect donors from being exploited. Women must be provided with education and counselling in order to give informed consent; the law should not treat women as being incapable of making the decision to be a living donor. (Sub. 63, Sub. 88, Sub. 186.)

6. "Slippery slope" arguments do not hold any weight in this debate. We must not block potentially valuable research on the spurious grounds that it might in the future be used for undesirable purposes. Parliament must continually respond to advances in human discovery in accordance with community standards and human rights. We do not believe that future Parliaments will be any less capable of performing this important task.

7. The Lockhart recommendations are very clear in stressing that reproductive cloning is unacceptable and the Bills propose very serious penalties for anyone attempting to do so. All technologies bring with them a risk of misuse, but the NHMRC is highly qualified to enforce the laws and ensure that community standards are adhered to. (Sub. 2, Sub. 20, Sub. 168.)

8. It has been argued that SCNT is unnecessary, because adult stem cell research has more promise. To the contrary, there have been numerous developments in the

field both in Australia and overseas suggesting that there is indeed great potential in SCNT. This evidence should demonstrate to Parliamentarians the urgency with which the recommendations should be implemented. This research is already being done throughout the world, and we must not allow Australia to fall further behind in the field. (Sub. 65, Sub. 73, Sub. 74, Sub. 93.)

9. While Parliament should be free to change its mind based on new arguments and better evidence, the claim that the Parliament unanimously agreed to a ban on SCNT in 2002 is inaccurate. In August 2001 the House of Representatives Standing Committee on Legal and Constitutional Affairs (recommendation 12.42) proposed that:

> "There should be a moratorium on the creation of embryos by means of somatic cell nuclear transfer techniques for three years, at which point the issue should be re-examined." (Sub. 72, Sub. 88.)

10. The Lockhart recommendations are the result of this process. This Government-appointed committee recommended that it is now time to lift the prohibition on SCNT. (Sub. 20, Sub. 74.)

11. The Lockhart Committee notes:

> "In the past 3 years, the following bodies have been sufficiently convinced of the merits of the science behind ESC research and its therapeutic potential to advocate for its support: the House of Lords; the UK Legislative Review team; the majority of US Senators (almost 2/3); 80 Nobel Laureates in the US; most, if not all, of the living medical Nobel Laureates in Australia; the Australian scientist of the year, Professor Ian Frazer; the American Medical Association; and the Canadian Medical Association. It is possible, though highly improbable that these groups and individuals are all wrong about the potential of human embryonic stem cell research." (Sub. 20c.)

We urge Senators and Members to support this Bill.

Senator Natasha Stott Despoja
AD, South Australia

Senator Ruth Webber
ALP, Western Australia

Senator Claire Moore
ALP, Queensland

Senator Carol Brown
ALP, Tasmania

Senator Kerry Nettle
AG, New South Wales

ADDITIONAL COMMENTS

SENATOR STOTT DESPOJA
SENATOR WEBBER

1. The Inquiry by the Senate Community Affairs Committee into *Legislative Responses to Recommendations of the Lockhart Review* considered both Senator Patterson's Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 and an exposure draft of our Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006.

2. The Lockhart Committee delivered their report to the then Minister for Ageing, the Hon Julie Bishop MP, on 19 December 2005. In closed door discussions Cabinet summarily rejected the findings of the extensive, independent and expert review process that it instituted.

3. The way the report of the Lockhart Committee was treated suggested the Government had a pre-determined view and sought only to justify that view.

4. Senator Stott Despoja announced her intention on 24 March 2006 to sponsor a private member's bill to implement the scientific recommendations of the Lockhart Review[1]. The exposure draft private members' bill was many months in the making and was intended to bring this debate out into the open where such an important scientific and ethical issue belongs.

5. We are glad to see that it has done so. After pressure from the Democrats, the Opposition, and Members of the Government's own backbench, the Prime Minister agreed to a debate and conscience vote on any legislation brought before Parliament intending to implement the recommendations of the Lockhart Review.

6. Following the Prime Minister's decision, Senator Patterson also announced that she would be tabling a bill to implement the Lockhart recommendations.

7. While acknowledging that the Government would be much more comfortable debating a bill from its own side, we persisted in tabling an exposure draft of our bill to enable the Community Affairs Committee to commence their inquiry with a complete bill.

8. The Community Affairs Committee has not made any judgement on the appropriateness or strength of either Senator Patterson's bill or our bill.

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[1] *The Age*, 24/03/2006.

9. In the interests of ensuring that Parliamentary debate focuses on the Lockhart recommendations and does not get bogged down by comparing two separate approaches to implementing them, we will not be tabling a final draft bill.

10. The Senate will focus on one bill only and we acknowledge the political reality that the Prime Minister would prefer to debate Senator Patterson's bill.

11. We will, however, be moving some amendments where we believe that our exposure draft bill affords a better approach or where the Committee process has highlighted key issues that should be addressed in any amended legislation. These include:

- Increasing the maximum penalty for all Division One offences to 15 years;
- Reducing the maximum life of a warrant from one month to 15 days;
- Replacing Schedule 2, Item 15, (referring to Subsection 20(1)) of Senator Patterson's bill with Schedule 2, Item 13 of our exposure draft bill. This will ensure that the legislation is not so prescriptive in what can be applied for with a licence that new techniques that might be developed fall outside the legislation. Our approach sets the overarching prohibitions but allows the NHMRC Licensing Committee some flexibility in awarding licences. Our view that this is a better approach has been supported by views offered during the Committee process suggesting that legislation has difficulty keeping pace with scientific change[2];
- Altering the clauses dealing with fresh ART embryos deemed unsuitable for implantation to include these embryos under the definition of 'excess ART embryos' – as laid out in Schedule 2, Item 5 of our exposure draft bill; and
- Removing reference to human eggs in Schedule 2 of Senator Patterson's bill, so any amended legislation does not extend to activities with human eggs beyond the prohibitions listed in Schedule 1. We support the view of organisations such as ACCESS and the Fertility Society of Australia that NHMRC guidelines are a more appropriate means of regulating activity with human eggs than legislation[3].

Senator Natasha Stott Despoja
AD, South Australia

Senator Ruth Webber
ALP, Western Australia

[2] Canon Alan Nichols, *Submission 7*, p.2.

[3] ACCESS, *Submission 176,* p.2; Fertility Society of Australia, *Submission 40,* p.2.

CORRIGENDUM

Additional Comments from Senator Kerry Nettle

Egg Donation

Issues were raised throughout the course of the Senate Inquiry about the donations of eggs by women for embryonic stem cell research.

Witnesses compared the procedures surrounding the donating of eggs for embryonic stem cell research to those surrounding the donating of organs or tissues.

Women's Forum Australia wrote on page 7 of their submission:
'a better model to describe egg donation by women is altruistic organ donation by living donors to strangers (for example a kidney or liver lobe)'

The issue was raised during the inquiry about whether or not women donating eggs and/or their families should have a right to any benefits or treatments that come about as a result of their donation.

Recommendation 45 of the Lockhart Review states:
'donors of tissue that is going to result in immortal stem cell lines 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.'

Some IVF clinics are making arrangements with women who donate eggs in relation to this issue.

Sydney IVF indicated in their submission:
'in each instance of embryo donation for research… we require of users of resulting stem cell lines their agreement that they will never object to our retaining early-stage stem cell samples for possible future use to benefit the family that made the donation.'

It is important for Parliament to not just leave it to IVF clinics to make different, individual, commercial arrangements with the women who donate eggs to them about this issue. Rather Parliament should indicate what rights, if any, women and their families have to benefits from research done on the woman's donated eggs. This can be done either through legislation, regulation or through the NHMRC guidelines and other procedures.

A comment in the Sydney hearings from Dr Sidhu of the Diabetes Transplant Unit at Prince of Wales Hospital and University of New South Wales highlighted this:
'That is a big issue at the present moment but, as I said, when the patients sign those papers what the regulations say from an ethics point of view and other points of view, depending on your institution, is that they sign that anything subsequently developed from that donation will not be the property of the patient.'

Recommendation 32 of the Lockhart Review states:
'the NHMRC should develop guidelines for egg donation' but it does not ask or require the NHMRC to go into any more detail about whether or not women who donate eggs should have access to any benefits or treatments that arise from research done using their donated eggs.

Senator Patterson asked Dr Sidhu from the Diabetes Transplant Unit at Prince of Wales Hospital and University of New South Wales about how possible it was to keep track of donors in order to link their donation with any breakthroughs in research.

Dr Sidhu*—There is a difficulty at the present moment, but I think we are improving at tracing back day by day—for example, keeping track with a database and other stuff. Possibly, yes, we can trace back to the donors, but the issue remains of the intellectual property at the present moment and which way we want to go.*

Sydney IVF wrote in their submission:
'The fact is that there is about a 25% chance (actually slightly less) that a human embryonic stem cell line created from an embryo from a couple will be completely immunologically compatible with any of that couple's children. Justice is not served if stem cells derived from such embryos are prevented from being "donated" to a child of the couple.

Please note that use on this basis within families applies only to the children of the couple; such stem cells are not genetically compatible with either parents or, for example, with any grandchildren.'

It is important to ensure that any system to ensure that women donating eggs and their children have access to any benefits or treatments derived from their eggs does not become a de facto method of payment to or inducement of women to donate eggs.

The committee did not hear any support for women being paid to donate eggs. Indeed the committee heard several groups express concern about the possibility of such payments occurring.

Women's Forum Australia describe on page 12 of their submission:
'The North East England Stem Cell Institute now offers women IVF at a reduced cost in return for their surplus eggs for research.'

The process described by Sydney IVF in their submission regarding arrangements with the users of stem cell lines derived from donated embryos to keep stem cell samples for the benefit of donor families may be a useful model for parliament to adopt. This model ensures that there is no direct link between a woman donating eggs and any benefits or treatments she or her family may receive that could become, or be seen as, a de facto method of payment or inducement to donate eggs.

Dr Munsie from Stem Cell Sciences Ltd. described the process that occurs in the UK.

Dr Munsie*—As I understand the UK system, when you obtain a licence in the UK you undertake to deposit a sample of your line in the bank. So that is perhaps something that could be contemplated in Australia.*

Recommendation

That the Parliament amend the Research Involving Human Embryos Act 2002 to require all licence holders to deposit a sample of any stem cell lines that they derive to be deposited in a publicly run national stem cell bank.

Commercialisation

The Senate Committee and the Lockhart Review heard a range of views about the commercialisation and privatisation of embryonic stem cell research and any benefits or treatments to arise from such research.

Victorian Premier Steve Bracks was reported in The Australian October 2 this year to have said that Australia will lose billions of dollars in income and lag behind the world scientific community if the ban on therapeutic cloning is not lifted.

The Lockhart Review states on page 140:
'People are concerned that these benefits and profits remain in the public domain, through public ownership, and that therapies remain available within the public health system.'

Witnesses that appeared before the Senate committee were asked to comment on these issues and responded with a number of suggestions about what needed to be done to ensure that any benefits of this research remained in the public domain.

Professor Bernie Tuch the Director of the Diabetes Transplant Unit at Prince of Wales Hospital and University of New South Wales stated that money was required to keep research in public hands:

***Senator NETTLE**—My particular interest in this area is in ensuring that any therapies that do come from embryonic stem cell research are available in the public domain and, ideally, through the public health system. Of course it is always a very difficult thing to do, and especially at this point in the development of the research. One proposal that has been put to me is about requiring people when they made applications to the licensing committee to address in their application, and then for the licensing committee to look at, what contribution their research would make to reducing the global health burden, or some similar phraseology to allow that public interest and public health component to be in it. I wondered if you have a view about the feasibility of that or how that would work, and if you have any other suggestions for ways to inject that public health component into—*

***Prof. Tuch**—Sure, it is called money. I work in a public hospital, as part of a university. We put our hands up some time ago and said, 'Thank you very much, we'd like to be able to create some embryonic stem cells lines and we'd like a good manufacturing practice facility to be able to produce them for the public good.' Basically government—let us leave out who—said 'That's nice,' but never supported it. In the end we had to do it privately to push the thing along. To create our embryonic stem cell line we took an initiative not from the public but from private foundations who had enough vision to be able to say, 'Let's move it; let's not sit around waiting.' To be able to do that, a relationship was built up with the hospital involved, the private foundation and the IVF foundation so that all parties would gain from it. So there was a benefit. But if you do not put money behind it you expect people to sit. They are not going to do nothing, in which case the only other options, I guess, are private organisations or foundations. You cannot expect, in five or 10 years time when things*

are developed, that things are going to be easy for the public situation unless you are prepared to put funding up-front to support it. In other words, once legislation gets passed—as it was passed four years ago—you have got to have the funding available generally to allow it to be implemented; otherwise you will not reap the benefits so easily.

Professor Tuch comment later:
'It is an issue of: if you want it, you invest the funds in development organisations and you say what is produced is public.'

Witnesses at the public hearings were asked whether the NHMRC could be required to assess whether any treatments would be provided through the public domain and how those treatments would be equitably delivered, through the public health care system or through other mechanisms.

Professor Warwick Anderson, Chief Executive Officer of the NHMRC replied that *'if parliament did wish for such a consideration to be taken into account, the NHMRC could certainly add that to the process.'*

Some witnesses indicated that given the preliminary nature of the current embryonic stem cell research into possible treatments for human disease such an assessment maybe difficult at this stage.

Recommendation
That the Parliament amend the Research Involving Human Embryos Act 2002 to require the NHMRC Licensing Committee in deciding whether to issue a licence to have regard to not only the likelihood of significant advance in knowledge or improvements in technologies for treatment as a result of the use of excess ART embryos proposed in the application and the capacity of such benefits to be delivered through the public health system and/or reduce the global disease burden.

Stem Cell Bank

The Research Involving Human Embryos Act 2002 and the Prohibition of Human Cloning Act 2002 both required the Lockhart Review to look at *'the applicability of establishing a National Stem Cell Bank.'*

Recommendation 47 of the Lockhart Review states:
'A national stem cell bank should be established.'

Neither Senator Patterson's Bill nor the exposure draft of Senator Stott-Despoja and Senator Webber's bill legislate for a national stem cell bank.

Senator Stott-Despoja indicated in her second reading speech that *'this is partly because a national stem cell bank does not necessarily require legislation.'*

Senator Stott-Despoja says in her second reading speech:
'This bill requires the Attorney-General's Department and the Department of Health and Ageing to examine in some detail the issues surrounding a stem cell bank.'

Senator Patterson's bill requires the Minister to report to Parliament within six months on the establishment of a National Stem Cell Centre.

The committee received submissions that highlighted the important role that a national stem cell bank can play in keeping this research in public hands.

Associate Professor Wendy Rogers from Flinders University stated in her submission:
'Finally, some of the key issues in the Lockhart Report have not been addressed in the proposed legislation. In particular the establishment of a stem cell bank and conditions for benefit sharing are not considered. Some of the reasons for these omissions have been explained, but in my view there is a serious ethical issue of equity that arises when tissues donated by Australians for the benefit of the Australian community (including both researchers and patients) are then used to develop commercial products for private enterprise. The products and profits from the research involving SCNT and the development of stem cell lines including a stem cell bank (should they proceed in Australia) should remain in public control, and equally available within the public healthcare system. The current climate of competition between the states for commercial biotechnology investment raises concerns that there will not be public ownership of many resources donated by Australian women for stem cell research. It is appropriate that any legislation recognises the interest of those groups who provide the basic resources for the development of potential therapeutic treatments in having access to those treatments.'

Professor Robert Williamson from the Australian Academy of
Science stated at the Canberra hearing why he supported a stem cell bank:
'I personally think—and I think it would be the academy's view on this—that everyone, whatever their view on the more general issues, should support this particular recommendation. In the first place, if we have a national stem cell bank, that bank reduces the number of experiments that will be done on embryos. In the second place, it guarantees a level of transparency because people will be noted as using it. And, in the third place, it will operate in practice to facilitate public rather than private research. For all of those reasons, I think everyone should support bringing this in as quickly as possible.'

Recommendations 48 of the Lockhart states:
'Consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem bell bank.'

In its submission to the Senate Committee the Australian Stem Cell Centre was supportive of this notion, suggesting it was:
'the logical organisation to oversee a national stem cell bank as it has an existing cell storage facility and trained staff.'

In the Prime Minister's press release of 23 June 2006 he indicated:
'The Government also supports further exploring the establishment of a national register of donated excess embryos created originally for ART purposes and a national stem cell bank. This infrastructure would offer a way of assisting research by making donated excess embryos and stem cell lines more widely available to the research community.'
Currently both Senator Patterson's Bill and the exposure draft of Senator Stott-Despoja and Senator Webber's bill require reports to be made to parliament about establishing a stem cell bank.

The establishment of a national stem cell bank is an important mechanism for ensuring that embryonic stem cell research occurs in the public domain and that any benefits from this research remain in the public domain.

The Australian Greens moved amendments to the Research Involving Human Embryos Act in 2002 that required the government to establish a national stem cell bank. These amendments were not passed by the Lockhart Review looked at the issue and recommended that a national stem cell bank should be established.

The Parliament must ensure that this occurs.

Professor Livesey, CEO of the Australian Stem Cell Centre described an overseas example where developing a stem cell bank had taken between 18months and 2 years.

Prof. Livesey*—It took us six months to develop our repository. As for developing that further into a bank after a feasibility study, the Scotland stem cell network has been involved in the development of a GMP bank there and they took somewhere between 18 months and two years to fully establish it.*

Recommendation
That the Parliament amend the Research Involving Human Embryos Act 2002 to require the government to establish a publicly run national stem cell bank within 2 years.

Senator Kerry Nettle
AG, New South Wales

Additional comments by Senators Polley, Stephens and Hogg

1. Cloning, whether to create embryos for destruction in research, or for implantation to birth, is still cloning. Neither language nor semantics can disguise this fact.

2. In 2002, both Houses of the Australian parliament unanimously rejected all forms of human cloning (i.e. reproductive and therapeutic) and approved the release of surplus IVF embryos for research and study.

3. However, only 30% of the surplus IVF embryos have been used for obtaining embryonic stem cells for research. The other 70% have been used for training clinicians and for refining infertility treatment.

4. Some scientists are now seeking other sources of embryonic stem cells, namely from cloned human beings or cloned animal/human hybrid embryos, achieved by the process of SCNT.

5. In 2002, the option was available for any Senator or Member of the House of Representatives to move an amendment to allow for therapeutic cloning whilst banning reproductive cloning. No one did.

6. This debate is about crossing an ethical line, i.e. deliberately creating cloned human embryos expressly for destruction to obtain stem cells for a wide range of research.

7. The current debate is not about the efficacy of adult stem cells versus human embryonic stem cells obtained from excess IVF embryos.

8. This quantum leap in research is being advocated well in advance of similar research being done on cloned animal embryos.

9. Some scientists are therefore asking for the freedom to pursue this research on relatively weak grounds purely and simply because they want to go down this path.

10 Bad science cannot justify this freedom, even if it may be regulated by a government authority.

11. We believe that the Patterson Bill and similar Bills should be rejected in their entirety.

Senator Helen Polley
ALP, Tasmania

Senator Ursula Stephens
ALP, New South Wales

Senator John Hogg
ALP, Queensland

FAMILY FIRST

Additional Comments

Inquiry into the Legislative responses to Recommendations of the Lockhart Review

We all want cures to debilitating diseases	FAMILY FIRST wants cures as much as anyone else. FAMILY FIRST wants scientists to find cures to all manner of debilitating diseases. However, the evidence presented to the Committee has reinforced FAMILY FIRST's concerns about the Lockhart Committee's report and reinforced our view that cloning human embryos will not produce the cures we all desire. Promising cures from such research is simply peddling false hope to some of the most vulnerable members of our community.
Embryonic stem cells from cloned embryos cannot be used for cures	The scientific facts must be considered. A number of scientists gave credible evidence that embryonic stem cells from cloned embryos will not be able to be used for cell therapies. Why then would we pursue this path, which is also fraught with ethical problems? Only adult stem cells can repair adult tissue.
Parliament should set ethical boundaries	Focussing on the ethics, it is appropriate that the Parliament set ethical boundaries around science to reflect medical ethics and community concern about cloning human embryos for research. FAMILY FIRST's comments focus on the Lockhart recommendations about cloning human embryos.
Three reasons to oppose cloning human embryos	While FAMILY FIRST wants cures, we strongly oppose cloning human embryos for research for three reasons: 1. The science tells us this will not produce cures; 2. Concerns about sourcing human eggs from women for cloning; and, 3. We would be crossing a major ethical line, because for the first time we would be deliberately creating a human being with the intention of then destroying it.

The Science

Evidence to the Committee challenges the prevailing view that cloning embryos is necessary to find cures to diseases.

Emeritus Professor John Martin from the University of Melbourne submitted that

> There is no evidence from animal experimentation, in Australia or elsewhere, that animal ES cells can be used as treatment for any disease in a manner that is effective, and is safe in the long term. Of course there have been no trials of human ES cells in man. Animal models of several of the relevant diseases exist, which provide this as an open and obvious way to search for evidence to support the credibility of therapeutic cloning. There could be no possible purpose in therapeutic cloning unless it is established that ES cell therapy can be applied effectively and with long term safety.[1]

Professor Martin argued that

> We need to do a lot more work in animals and a lot more work on the properties of human embryonic stem cells, which is already permitted under the legislation. Until we have all that information, what could be the specific reason for trying to make an embryonic stem cell line that is specific to an individual? If this legislation were to go through, what would be the first question to be asked? It would be difficult to justify anything.[2]

Professor James Sherley from the Massachusetts Institute of Technology testified that

> … embryonic stem cells cannot be used to develop new adult therapies … based on the fact that the only way it is possible to do it is to take the embryonic stem cells and turn them into adult stem cells. If we were to go to that path, then all of these problems that are being presented to us in adult stem cells would also exist on that path as well, and in addition to those problems would be all the problems that embryonic stem cells bring along with them, and that is the tumour information and the problems with gene expression.[3]

Professor Sherley explained that

> … embryonic stem cells cannot fulfil the job of adult stem cells and mature tissues because they were designed by Mother Nature to work in the embryo and not in the adult. Effective repair and regeneration of mature tissues can only be done by adult stem cells … The corollary to this failing of embryonic stem cells is that continued advances in research on adult stem cells, which are the natural cells for repair and regeneration of mature adult tissues, hold promise for continuing advances in medicine for currently incurable diseases in children and adults.[4]

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1 Professor T John Martin, submission 35

2 Professor T John Martin, Committee Hansard, 24 October 2006, page CA35

3 Professor Sherley, Committee Hansard, 24 October 2006, page CA54

4 Professor Sherley, Committee Hansard, 24 October 2006, page CA44

Professor Peter Silburn from Griffith University asked the rhetorical question: "do we need to clone to get adult cells to try and treat disease? No, we do not."[5] "From my point of view as a scientist, I do not think that we need to go and use somatic cell nuclear transfer to generate cells to study disease or treat patients."[6]

Dr Renate Klein, former associate professor at Deakin University, explained how cloning damages the embryo and the embryonic stem cells extracted from the cloned embryo:

> The difference with embryonic stem cells derived from a clone is that they are even less useful than embryonic stem cells from an IVF embryo. When you clone, the process of cloning so damages the software in that embryo that you get epigenetic damage to the point that cloned embryonic stem cells can be rejected as foreign even by the animal that was cloned because of the genetic damage that accumulates.[7]

There is also dispute over whether conditions like Alzheimer's can be treated by embryonic stem cells from cloned embryos.

> Professor Colin Masters, Australia's leading authority on degenerative diseases of the brain, dismissed as "beyond our imagination" any proposal for stem cell therapy in Alzheimer's. Adelaide embryo researcher, Professor Peter Rathjen, put it more bluntly in the Australian newspaper as "bloody nonsense". No serious medical expert, here or overseas, will dispute that judgment.[8]

In contrast to the difficulties of using embryonic stem cells from cloned embryos, "adult stem cells are the only type of stem cells for which there are current clinical treatments. Transplantation of bone marrow, which contains adult blood stem cells, to restore blood cell production is a well-known adult stem cell therapy."[9]

Professor Silburn explained the usefulness of adult stem cells:

> … adult stem cells exist and from a single person can be turned into multiple different cell types in animals as well as humans (Murrell et al 2005). Importantly disease specific and patient specific adult stem cells have already been generated in Australia from patients with different diseases. Each disease type attempted has resulted in stem cells being obtained and cells have been generated which involve the disease cell type as well as others.[10]

Professor Alan Mackay-Sim from Griffith University spoke about the advantages of adult stem cells:

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5 Professor Peter Silburn, Committee Hansard, 20 October 2006, page CA27

6 Professor Peter Silburn, Committee Hansard, 20 October 2006, page CA30

7 Dr Renate Klein, Committee Hansard, 24 October 2006, page CA109

8 Do No Harm, submission 105

9 Professor James Sherley, submission 181

10 Professor Peter Silburn, submission 180

> I can tell you now that we have over 50 cell lines from people with disease, and they are much easier to make than somatic cell nuclear transfer therapeutically cloned cells, which cannot be made currently in humans. You could take them from people with a range of diseases, for some of whom you know the genetic cause and for some of whom you do not, but they have the same clinical symptoms, and you could compare the cell biology of tho se and find out what is commonly going wrong. That is unlikely to happen with somatic cell nuclear transfer or therapeutically cloned cells because of the difficulty.[11]

There was also evidence that the Lockhart Committee's proposal that animal eggs be used to clone human/animal hybrid embryos for research be rejected:

> Both the Stem Cell Sciences submission and mine quite independently make the point that in relation to research [use of animal eggs] would be uninterpretable, in relation to training it is unnecessary and in relation to therapy it would be totally unacceptable by any regulatory body.[12]

Professor Sherley questioned the logic of funding research into embryonic stem cells from cloned embryos which would not produce cures.

> Opportunity costs are often overlooked. The cost of taking money that is available now for conventional disease research and money that could be dedicated to increasing the amount of support for adult stem cell research and shifting it to embryonic stem cell research would be okay if there were going to be the benefits from embryonic stem cell research that have been promised. My main message both before and now is that the money that goes into cloned embryos and the stem cells derived from that may very well give information about the science of human embryos, but it will not lead us to new therapies for adults and children. If the goal is to improve the health and the welfare of the Australian people, this is not the way to do it.[13]

Professor Martin stressed that Australia would not lose if Parliament did not approve cloning human embryos:

> We have waited over the last four years and nothing of any substance has happened to advance the case towards a compelling argument for the very specific step of SCNT, or therapeutic cloning. When you say that Australia will suffer from this, I cannot actually see how Australian science will suffer from it. The first step that would need to be taken is a major effort to successfully undertake human SCNT. No-one in the world has ever done it.[14]

This was backed by the report of mpconsulting, which told Cabinet there had been no scientific developments to justify lifting the ban on cloning embryos:

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11 Professor Mackay-Sim, Committee Hansard, 23 October 2006, page CA84

12 Dr Peter McCullagh, Committee Hansard, 20 October 2006, page CA23

13 Professor Sherley, Committee Hansard, 24 October 2006, page CA55

14 Professor T John Martin, Committee Hansard, 24 October 2006, page CA36

> On the basis of advice from the NHMRC it would not appear that there have been any other scientific developments relevant to the question of whether the ban on the creation of embryos by SCNT should be lifted.[15]

Several submissions noted that the Lockhart Committee had been unable to point to scientific advances to justify changing the law:

> The only peer-reviewed papers reporting successful human cloning to blastocyst stage in the Lockhart Report were those by Hwang et al. This work has since been discredited. … In view of the original brief to the Committee, since there has been no scientific progress to justify a change in the law, we suggest that all forms of human cloning should continue to be prohibited.[16]

> The failure [of the Lockhart Committee] to address whether there was an established necessity to create human embryos for research purposes was an instance of a failure to address the facts. In fact the animal studies so far have not established proof of concept for stem cell therapies derived from SCNT embryos.[17]

> … the Lockhart Report was unable to report any clinical advances to justify a change in the law. Even if human embryonic stem cells were produced from human clones tomorrow, it would not be possible to use them on human subjects and we are concerned that this problem is not sufficiently addressed in the report.[18]

FAMILY FIRST concludes there are no strong scientific reasons to change the law to allow cloning of human embryos.

Ethical limits to science

There was concern about ensuring appropriate ethical limits to science. Dr Megan Best argued "there are some things which we have to accept we will never know because the method by which we can discover them is unacceptable on ethical grounds."[19]

There were particular concerns about the Lockhart Report's approach to ethics:

> … a basic concern of the SIE is that the notion of 'what can be done must be done' pervades the Lockhart review, with the accompanying ethos that if any scientific advantage can be had, however theoretical, then any ethical concerns are immediately outweighed. Yet ethical boundaries in medical

15 mpconsulting, *Analysis of Advice on Developments in Assisted Reproductive Technology and Related Medical and Scientific Research*. Prepared for the Department of the Prime Minister and Cabinet, June 2006. Page 22.

16 Social Issues Executive, Anglican Church, submission 41

17 Dr Nicholas Tonti-Filippini, submission 15, page 8

18 Social Issues Executive, Anglican Church, submission 41

19 Dr Megan Best, Social Issues Executive, Anglican Church, Committee Hansard, 23 October 2006, page CA15

> research have not caused medical research to stop progressing, but instead have moved it forward by promoting creative solutions …[20]

There was also a warning that, should Parliament allow the cloning of human embryos for research, we would be looking next to reproductive cloning, or cloning to produce a live baby.

> My concern is that there is no way once technology is developed that we can restrain its applications. I know that we have safeguards in the bill and I think, as I said in my submission, it is very touching that we have such faith in human nature, but our history as human beings has shown that once technology is developed we cannot restrain its application for bad purposes as well as good. I think we all accept that our community is opposed to reproductive cloning and the only way we can ensure that it will not go ahead is to stop the development of cloning technology.[21]

Professor Mackay-Sim said technology had not always been used in ways originally intended:

> But I do not see a distinction in the technology between making a blastocyst one way going to therapeutic cloning and one way going to cloning human beings. I think that process is the same, and I think that is the ethical decision that is being made. If you go by the history of technology, that technology will be used for purposes for which it was not intended in the particular jurisdiction—that is, to do therapeutic cloning.[22]

Professor Mackay-Sim pointed to a practical example:

> I remember hearing Professor Wilmut being interviewed on the radio when Dolly the sheep was cloned—and he, of course, led that group. He was asked about human cloning and he said, 'Why would anybody want to clone human beings?' He is now the second person in the UK who has applied for a licence to do therapeutic cloning. Views change; science changes. Once one can see the potential, people will change their views.[23]

In fact, Professor Wilmut has gone even further and now advocates reproductive cloning as the GeneEthics Network documents:

> In 1997, when Ian Wilmut announced Dolly the sheep had been cloned, the almost universal response from all section of society was that this technology must never be used on human beings. But within a short time advocates began to propose a variety of possible justifications for cloning in human research and for human reproduction. Wilmut has shifted from his 2002 position that, "nobody should be attempting to clone a child" to now advocating cloning and germline gene manipulation, to produce children.[24]

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20 Social Issues Executive, Anglican Church, submission 41

21 Dr Megan Best, Social Issues Executive, Anglican Church, Committee Hansard, 23 October 2006, page CA16

22 Professor Mackay-Sim, Committee Hansard, 23 October 2006, page CA75

23 Professor Mackay-Sim, Committee Hansard, 23 October 2006, page CA91

24 GeneEthics, submission 106

FAMILY FIRST believes there must be appropriate limits on science and the Lockhart Report goes too far by advocating embryo cloning.

Definition of an embryo

Definitions of human embryos have become central to the debate because: (1) the two embryo cloning bills have adopted a new definition, (2) it has been claimed that an embryo cloned by somatic cell nuclear transfer is not really an embryo or not if it is not implanted in a uterus, and (3) it is also claimed that cloned embryos do not have the same moral status as conventionally produced embryos.

The Private Members Bills of Senators Patterson and Stott Despoja both use a definition contained in a *discussion paper* by a National Health and Medical Research Council (NHMRC) Working Party. The NHMRC actually confirmed in the hearings that "this does not represent council's definition of an embryo."[25]

A number of submissions and witnesses expressed concern at this definition, as it omits stages of embryonic development covered by the current definition and could be used by scientists to escape regulation.

> The new definition enables destructive research on whole classes of embryos either presently protected, or whose generation is prohibited by the 2002 legislation. [26]

There was discussion about the failures of the new definition:

> Part (a) arbitrarily makes the beginning [of the human embryo] not when the first cell is formed, but at a point sixteen hours later when the first cell begins to divide to form two cells. The new entity exists when the first cell is formed by the fusion of the two cells … The effect would thus be to remove the embryo for the first sixteen hours of development from the scope of regulation, either ethical or legal.[27]
>
> … the second part of the definition would allow an interpretation that a cloned embryo was only an embryo if it is to be implanted. Thus it would be permissible, using this definition, to form embryos by cloning, as long as they were not to be transferred into an environment where it would be possible for implantation to occur and development to the stage of the formation of a primitive streak. Those unimplanted, cloned embryos would then be completely outside the regulatory framework established by the guidelines and by the proposed legislation.[28]

It is inappropriate to use a draft definition in such a technical area in important legislation.

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25 Professor Anderson, NHMRC, Committee Hansard, 20 October 2006, page CA19.

26 Australian Federation of Right to Life Associations, submission 37

27 Dr Nicholas Tonti-Filippini, submission 15, page 3.

28 Dr Nicholas Tonti-Filippini, submission 15, page 3.

Some people have also claimed that human embryos cloned by somatic cell nuclear transfer are not really embryos, because they are not created in the usual way by the union of ova and sperm.[29]

This position was refuted by the current legislation banning cloning, by the Lockhart Committee and by numerous witnesses.

The Lockhart Committee found:

> … human embryo clones are human embryos and that, given the right environment for development, could develop into a human being. Furthermore, if such an embryo were implanted into the body of a woman to achieve a pregnancy, this entity would certainly have the same status as any other human embryo, and were this pregnancy to result in a live birth, that child would enjoy the same rights and protection as any other child.[30]

But the Lockhart Committee did regard cloned embryos "as having a different moral status from the embryos that are created in fertility programs."[31]

The Social Issues Executive of the Anglican Church explained:

> The Lockhart Committee denied the moral significance of a cloned human embryo on the grounds that it was indeed created for destruction; but the nature of a human embryo does not alter because of others' plans for it. It remains a human being and dismissing it as 'a cellular extension of the original subject' (p.xvii) is a mere semantic claim that changes neither the biology of this kind of embryo nor the moral concerns inherent in its use.[32]

Professor James Sherley stated that "It is the cellular make-up of an embryo that makes it an embryo. Not its location."[33]

> … the embryo is defined by its cellular properties. It is a fact that we have a complete human genome – that is in the cytoplasm of the milieu of an egg, which has been reprogrammed by that egg to start the developmental process. It does not really matter whether you have it in a dish or in the uterus of a woman; it is an embryo.[34]

Do No Harm said claiming a cloned embryo was not a real embryo was "biological nonsense".

> An embryo is an embryo no matter how it is made. Cloning is simply one way of making an embryo; uniting egg and sperm is another. Dolly the

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29 For example, Committee Hansard, 23 October 2006, page CA81 or Committee Hansard, 24 October 2006, page CA104.

30 Legislation Review Committee (Lockhart Committee), Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002. December 2005. Page 170

31 Professor Loane Skene, Committee Hansard, 20 October 2006, page CA9

32 Social Issues Executive, Anglican Church, submission 41

33 Professor James Sherley, submission 181

34 Professor Sherley, Committee Hansard, 24 October 2006, page CA53

> sheep, formerly Dolly the embryo, did not result from the union of egg and sperm, but was clearly no different to any other embryo in that she was able to be born as a lamb. In the *Prohibition of Human Cloning Act 2002* the definition of embryo clearly includes those made "by any means other than by the fertilisation of a human egg by human sperm", specifying cloning techniques (SCNT) as one such means. [35]

Dr David van Gend referred to an editorial in the journal *Nature* which

> …condemned the International Society for Stem Cell Research in a very short editorial called 'Playing the name game'. It said:
>
> > 'Stem-cell biologists should not try to change the definition of the word 'embryo'.'
>
> In this very powerful, brief editorial—I am sorry it is not in your current collection, but I have tabled it—it said:
>
> > 'Whether taken from a fertility clinic or made through cloning, a blastocyst embryo has the potential to become a fully functional organism, and appearing to deny that fact will not fool diehard opponents of the research. If anything, it will simply open up scientists to the accusation that they are trying to distance themselves from difficult moral issues by changing the terms of the debate.'[36]

The same *Nature* article details the work of the International Society for Stem Cell Research in deciding to use the term 'somatic cell nuclear transfer' instead of 'therapeutic cloning' because "… the work 'cloning' was generating public concern".[37]

Some people have tried to portray cloning embryos for research as a different technique to cloning embryos for reproduction. Professor Mackay-Sim explained:

> The development of stem cells—the development of the technology to make blastocysts to make therapeutically cloned cells—is, to my interpretation of the science, no different. You do the somatic cell nuclear transfer—you make your blastocyst—and, on the one hand, under some jurisdictions, you put those into a dish and make embryonic stem cells; however, in other jurisdictions, and in an international context, you could clone human beings with that technology.[38]

FAMILY FIRST believes it is important that people in the embryo cloning debate do not use language designed to confuse people or hide the truth.

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35 Do No Harm, submission 105

36 Dr David van Gend, Committee Hansard, 24 October 2006, page CA112

37 Playing the Name Game, *Nature*, Vol 436, 7 July 2005

38 Professor Mackay-Sim, Committee Hansard, 23 October 2006, page CA71

Source of eggs for cloning

Cloning embryos requires a supply of eggs and the only source of human eggs is the ovaries of women. Given the discredited Korean cloning research team used more than 2000 eggs for no result, this is a real cause for concern. [39]

Professor Silburn explained that "as cloning is extremely inefficient it has long been recognised that there will not be enough eggs to permit the achievement of the goal of obtaining disease specific or patient specific stem cells from human cloning by Somatic Cell Nuclear Transfer (SCNT) and use of human eggs."[40]

Some groups fear the implications of a demand for eggs if embryo cloning is permitted.

Women's Forum Australia detailed dangers for women in their submission:

> Cloning depends on a continuous supply of ova which can only be achieved with high doses of ovulation stimulating agents. There is increasing evidence that the super-ovulation process is associated with serious health risks, including death. The long-term health impacts might include reproductive cancers.[41]

FINRRAGE pointed out that:

> These serious health risks are not surprising considering that superovulation drugs can stimulate women's ovaries to produce up to 30 eggs a month instead of the usual one in a natural cycle.[42]

Dr Sheryl de Lacy said cloning should be banned until such issues are resolved.

> It is my view that we should not proceed further by expanding regulatory policy to include SCNT research until we have fully considered the implications to the community in sourcing material for this work. Specifically we need to consider where the genetic material required for progress will be sourced and under what conditions we are comfortable with it being obtained.[43]

WFA questioned the usefulness of informed consent regimes when the full risks of the procedure for taking eggs are not understood:

> It is not meaningful to speak of 'informed consent' when there is a lack of independent assessments about the long term health risks of egg harvesting. … consent must be viewed against the background of powerful social and economic influences that can encourage researchers to downplay the risks of egg harvesting. As Beeson and Lippman have noted, some physicians who extract eggs are also involved in cloning research. 'Seeking consent from

39 Dr Monique Baldwin, submission 57

40 Professor Peter Silburn, submission 180

41 Women's Forum Australia, submission 80

42 FINRRAGE, submission 32

43 Dr Sheryl de Lacy, submission 27

> women in these circumstances is problematic when clinicians have an interest in obtaining their eggs'.[44]

When questioned about whether donating eggs for cloning was the same as extracting eggs for IVF, Katrina George explained that:

> … every medical procedure, as you know, has risks and benefits. It is always a matter of weighing the benefits against the risks. A woman who undergoes egg extraction for IVF assumes same health risks, but the potential benefits are entirely different. She has up to a 40 per cent chance of producing a baby for herself. Where women undergo egg extraction for research, there is absolutely no benefit to them and, indeed, no certain benefit to anybody.[45]

The proposed legislation would make selling eggs illegal, but expenses could be reimbursed. FINRRAGE argued:

> Reimbursement of women's 'expenses' or 'inconvenience' for 'donating' ova may not seem profitable to the people considering this legislation, but it can represent a substantial sum of money to poorer women, particularly students and unskilled or unemployed women.[46]

Inducements did not have to be money.

> … inducements are widely recognised as coming in many forms other than money (Grady 2001). For example, it has recently been argued that so-called informed decisions in medical care and participation in research can sometimes involve simple deference to medical authority rather than self-determination.[47]

Already international restrictions on paying women for their eggs are under pressure because of the demand for eggs:

> It is irresponsible and premature to allow research cloning without identifying a viable source of ova that is safe for women. … Only a few years after the legalisation of research cloning in the UK, the licensing authority has begun to authorise commercial incentives for supplying ova for research.[48]

Failures of the Lockhart Committee

The Lockhart Committee was set up to review the scientific evidence to see if scientific developments justify overturing the ban on cloning embryos and determine if community attitudes supported a change.

Professor Sherley highlighted some of the scientific weaknesses of the Committee:

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44 Women's Forum Australia, submission 80

45 Ms Katrina George, Women's Forum Australia, Committee Hansard, 24 October 2006, page CA59

46 FINRRAGE, submission 32

47 Dr Sheryl de Lacy, submission 27

48 Women's Forum Australia, submission 80

> The constitution of that [Lockhart] committee did not equip it to consider the science adequately in my view. It could have used all the people who were on it, but it needed a broader participation as well. It especially needed an uninvolved, critical view of the science. It also needed the participation of a few people in cell and molecular developmental biology and somebody with experience and expertise in research in at least one of the main diseases that is being talked about as being a therapeutic possibility. My arguments have been based on the science, and I simply do not think the science was adequately canvassed in the Lockhart committee's report.[49]

The Do No Harm submission states that at least three Committee members, including deputy chair Loane Skene, were on the record as strong supporters of cloning embryos for research before they were appointed to the Committee. [50] They already had a predetermined position.

In addition, the Committee has admitted helping to draft the two cloning bills before the Senate:

> [Lockhart] Committee members have assisted both Senator Patterson and Senator Stott Despoja in the preparation of their respective draft Bill and Exposure Draft.[51]

Several submissions complained about the inadequacy of the Committee's approach to determining community attitudes.

> … when it comes to the most crucial part of the Lockhart committee report—which is assessing where the community is at—the report openly makes it clear that it does not have an evidence based perspective. But given that lack of an evidence based perspective, it makes a profound shift and purports to then represent where the community is at. I find that quite astounding …[52]

Do No Harm asks the very reasonable question:

> … why did the [Lockhart] Committee ignore the one major piece of published research, that of Swinburne University in 2004, which found a substantial majority of us – 63% - did not feel comfortable with scientists cloning embryos for stem cells? The Committee preferred to be guided by a non-academic phone poll conducted by … Biotechnology Australia.[53]

The Lockhart Committee did not refer to opinion poll research by Swinburne University and the Sexton Marketing Group for the Southern Cross Bioethics Institute, both of which showed community opposition to embryo cloning.

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49 Professor T John Martin, Committee Hansard, 24 October 2006, page CA41

50 Do No Harm, submission 105

51 Members of the Lockhart Committee, submission 20, page 3

52 Dr Megan Best, Social Issues Executive, Anglican Church, Committee Hansard, 23 October 2006, page CA14

53 Do No Harm, submission 105

Professor Martin notes the Lockhart Committee referred "… to a 2006 Morgan Poll as though it was the only community survey available." But "the information given to respondents is false" in the Morgan poll. "No scientist has yet made a human embryonic stem cell [from cloning]. It also gives an entirely misleading description of cloning. Most lay people would not understand from this description that this process would still form a living human embryo which is then destroyed by the extraction of stem cells."[54]

FAMILY FIRST condemns the Lockhart Committee for failing to do a proper job in critically assessing the important issue of cloning human embryos for research.

Conclusion

FAMILY FIRST believes the Lockhart Committee and supporters of the embryo cloning bills have not made a convincing case for overturing the ban on embryo cloning.

The Senate Committee heard from a number of scientists that there are no strong scientific reasons to change the law to allow cloning of human embryos.

FAMILY FIRST wants cures as much as anyone else. FAMILY FIRST wants scientists to find cures to all manner of debilitating diseases. However, the evidence presented to the Committee has reinforced FAMILY FIRST's concerns about the Lockhart Committee's report and reinforced our view that cloning human embryos will not produce the cures we all desire.

Senator Steve Fielding
Leader of the FAMILY FIRST Party
FAMILY FIRST Senator for Victoria

54 Professor T John Martin, submission 35

APPENDIX 1

LIST OF PUBLIC SUBMISSIONS AND TABLED DOCUMENTS AUTHORISED FOR PUBLICATION BY THE COMMITTEE

1 Tuch, Professor Bernie & Sidhu, Dr Kuldip (NSW)

Supplementary information

- 8 articles tabled at hearing 23.10.06 –

  Rideout WM et al, Correction of a Genetic Defect by Nuclear Transplantation and Combined Cell and Gene therapy, Cell v109 17-27 5April 2002

  Barberi T et al, Neural subtype specification of fertilisation and nuclear transfer embryonic stem cells and application in parkinsonian mice, Nature Biotechnology 21 1200-1207 (2003)

  Owen-Smith J, An international gap in human ES cell research, Nature Biotechnology 24 391 (2006)

  D'Amour et al, Production of Pancreatic hormone-expressing endocrine cells from human embryonic stem cells, Nature Biotechnology published online 19 October 2006-10-25

  Sidhu KS and Tuch BE, Derivation of Three Clones from Human Embryonic Stem Cell Lines by FACS Sorting and Their Characterisation, Stem Cells and Development 15:61-69 (2006)

  Sidhu KS et al, Transgenic Human Fetal Fibroblasts as Feeder Layer for Human Embryonic Stem Cell Lineage Selection, Stem Cells and Development 15:XXX-XXX (2006)

  Lim U-Ming et al, Derivation of Motor Neurons from three Clonal Human Embryonic Stem Cell Lines, Current Neurovascular Research 2006 v3 no4

  Klimanskaya I et al, Human embryonic stem cell lines derived from single blastomeres, Nature published online 23 August 2006

- Response to questions on notice following hearing received 26.10.06.

2 Brock, Dr Paul (NSW)

3 Medway, Rev Brian (ACT)

4 Motor Neurone Disease Association of Victoria Inc (VIC)

5 Soderlund, Mr Benjamin (VIC)

6 Rolfe, Professor Barry G (ACT)

7 Nichols, Canon Alan (VIC)

8 Humanist Society of Victoria Inc (VIC)

9 Pritchard, Br Chris

10 Coyle, Dr Tim (QLD)

11 Name withheld

12 Medicine With Morality (WA)
13 Magree, Mr Brian (VIC)
14 Woodbury, Ms Maria
15 Tonti-Filippini, Dr Nicholas (VIC)
16 Southern Cross Bioethics Institute (SA)
17 Drum, Ms Nola (NSW)
18 Purnell, Mr Bevil (ACT)
19 Fallon, Fr Michael (ACT)
20 Members of the Lockhart Committee (VIC)

Supplementary information

- Letter from Dr PA McCombe dated 18.10.06 *Why I Changed my mind about stem cell research,* tabled at hearing 20.10.06
- Clarification of information and response to questions on notice following hearing on 20.10.06, received 23.10.06, 25.10.06 and 26.10.06

21 Coalition for the Advancement of Medical Research in Australia (CAMRA) (NSW)
22 Motor Neurone Disease Association of NSW Inc (NSW)
23 Coalition for the Defence of Human Life (WA)
24 Sobb, Mr Michael (NSW)
25 Santamaria, Dr Joseph (VIC)
26 Catholic Health Australia (ACT)
27 de Lacey, Dr Sheryl (SA)
28 Apelt, Emeritus Professor Colin (QLD)
29 SpinalCure Australia (NSW)
30 Evangelicals for Life (NSW)
31 Queensland Bioethics Centre (QLD)
32 FINRRAGE (Australia) (VIC)
33 Catholic Women's League of Victoria & Wagga Wagga Inc (VIC)
34 Festival of Light Australia (SA)
35 Martin, Emeritus Professor T John (VIC)

Supplementary information

- Comments on Gough review and Foursight commentary, received 25.10.06

36 Right to Life Australia Inc (VIC)
37 Australian Federation of Right to Life Associations (ACT)
38 Motor Neurone Disease Association of Australia (NSW)
39 Australian Catholic Bishops Conference (ACT)
40 Fertility Society of Australia (VIC)

Supplementary information

- Response to questions on notice following hearing 23.10.06 received 30.10.06.

41 Anglican Diocese of Sydney, Social Issues Executive (NSW)
Supplementary information
- Letter by Doctors Against Cloning dated 16.10.06, tabled at hearing 23.10.06

42 Endeavour Forum Inc (VIC)
43 Pro-Life Victoria (VIC)
44 McLindon, Dr Luke (QLD)
45 Guild of Saint Luke (Catholic Doctors Queensland) (QLD)
46 Roberts, Dr Noel (TAS)
47 Matthews, Mr Leonard (QLD)
48 Burke, Dr Andrew (QLD)
49 Pelekani, Dr Con (SA)
50 Bernauer, Mr Anthony (NSW)
51 Smallhorn, Mr Ron
52 Perrin, Mr David (VIC)
53 Johnston, Mr Adam
54 McEwen, Mr John (NSW)
55 Wilkins, Dr Barry (NSW)
Supplementary information
- Clarification of response following hearing on 23.10.06, received 27.10.06

56 Kidney Health Australia (VIC)
57 Baldwin, Dr Monique (NSW)
58 Heesh, Dr John (NSW)
59 Brenton, Ms Cecily
60 Right to Life Australia Queensland Office (QLD)
61 Rasko, Professor John (NSW)
62 Anglicare South East (NSW)
63 Australian Stem Cell Centre (VIC)
Supplementary information
- Response to comments made at hearing on 24 October, dated 26.10.06

64 Waterhouse, Rev Rod (TAS)
65 Bio21 Australia Ltd (VIC)
66 Australian Family Association (SA Branch) (SA)
67 Rogers, A/Professor Wendy (SA)
68 Caroline Chisholm Centre for Health Ethics (VIC)
69 Calilhanna, Mr Gerard (NSW)
70 Bennett, Mrs Catherine
71 Australian Society for Medical Research (NSW)

72 Federation of Australian Scientific and Technological Societies (FASTS) (ACT)

Supplementary information

- Comments on numbers of embryos and stem cell lines, received 24.10.06

73 Monash Immunology and Stem Cell Laboratories Senior Researchers –

Trounson, Professor Alan
Jenkin, Professor Graham
Elefanty, A/Professor Andrew
Stanley, Dr Edouard
Boyd, Professor Richard (VIC)
Carm, Dr David
Ricardo, Dr Sharon
Bernard, Professor Claude
Wilson, Professor John

Supplementary information

- D'Amour et al, Production of Pancreatic hormone-expressing endocrine cells from human embryonic stem cells, Nature Biotechnology published online 19 October 2006, provided at hearing 24.10.06
- Additional information and response to questions on notice following the hearing, received 25.10.06, 26.10.06

74 Nossal, Professor Emeritus Sir Gustav (VIC)

75 NSW Right to Life Association, Bioethics Committee (NSW)

76 Bullock, Mr Geoffrey (QLD)

77 Lutheran Church of Australia Commission on Social & Bioethical Questions (SA)

78 Catholic Archdiocese of Adelaide, Office of Family and Life (SA)

79 Schroeder, Mrs Lorraine

80 Women's Forum Australia (NSW)

Supplementary information

Response to comments in submission 186, received 26.10.06

81 Religious Freedom Institute Inc (NSW)

82 Sydney IVF Limited (NSW)

Supplementary information

- Response to questions on notice following hearing on 23.10.06, received 23.10.06
- Clarification of response at hearing on 23.10.06, received 27.10.06

83 Don't Cross the Line (NSW)

84 Dodds, Professor Susan (NSW)

85 McCullagh, Dr Peter (NSW)

86 Family Life International Australia Ltd (NSW)

87 Presbyterian Church of Australia (Federal) Church & Nation Committee (SA)

88 Cooper, Ms Donna (QLD)

89 Family Council of Queensland Inc (QLD)

90 Australian Christian Lobby (ACT)

91 Catholic Women's League of Tasmania Inc Social Issues Committee (TAS)

92 Australian Academy of Science (ACT)

Supplementary information

- Key Recent Advances in Human Embryonic Stem Cell Research: *A Review of Scientific Literature Commissioned by the Department of Innovation, Industry and Regional Development, Government of Victoria*
- Progress in Stem Cell R & D, commentary on technological developments in recent years prepared by GJV Nossal and GF Mitchell for the Victorian Government

93 Waite, Professor Phil (NSW)

Supplementary information

- 3 articles tabled at hearing 23.10.06 -

  Keirstead, Hans S et al, Human Embryonic Stem Cell-Derived Oligodendrocyte Progenitor Cell transplants Remyelinate and Restore Locomotion after Spinal Cord Injury, J Neurosci 11 May 2005 25(19):4694-4705 tabled at hearing 23.10.06

  Nistor, Gabriel I et al, Human Embryonic stem Cells Differentiate into Oligodendrocytes in High purity and Myelinate After Spinal Cord Transplantation, GLIA 49:385-396 (2005)

  Faulkner, Jill and Keirstead Hans S, Human embryonic stem cell-derived oligodendrocyte progenitors for the treatment of spinal cord injury, Transplant Immunology 15 (2005) 131-142
- Clarification of response at hearing on 23.10.06, received 26.10.06

94 Christian Democratic Party (NSW)

95 Family Council of Victoria (VIC)

96 Joseph, Ms Rita (ACT)

97 Australian Family Association (VIC)

98 Australian Family Association (NSW) (NSW)

99 Salt Shakers Christian Ethics Group (VIC)

100 Catholic Archdiocese of Sydney, Life Office (NSW)

101 Presbyterian Church of Queensland (QLD)

102 Queensland Right to Life (QLD)

103 Catholic Women's League Australia – New South Wales Inc (NSW)

104 Stem Cell Sciences Ltd (VIC)

105 DO NO HARM – Australians for Ethical Stem Cell Research (QLD)

Supplementary information

- Additional submission and 5 articles provided at hearing 24.10.06 –

  Playing the name game, editorial, Naturev436 7 July 2005

  Proceed with caution, editorial, Nature Biotechnology v23 7 July 2005

  Murrell W et al, Multipotent Stem Cells From Adult Olfactory Mucosa, Developmental Dynamics 233:496-515, 2005

  Savulescu, Julian, Should we clone human beings? Cloning as a source of tissue for transplantation, J Med Ethics 1999, 25:87-95

  Elsner D, Just another reproductive technology? The ethics of human reproductive

cloning as an experimental procedure, J Med Ethics 2006, 32:596-600

- Comments on Gough review and Foursight commentary, received 24.10.06
- Response to comments made at hearing on 24.10.06, dated 27.10.06

106 GeneEthics Network (VIC)

Supplementary information

- Oral submission by Bob Phelps tabled at the hearing 24.10.06

107 Catholic Women's League Australia Inc (ACT)

108 Catholic Archdiocese of Melbourne, Respect Life Office (VIC)

109 Name withheld (VIC)

110 Barbero, RV & PJ (NSW)

111 Murray, Mr Peter & Ms Marianne (VIC)

112 Cooney, Mr Anthony (VIC)

113 Munro, Ms Jane (VIC)

114 Pender, Ms Karen

115 James, Mr Gabriel (NSW)

116 Grocott, Dr Dianne (NSW)

117 Perez, Ms Michele (NSW)

118 Perez, Ms Maria (NSW)

119 Name withheld

120 Higgs, Mr Kenneth (TAS)

121 Gawler, Dr David (NT)

122 Wyborn, Ms Helen (NSW)

123 Harrold, Ms Cheryl (QLD)

124 Goodwin, Dr Belinda (QLD)

125 Malley, Mr Alex

126 Percy, Rev Les (QLD)

127 Name withheld (ACT)

128 McNeice, Mr Grant (ACT)

129 Martello, Ms Angela (NSW)

130 Kenneally, Mr Desmond & Ms Josephine (VIC)

131 Pollock, Mrs Susan (QLD)

132 Denning, Mr Neville (NSW)

133 Mines, Mr Brian (QLD)

134 Turner, Mr Peter (QLD)

135 Nyhuis, Mr Rob (VIC)

136 Dolan, Mr Peter (NSW)

137 Ryan, Dr Neil (VIC)

138 Glancy, Mr John (WA)

139 Briscoe-Hough, Mr Greg (NSW)

140 Mong, Ms Purita
141 McKenna, Ms Bernice (TAS)
142 Wright, Ms Kathy (NSW)
143 Alford, Mrs Margaret (NSW)
144 Buhagiar, Mark, Marie-Rose, Bethany & Joanna (NSW)
145 Barich, Mr John (WA)
146 Holmes (TAS)
147 Constable, Mr Charles (NSW)
148 Caswell, Mr Evan & Ms Kerri-ann (QLD)
149 Blair, Mr Jack & Ms Nanette (NSW)
150 Haines, Mrs Marina (NSW)
151 Young, Mr Peter (SA)
152 Williams, H P (VIC)
153 Brimage, Ms Catherine (ACT)
154 Field, Ms Felicity (VIC)
155 Salkin, Ms Vicki (ACT)
156 Pierce, Mr James & Ms Valda (VIC)
157 Fearis, Mr Neil (WA)
158 Welsh, Mr David (QLD)
159 Jackson, Ms Gillian M (SA)
160 Gill, Dr John A (VIC)
161 Kalpakoff, Mr Daniel (TAS)
162 Nicholls, Dr Ruth (WA)
163 Robinson, Mr Philip & Robinson, Ms Veronica (ACT)
164 Newland, Mr Peter (VIC)
165 Webb, Mr Paul
166 Roberts, Mr David (NSW)
167 Little, Professor Melissa (QLD)
168 National Health and Medical Research Council (ACT)

Supplementary information

- Four booklets: General information about the RIHE Act and PHC Act; Applying for licences; Monitoring Compliance and Information for human research ethics committees tabled at hearing 20.10.06
- Additional information received following the hearing on 20.10.06, received 26.10.06

169 van Oploo, Ms Paula (NSW)
170 Munro, Mr Ronald (VIC)
171 Morley, J M (VIC)
172 Dowling, Mr William (VIC)

173 Wells, Ms Shirley (QLD)

174 Griffin, Miss Margherita (VIC)

175 SA Council on Reproductive Technology (SA)

176 ACCESS (NSW)

Supplementary information

- Response to comments made at hearing 23.10.06 received 30.10.06.

177 Phillips, Mr Peter (VIC)

178 Mackay-Sim, Professor Alan (QLD)

Supplementary information

- Response to comments made at hearing 23.10.06 received 30.10.06.

179 Harradine, Mr Brian (TAS)

180 Silburn, Professor Peter (QLD)

181 Sherley, A/Professor James L (USA)

Supplementary information

- Supplementary submission received 26.10.06

182 Van Strijp, Mr James & Ms Eva

183 Hider, Mr Colin
Hider, Ms Helen
Hider, Ms Catherine
Hider, Mr Colin Jnr (NSW)

184 Lynch, Dr Thomas (QLD)

185 ACT Government (ACT)

186 Finkel, Dr Elizabeth (VIC)

187 Tierney,Mr Jim (NSW)

188 Bowler, Mr David (SA)

189 Lynch, Mr Troy (VIC)

190 Helgeson, Mrs Julie (SA)

191 Peet, Mr Geoff (NSW)

192 Ridley, Ms Alison & Mr Nick (SA)

193 Allen, Ms Joan (SA)

194 Le Page, Mr Clinton (VIC)

195 Vander Linden (WA)

196 Cerdor, Ms Pauline (VIC)

197 Shenton, Mr John

198 Wakefield, Mr Mark & Ms Sue (QLD)

199 Bishop, Ms Jennette (SA)

200 Mulder, Mr Owen (WA)

201 Hartwig, Dr Arthur (QLD)

202 Hartog, Mr Joshua (QLD)

203 Bennett, Ms Shirley (QLD)
204 Worzfeld, Mrs Sue (SA)
205 Bryan, Ms Samantha (QLD)
206 van der Arend, Mr Peter (SA)
207 Treasure, Ms Anita (SA)
208 Ulett, Mr Arthur (QLD)
209 Harvey, Mrs Irene M (SA)
210 Manners, Mr Craig (VIC)
211 Pitt, Mr Ed & Ms Ann (QLD)
212 Wright, Mrs R A (SA)
213 Griffin, Miss Betty (VIC)
214 Thomas, Mr Rob (QLD)
215 McManus, Ms Louise (NSW)
216 Carolan, Mr Joseph (NSW)
217 The Woman's Christian Temperance Union of Western Australia (WA)
218 Morgan, Mr Barry (WA)
219 McColl, Mr Andrew (QLD)
220 Lacey, Mr Norman & Lacey, Ms Heather (QLD)
221 Cassey, Mrs Marie & Cassey, Mr John
222 Royal, Ms Margaret (SA)
223 Rankine, Mrs Shirley C (SA)
224 Carseldine, Ms Susie (QLD)
225 Copp, Mr Andrew (ACT)
226 Pigott, Mrs Kathleen (QLD)
227 Jones, Mr Robert (VIC)
228 Janes, Mr Barry & Ms Anne
229 Allison, Mrs Ruth
230 Parsonson, Mr Kevin (QLD)
231 Brown, Ms Susannah (NSW)
232 Moncrieff, Mr Ian (QLD)
233 Haynes, Miss Rhonda (WA)
234 Curtis, Mrs Kimberley (QLD)
235 Robinson, Miss R (VIC)
236 Donjerkovic, Ms Mary (NSW)
237 Gray, Ms Camille
238 Smeaton, Mrs E & Smeaton, Mr John (VIC)
239 Green, Dr David (SA)
240 Benz, Mr Barry and Ms Elke (QLD)

241 Webb, Mr Andrew
242 Harrop, Mrs Trish (WA)
243 Barnes, Ms Felicity (QLD)
244 Dwyer, Mr Timothy (SA)
245 Mitchell, Ms Shirley (QLD)
246 Welsh, Mr Shane and Ms Rhonda
247 Fishley, Mr Stan and Ms Katherine (VIC)
248 Hipkiss, Ms Robyn (ACT)
249 Parker, Mr Ron (QLD)
250 Threadgold, Mr Ross (SA)
251 Cummings, Mrs Ruth (VIC)
252 White, Mr Jason and Ms Sharon
253 Martin, Mr Rick (SA)
254 Stone, Mr Clive (VIC)
255 Elliott, Mrs Kristy (QLD)
256 Townsend, Mr Bruce (SA)
257 Dunstan, Ms Barbara and Mr Desmond (NSW)
258 Todd, Ms Lee-anne (QLD)
259 Dwyer, Mr Ben (SA)
260 Bezemer, Ms Lynette
261 Broomhead, Mr Chris (VIC)
262 Bennett, Mr Bruce ()
263 Carman, Ms Gaye (QLD)
264 Jenkin, Mr Craig
265 Lindsay, Ms Corinne (QLD)
266 Smithers, Mr Paul
267 Westall, Mr Paul
268 Beauchamp, Mr Peter and Ms Jan (NSW)
269 Hancock, Mr Bill and Ms Milly (QLD)
270 Ross, Mrs Merle (QLD)
271 McKenzie, Mrs Maureen (SA)
272 Oliveira, Ms Janet
273 Hoon, Lee (NSW)
274 Gasparovic, Ms Karolina (SA)
275 Thew, L & D (NSW)
276 Carden, Rev Robert (WA)
277 Bennett, Ms Ursula (NSW)
278 Hendy, Mrs Margaret

279 Pfeiffer, Ms Esther (SA)
280 Dixon, Mr Peter (VIC)
281 Carter, Ms Annelle (QLD)
282 Haines, Mr Geoff (WA)
283 McDonald, Ms Jenny (VIC)
284 Findlay, Mr Peter (QLD)
285 McMullin, Mr Ken (WA)
286 Hoolihan, Mr Shannon
287 Hoysted, Mr Alan (VIC)
288 Lonergan, Mr Chris (NSW)
289 White, Ms Michelle (VIC)
290 Bond, Mrs Judith (NSW)
291 Hunter, Ms Karen (QLD)
292 McGurk, Mr Brendan (WA)
293 Reardon, Mr Richard (VIC)
294 Pfeiffer, Mr Geoff (SA)
295 Rose, Mr Simon (WA)
296 Sestan, Ms Marija (NSW)
297 Lowe, Ms Judy
298 Garnett, Mr Graham
299 De Costa, Ms Susan (NSW)
300 Hooper, Mr Bradley (QLD)
301 Ratcliff, Ms Judith
302 Purcell, Ms Jacinta
303 Kinsella, Ms Kathleen
304 Willis, Ms Julie-Anne
305 Bourke, Dr Wendy
306 Burton, Fr Eric
307 Brohier, Mr Christopher and Ms Amanda (SA)
308 Kenneally, Mr Desmond and Ms Josephine (VIC)
309 Rose, Mrs Mary (WA)
310 Madden, Ms Sharon and Mr Pat (QLD)
311 Cocks, Ms Felicity and Mr Chris (SA)
312 Jackson, Ms Lorraine (QLD)
313 Althaus, Ms Anne-Maree and Ms Margaret Rose (QLD)
314 Pasco, Mrs Amber (WA)
315 Grant, Mr Jim and Ms Bridget (VIC)
316 Sharp, Mr David (VIC)

317 Nott, Mr Randolph (NSW)
318 Ellwood, Ms Margaret (NSW)
319 Watson, Ms Anna
320 Mauloni, Ms Mary and Mr Fred (QLD)
321 Purcell, Mr Gerard
322 Hutchinson, Mr Lyle (ACT)
323 McManus, Ms Claire (VIC)
324 Birchley, Mr Joshua
325 Stanley, Mrs Alison (VIC)
326 Esdaile, Mr David and Ms Helen (NSW)
327 Smyth, Mrs Eris (TAS)
328 Grant and Lorna
329 Stevens, Ms Marianne (NSW)
330 Denney, Mrs Celia
331 Kirk, Mr Jon and Mrs Susan (QLD)
332 Gresser, Mr John and Mrs Jane (NSW)
333 Hewitt, Mr Dennis and Ms Heather
334 Flood, Mr Gerard (VIC)
335 McLinden, Ms Therese
336 Horgan, Mr Michael (NSW)
337 McDonald, Julie
338 Shepherd, Mrs Anna (SA)
339 Goodhew, Mr Graham (QLD)
340 O'Donnell, Ms Leonie (VIC)
341 Vieira, Mrs Michele
342 Stephens, Ms Elizabeth
343 Speirs, Mr and Mrs (VIC)
344 Goodwin, Ms Angela (QLD)
345 Davies, Ms Debra (SA)
346 Van Netten, Ms Hilary (VIC)
347 Moriarty, Mr Mark (NSW)
348 Brandie, Mr David and Ms Judy (QLD)
349 Gawler, Ms Isobel (NT)
350 McCarthy, Mr John (ACT)
351 Pike, Ms Anne-Marie (WA)
352 Brandt, Ms Veronica (NSW)
353 Holden, Ms Kay
354 Hooper, Ms Judith (QLD)

355 Lynch, Mr Justin (QLD)
356 Bartlett, Rev Steve (NSW)
357 Jackson, Mr David
358 Adams, Miss Darilyn (VIC)
358 Askew, Miss Lynn (SA)
360 Owen, Ms Judith and Mr Trevor (ACT)
361 Carey, Mr John (QLD)
362 Le Mottee, Ms Louise (SA)
363 Friel, Patricia (QLD)
364 Gill, Ms Elizabeth (QLD)
365 Oldfield, Mrs Betty (SA)
366 Padgett, Ms Rosalie (NSW)
367 Harden, Mr Stewart and Ms Linda (QLD)
368 Hainey, Ms Maureen (QLD)
369 Myatt, Mr Ken and Ms Ann (QLD)
370 Strub, Ms Diane (QLD)
371 Allan, Ms Gwenda (VIC)
372 Cook, Ms Susanne (SA)
373 Webb, Mr Bill and Mrs Mynette (QLD)
374 Keane, Mr Gerard (VIC)
375 Kinsella, Ms Kathleen ()
376 Webb, Ms Julianne (QLD)
377 Budge, Dr. Garnet (QLD)
378 Tibben, Ms Hannah (QLD)
379 Elliott, Mr Charles (QLD)
380 Tardrew, Mr Garry
381 Bennett, Mr Stephen
382 Grierson, Ms Noela
383 Brewer, Mr roger and Ms Anne
384 Hoolihan, Ms Deborah
385 Morris, Ms Janice (QLD)
386 Hallett, Mr Christopher
387 Mack, Ms Anne
388 Cooper, Dr A (VIC)
389 Beecroft, Mr Geoffrey (VIC)
390 Latimer, W (QLD)
391 Smith, Mrs M.N (SA)
392 Lausberg, Mr Eric (VIC)

393 Palmer, Mr Clifton (QLD)
394 Summer, Ms Anne and others (QLD)
395 Young, Mr John (VIC)
396 The Woman's Christian Temperance Union of Western Australia (WA)
397 Cracknell, Mr Ben (VIC)
398 Toner, Mrs Anita (VIC)
399 Costello, Mr Peter and Mrs Kathryn (VIC)
400 Fraser, Mrs Jeanette (NSW)
401 Harrison, Ms Pauline (SA)
402 Brazier, Mr Matt (NT)
403 Fogarty, Ms Teresa (VIC)
404 Williams, Ms Dorothy (VIC)
405 Sullivan, Miss Wendy (SA)
406 Vaughan, Mrs Erica (TAS)
407 Worden, Mr Gerry (SA)
408 Landy, Mr John (ACT)
409 den-Bakke, Mrs Denise (VIC)
410 Skinner, C (NSW)
411 Rowe, H.R. (SA)
412 Haines, Ms Jacqueline (NSW)
413 Elsley, Miss K (SA)
414 Clapinski, Mr Klaus (VIC)
415 Murray, Ms Noela (NT)
416 Keating, Mr Colin (NT)
417 Clay, Mr Josiah (NT)
418 Boneham, Ms Rosemarie (NSW)
419 Bawden, Mr Robert (NSW)
420 Howarth, Mr Geoff (WA)
421 Casamento, Mr John and Mrs Maria (VIC)
422 Harwood, Mr Kevin and Mrs Helen (VIC)
423 Ryan, Mrs Marita (VIC)
424 Cummins, Mrs Mary (VIC)
425 Ryan, Mr Peter (VIC)
426 Callaghan, Mr Michael (VIC)
427 Callaghan, Mrs Moira (VIC)
428 Morris, Ms Dawn (TAS)
429 Boyd, Mr Thomas Edmund (WA)
430 Smith, Mr John (TAS)

431 Smith, Ms Julie (TAS)
432 Griffiths, Mrs Margaret (QLD)
433 Argent, Ms Rita (SA)
434 Sheffield, Ms Ann (SA)
435 O'Kane, Ms Carmel (VIC)
436 Semple, Mr Laurence (QLD)
437 Brian, Mrs Ellen (QLD)
438 Roney, B J (VIC)
439 Giles, P (NSW)
440 Micheelsen, Ms Inge (QLD)
441 Lever, Ms Leone (NSW)
442 Wright, Mrs Rosabelle (SA)
443 Reeves, Mr Bill and Mrs Margaret (NSW)
444 Batten, Mr John (NSW)
445 Bovey, Ms Margaret (VIC)
446 Boardman, Mr Trevor (WA)
447 Evans, Mrs J. (VIC)
448 O'Grady, Ms Fay (NSW)
449 Secombe, Mr Peter (QLD)
450 Taskis, Mr Kevin (VIC)
451 Trevor, M.H and Pryce (QLD)
452 Jones, Ms Mary (QLD)
453 Mackenzie, J. (QLD)
454 O'Keeffe, Mr Gerard (VIC)
455 Walker, Mrs P.M. (TAS)
456 Marsham, Mrs T D (VIC)
457 Kenzler, Mrs M.A (QLD)
458 Healy, Mrs Margaret (VIC)
459 Grigor, Miss I (QLD)
460 Griffin, Miss Betty (VIC)
461 Jongebloed, Mrs Maureen (VIC)
462 O'Hare, Mrs B. (WA)
463 Hill, P (QLD)
464 Prouse, Ms Joy (VIC)
465 Fry, Mr Bruce (QLD)
466 Britton, Mrs Joy (QLD)
467 Gray, Mrs Betty (QLD)
468 Fajzullin, Mrs Susanne (QLD)

469 Watson, Mr Don (ACT)
470 McCarthy, Mrs Marie (VIC)
471 deBeer, Mrs C.M (VIC)
472 Evans, Mr T.R. (NSW)
473 Arnold, Mrs Beryl (QLD)
474 Hall, J.J. (NSW)
475 Irvine, Mr John and Mrs Beth (QLD)
476 Reid, R. (QLD)
477 Casanova, Mr John (VIC)
478 Vladich, Mrs Glenice (TAS)
479 Johnson, Mrs H.A. (SA)
480 Daniell, Ms Deborah (SA)
481 Marshall, Mr Stanley (NSW)
482 Griffin, Miss Margherita (VIC)
483 Dale, M.H. (WA)
484 Kirby, M.E. (TAS)
485 Cowell, Ms Margaret (ACT)
486 Doepel, Mr Geoffrey (ACT)
487 Burrows, Ms Betty (QLD)
488 Smith, Mr Sean
Kelly, W
Rimell, Ms Nicole
Humphries, Ms Ebony
Noble, Mr Joshua
Size, Mr Brenton
Barrett, Ms Pauline
Geyer, Ms Aija
Harper, Mr Donald
Lang, Ms Sonia
Grant, Ms Diane
Warren, E (SA)
Schutz, Ms Heather
Kelly, Michael
489 Darcey, Pat (NSW)
490 Kerr, Dr Trevor (VIC)
491 Quirk, Associate Professor Patrick (USA)
492 Treacy, Mr Michael (VIC)
493 O'Shea, Mrs Lynda (WA)
494 Friel, Mr Anthony (QLD)

Additional Information

Information provided by the Hon Steve Bracks, Premier, and the Hon John Brumby, Treasurer, Government of Victoria

Key Recent Advances in Human Embryonic Stem Cell Research: A review of scientific literature commissioned by the Department of Innovation, Industry and Regional Development, prepared for Government of Victoria by Dr Nicholas Gough, dated 8.9.06

Progress in Stem Cell R & D, commentary on technological developments in recent years prepared by GJV Nossal and GF Mitchell (Foursight Associates) for the Victorian Government, dated 12.9.06

Communique, Victorian Scientific Leaders Forum on Stem cell research, position in response to the Lockhart review of human cloning and embryo research legislation

Senator Concetta Fierravanti-Wells

MP Consulting report for the Department of the Prime Minister and Cabinet dated June 2006 (tabled at hearing 20.10.06)

Nuremberg Code and World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects (tabled at hearing 20.10.06)

Senator the Hon Kay Patterson

The Politics and Promise of Stem Cell Research, Robert S. Schwartz, New England Journal of Medicine, 21 September 2006; *Adult Stem Cell Treatments for Diseases?* S. Smith, W. Neaves, S. Teitelbaum, Science v313, 28 July 2006 (tabled at hearing 20.10.06)

3 articles provided at hearing 24.10.06 -

Large majority of Australians approve extraction of stem cells from human embryos for medical research, Roy Morgan Research, Findings 4036, 21.6.06

Georgians support stem cell research, David Adelman, 20.9.06

Survey of Georgia registered voters regarding stem cell research September 5-7 & 9-10 2006, Summary of Findings, Ayres McHenry Associates

Professor John McNeil

Presentation to the Committee provided at hearing 24.10.06

Dr Nicholas Gough

Response to comments made at hearing on 24 October, dated 26.10.06

APPENDIX 2

WITNESSES WHO APPEARED BEFORE THE COMMITTEE AT PUBLIC HEARINGS

Friday, 20 October 2006
Parliament House, Canberra

Committee Members in attendance

Senator Humphries (Chair)
Senator Moore (Deputy Chair)
Senator Adams
Senator Barnett
Senator Bartlett
Senator Boswell
Senator Carol Brown
Senator Fielding
Senator Fierravanti-Wells
Senator Hogg
Senator Nettle
Senator Patterson
Senator Polley
Senator Stephens
Senator Webber

Witnesses:

Lockhart Review Members
Associate Professor Ian Kerridge
Professor Peter Schofield
Professor Loane Skene

National Health and Medical Research Council
Professor Warwick Anderson, Chief Executive Officer

Dr Peter McCullagh

Professor Peter Silburn

Australian Academy of Science
Professor Robert Williamson, Chair, National Committee for Medicine
Professor Philip Kuchel, Secretary, Science Policy
Professor Marilyn Renfree

Federation of Australian Scientific and Technological Societies
Mr Bradley Smith, Executive Director

Australian Catholic Bishops Conference
Bishop Anthony Fisher

Southern Cross Bioethics Institute
Dr Gregory Pike, Director

Monday, 23 October 2006
Mercure Sydney Hotel, George St, Sydney

Committee Members in attendance

Senator Humphries (Chair)
Senator Moore (Deputy Chair)
Senator Adams
Senator Barnett
Senator Carol Brown
Senator Ferris
Senator Fierravanti-Wells
Senator Hogg
Senator Nettle
Senator Patterson
Senator Polley
Senator Stephens
Senator Stott Despoja
Senator Webber

Witnesses:

Catholic Archdiocese of Sydney, Life Office
Dr Brigid Vout, Executive Officer

Catholic Health Australia
Mr Francis Sullivan, Chief Executive Officer

Don't Cross the Line
Mr Rocco Mimmo, Convenor

Anglican Diocese of Sydney Social Issues Executive
Dr Megan Best, Member, Social Issues Committee

Coalition for the Advancement of Medical Research in Australia
Ms Joanna Knott, Convenor
Dr Kuldip Sidhu, Manager, Embryonic Stem Cell Group, Diabetes Transplant Unit, Prince of Wales Hospital

SpinalCure Australia
Mr Robert Turner, Chief Executive Officer

Motor Neurone Disease Association of Australia
Mr Graham Opie, NSW Chief Executive Officer

Dr Paul Brock

Sydney IVF Ltd
Professor Robert Jansen, Managing Director

ACCESS Australia
Ms Sandra Dill, Chief Executive Officer

Fertility Society of Australia
Dr Adrianne Pope, President

Professor Alan Mackay-Sim, Eskitis Institute for Cell and Molecular Therapies, Griffith University & Director, National Adult Stem Cell Centre

Dr Barry Wilkins, Senior Staff Intensive Care Physician, The Children's Hospital at Westmead, Sydney

Professor Bernard Tuch, Director, Diabetes Transplant Unit, Prince of Wales Hospital

Professor Phil Waite, Head, Neural Injury Research Unit and Chair of Research Committee, Medical Sciences, University of New South Wales

Australian Society for Medical Research

Professor Levon Khachigian, President

Tuesday, 24 October 2006
St James Court Conference Centre, Melbourne

Committee Members in attendance

Senator Humphries (Chair)
Senator Moore (Deputy Chair)
Senator Carol Brown
Senator Ferris
Senator Fielding
Senator Fierravanti-Wells
Senator Hogg
Senator Nettle
Senator Patterson
Senator Polley
Senator Stephens
Senator Stott Despoja
Senator Webber

Witnesses

Australian Stem Cell Centre

Professor Stephen Livesey, Chief Scientific Officer

Professor Paul Simmons

Professor Martin Pera, Center for Stem Cell and Regenerative Medicine, University of Southern California USA – *via teleconference*

Professor John McNeil, Head of Department of Epidemiology and Preventive Medicine, Monash University

Stem Cell Sciences Ltd

Mr David Newton, General Manager

Dr Megan Munsie, Scientific Development Manager

Emeritus Professor John Martin, Emeritus Professor of Medicine, University of Melbourne – *via teleconference*

Professor James Sherley, Biological Engineering Department, Massachusetts Institute of Technology, Cambridge, Massachusetts USA – *via teleconference*

Women's Forum Australia

Ms Katrina George

Monash Immunology and Stem Cell Laboratories Senior Researchers

Professor Graham Jenkin, Associate Director

Associate Professor Andrew Elefanty, Senior Scientist and Laboratory Head

Dr Edouard Stanley, Senior Research Fellow

The Hon John Brumby, Treasurer, Minister for Innovation and Minister for State and Regional Development, Victorian Government

Feminist International Network of Resistance to Reproductive and Genetic Enginerring (FINRRAGE)

Dr Renate Klein, Coordinator

Queensland Bioethics Centre and Catholic Archdiocese of Brisbane

Mr Raymond Campbell, Director, Queensland Bioethics Centre

Do No Harm – Australians for Ethical Stem Cell Research

Dr David van Gend, National Director

Mr Richard Egan, Campaign Director

Dr Eloise Piercy

GeneEthics

Mr Bob Phelps, Executive Director

APPENDIX 3

SUMMARY OF LOCKHART RECOMMENDATIONS AND HOW THESE ARE ADDESSED IN THE PATTERSON 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 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.'	This was the NHMRC's draft definition at the time the Lockhart 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.

Source: Senator the Hon Kay Patterson, Senate Hansard, 19 October 2006, pp.14-19.

APPENDIX 4

STEM CELLS, CLONING AND RELATED ISSUES

National Health and Medical Research Council, Australia

What are stem cells?

- Stem cells are 'unspecialised' cells that have the unique potential to develop into 'specialised' cell types in the body (for example blood cells, muscle cells or nerve cells). This can be either for growth and development, or for replenishment and repair.

- Stem cells occur at all stages of human development, from embryo to adult— but their versatility and numbers tend to decrease with age.

- Given the right conditions in the body or the laboratory, stem cells (unlike muscle cells, nerve cells and or blood cells) can replicate themselves many times over.

- When a stem cell replicates, the resulting cells can either remain as stem cells or can become specialised cells.

Why is stem cell research important?

Doctors and scientists believe that stem cell research has the potential to revolutionise medical treatment in two main areas:

- **Better understanding of diseases such as cancer.** By understanding how stem cells transform into the specialised cells that make us what we are, we can better understand and cure diseases such as cancer. Cancer is a major example of where this process has gone wrong.

- **Making cells and tissues to replace or regenerate tissues that are either diseased or have been destroyed.** Organ transplants can be used for this in some cases, but the demand for suitable donated organs exceeds supply. Stem cells offer the possibility of a source of replacement cells that could be used to treat diseases and conditions from Parkinson's disease to heart disease, spinal cord injury, diabetes and arthritis.

What are embryonic stem cells and adult stem cells?

Embryonic stem cells

- Embryonic stem cells, as their name suggests, are derived from human embryos. They have the potential to develop into **all** cell types in the body.

- In Australia, embryonic stem cells are derived from human embryos that are left over from assisted reproductive technology (ART) treatment programs and have been donated to research by the couple for whom they were created. They are **not** derived from eggs fertilised in a woman's body.

- As part of a couple's infertility treatment these ART embryos would have been placed in cold storage within 2–6 days of fertilisation.

Adult stem cells

- Adult stem cells (often called **somatic stem cells**) are found in many organs and tissues of the body, where their main function is to replace cells that have died in the tissue or organ where they are located.
- In certain circumstances, adult stem cells may "transdifferentiate" into othercell types.
- Adult stem cells extracted from the bone marrow of patients or compatible donors are used routinely in treating diseases such as leukaemia. (All blood cells in the body are manufactured in the bone marrow).
- Umbilical cord blood, extracted from the umbilical cord and placenta when a baby is born, is a rich source of adult stem cells. These cells may be useful for medical research or therapeutic use in the future. In the USA in particular, a whole industry has developed where people are having cord blood frozen for possible use later in life.

Embryonic and adult stem cells in medical research

- Most experts think that research involving both embryonic and adult stem cells will lead to a new understanding of, and new therapeutic treatments for, injury and disease.
- The advantages of embryonic stem cells are that they can be grown in the laboratory for long periods and be made to change into most types of tissue found in the human body.
- Some people have genuine and strongly held views against the use of embryonic stem cells in research. This is because deriving stem cells from embryos destroys the embryo.
- Adult stem cells are present in the body in low numbers, and, with the exception of bone marrow, are difficult to obtain.
- Although adult stem cells are currently difficult to grow in the laboratory and may not develop into every kind of cell, recent developments in this field are promising.

What about cloning?

- The *Prohibition of Human Cloning Act 2002* does not permit the creation of human embryo clones for any purpose (see next section on Current Guidelines and Laws in Australia).
- The scientific technique through which human embryo clones can be created is called somatic cell nuclear transfer, or SCNT. This was the technique used to create the first cloned mammal, 'Dolly' the sheep.
- SCNT involves obtaining a woman's egg cell in the same way eggs are obtained for ART treatment, then removing the genetic material (DNA) from it and replacing it with DNA from a cell of a person's body (e.g. a skin cell). With the right triggers this new cell can be turned into an embryo.
- SCNT is controversial for two reasons:

1. *The resulting embryo could, in theory, lead to cloned human beings.* If a cloned embryo is placed into a woman's uterus, and it implants and develops to birth, a new human being will be created whose nuclear DNA will be identical to the person who donated the original body cell. There is no scientific evidence that a human being has ever been cloned, and attempts to clone other primates have been unsuccessful. This possibility is referred to as '**reproductive cloning**', which many people find completely unacceptable.

2. *Stem cells could be harvested from the cloned embryo, which would destroy the embryo*. If a cloned embryo is grown in the laboratory for a few days, stem cells could be harvested from it to form a new embryonic stem cell line. This possibility is often referred to as '**therapeutic cloning**', since the embryonic stem cells could be encouraged to develop into human tissue or (possibly in the future) a complete organ for transplant. Because the stem cells from a cloned embryo have identical nuclear DNA to the person who donated the original body cell, this theoretically overcomes the 'rejection' hurdle that exists with current organ or tissue transplants or with stem cells derived from embryos left over from IVF treatment programs.

- The *Prohibition of Human Cloning Act 2002* does not distinguish between 'reproductive' and 'therapeutic' cloning.

- It has also been suggested that so-called 'therapeutic cloning' could be achieved by transferring human DNA into animal eggs (such as rabbit eggs), as a way of reducing the demand for human egg donations.

- The technique would be illegal in Australia under the *Prohibition of Human Cloning Act 2002* because it could result in the creation of a hybrid embryo.

Current guidelines and laws in Australia

Use of cell lines in research

- The use of human or animal cell lines in health and medical research is covered by guidelines and other statements issued by the National Health and Medical Research Council (NHMRC).

- Researchers should abide by the provisions of the *National Statement on Ethical Conduct in Human Research* (1999, under review).
[http://www.nhmrc.gov.au/publications/synopses/e35syn.htm]

- The NHMRC has also prepared a supplement to the *National Statement*, on preparation and review of research protocols relating to the use of embryonic and non-embryonic human stem cells. [http://www.nhmrc.gov.au/ethics/human/issues/stemcell.htm]

Use of human embryos to derive embryonic stem cell lines

Research Involving Human Embryos Act

- The use of human embryos to derive human embryonic stem cell lines for research is governed by the *Research Involving Human Embryos Act 2002*. The Act states that only embryos that are left over from ART (Assisted Reproductive Technology) treatments can be used can be used in this kind of research. Embryos cannot be created purely for the purposes of research.

[http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/41F0A356529C8567CA25719C0031E76D/$file/Research+Involving+Human+Embryos+Act+2002_WD02.pdf]

Assisted Reproductive Technology (ART) guidelines

- ART includes techniques such as IVF (in-vitro fertilisation, or fertilisation in an artificial environment such as a test tube).
- ART itself is subject to ethical guidelines on ART, and supplementary statements on the use of human tissue in research, issued by the NHMRC. [http://www.nhmrc.gov.au/ethics/human/issues/art.htm]
- The ethical guidelines on ART outline the comprehensive consent process for couples who wish to declare embryos as excess to their requirements, and to allow the embryos to be used for research purposes.

Embryo Research Licensing

- The use of excess ART embryos in research, including as a source of embryonic stem cell lines, can only be undertaken if authorised by a licence issued by the **NHMRC Embryo Research Licensing Committee**. More information on the Committee, its functions and current membership [http://www.nhmrc.gov.au/about/committees/lc/index.htm]
- More information on the issuing of licences to use excess assisted reproductive technology embryos is available on our licensing FAQs page. [http://www.nhmrc.gov.au/embryos/information/faqs.htm]

Human cloning

- Human cloning, in any form, is banned in Australia under the *Prohibition of Human Cloning Act 2002*. [http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/4374F568FE759928CA2570450002C19A/$file/ProhibHumanCloning2002_WD0 2.pdf]

More information and advice on the regulatory framework

- More information and advice on the regulatory framework relating to human cloning and research involving human embryos, and Commonwealth and State and Territory legislation, is available on the NHMRC's Policy and Guidance web page. [http://www.nhmrc.gov.au/embryos/information/index.htm]

The Lockhart Review

- The Legislation Review Committee established to review the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*, reported to Parliament and the Council of Australian Governments on 19 December 2005. The review is known as the Lockhart Review, after its Chair, the late Justice John Lockhart.
- The Review Committee's reports cover areas involving difficult ethical issues, about which people have divergent and deeply held views.

- The Committee endorsed the strong regulatory framework which regulates research involving excess assisted reproductive technology embryos, and prohibits human cloning.

- The Review Committee made 54 recommendations, many of which are interlinked. These recommendations are explained briefly below (the groupings are not related to any perceived merits or otherwise of the recommendations):

  – **(a) Maintaining the existing legislative framework, including the ban on reproductive cloning**

    These recommendations provided strong support for the current regulatory framework, including the use of excess assisted reproductive technology (ART) embryos in research.

    Recommendations 1 to 14; 31; 33, 34; 37; 38; 40; 43, 44; 46.

  – **(b) Development of advice, guidance and infrastructure within the existing regulatory framework:**

    These recommendations are of an administrative nature and are directed at the NHMRC, government and other parties. For example, recommendation 18 recommends the NHMRC develop a pro-forma licence application. Other recommendations relate to advice and criteria for licensing the use of fresh ART embryos that are unsuitable for implantation into a woman. There are also recommendations that a national Australian stem cell bank and a national register of donated excess ART embryos be established.

    Recommendations 18, 20, 21, 22, 29, 30, 32, 36, 45, 46, 47, 48, 49, 54.

  – **(c) Allowing 'therapeutic cloning' and other currently prohibited techniques:**

    Recommends that so-called 'therapeutic cloning' be permitted using a technique known as somatic cell nuclear transfer (SCNT).

    Recommends allowing creation of other types of embryos whose creation is currently prohibited by the *Prohibition of Human Cloning Act 2002*, including through SCNT using animal eggs (to reduce the demand for human eggs), and cytoplasmic transfer (creation of human embryos using the genetic material from more than two people).

    Recommends extending the role of the NHMRC Embryo Research Licensing Committee to include licensing these additional activities.

    Recommendations 23, 24, 25, 26, 27, 35, 42.

  – **(d) Amending the definition of human embryo:**

    Recommendation that the definition of human embryo be amended. The proposed definition starts at the point of the first cell division after ertilisation of a human egg by a human sperm.

    Recommendation 28.

  – **(e) Allowing research on fertilisation up to the point of the first cell division:**

    These recommendations are linked to the recommended change to the definition of a human embryo and are aimed at facilitating research into fertilisation, testing

of eggs for maturity, and cytoplasmic transfer up to, but not beyond, the point of the first cell division.

Recommendations 15, 16, 17, 19.

- **(f) Provide additional powers to NHMRC inspectors:**

  Recommendation that inspectors be given powers of entry, inspection and enforcement in relation to non-licensed facilities.

  Recommendation 39.

- **(g) Removing restrictions on the import and export of human embryos:**

  Recommendation for streamlining provisions relating to a patient's reproductive material (including ART embryos), for that person's ongoing ART treatment.

  Recommendation 41.

- **(h) NHMRC Embryo Research Licensing Committee rulings:**

  Recommendation that the legislation be amended to give the Licensing Committee the power to make binding rulings in relation to interpretation of the legislation, in order to provide greater regulatory flexibility in this fast-moving field.

  Recommendations 50 to 52.

- **(i) Provide for further review of national legislation:**

  In view of the fast-moving developments in the field the two Acts should be subject to a further review either six years after Royal Assent to the current Acts or three years after Royal Assent to any amended legislation.

  Recommendation 53

- The Committee's reports are available at www.lockhartreview.com.au.
- The NHMRC submission to the review is available at http://www.lockhartreview.com.au/_pdf/701-800/LRC790.pdf
- Australian Governments are currently considering the Review Committee's reports.

Facts and figures on embryos, licences and funding

Number of embryos and licences

- There were 104,830 embryos in frozen storage in 2003. Almost all of these were embryos intended to be used to achieve a pregnancy.
- Very few ART embryos in storage have been declared to be excess to ART requirements.
- At 31 March 2006:
  - 170 excess ART embryos had been used in licensed research in Australia
  - the NHMRC Embryo Research Licensing Committee had issued 9 licences authorising the use of up to 1,735 excess ART embryos

  - 4 of the 9 licences authorised the use of up to 550 excess ART embryos for the derivation of human embryonic stem cells.
  - under the 4 licences, 122 excess ART embryos had been used.
- More information on embryo and licence numbers is available at http://www.nhmrc.gov.au/embryos/information/faqs.htm

Australian Government funding for stem cell research

NHMRC funding

- Around $40 million of NHMRC funding in 2006 is committed to research that involves the use of animal or human stem cells. This is approximately 9% of NHMRC research expenditure in 2006 ($435 million).
- Approximately $1.8 million in research funding involves use of human embryonic stem cells.
- A complete breakdown of NHMRC funding in 2005 and 2006 for research involving stem cells is available at http://www.nhmrc.gov.au/publications/_files/stemcell_funding.pdf

Other Australian Government funding

Australian Stem Cell Centre, Melbourne

- In 2002 the Australian Government provided the Australian Stem Cell Centre in Melbourne with a competitively awarded grant of $43.55 million through the Government's *Backing Australia□s Ability*, Biotechnology Centre of Excellence Program (*Backing Australia□s Ability* is coordinated across five principal portfolio Departments).
- In May 2004, the Prime Minister announced a further $55 million grant under *Backing Australia□s Ability II*, to support the Australian Stem Cell Centre's activities from 2006 to 2011.
- The Australian Stem Cell Centre is a key driver and catalyst in developing world-class capability in biotechnology research, and its application for the economic and social benefit of Australia.
- More information on the Australian Stem Cell Centre is available at http://www.stemcellcentre.edu.au/ascc_home.html

Adult Stem Cell Research Centre, Brisbane

- On 2 May 2006 the Government announced that it had decided to provide $22 million over four years to fund an Adult Stem Cell Research Centre at Griffith University in Queensland.
- This Centre is funded through the Commonwealth Department of Health and Ageing, and will complement the work of the Australian Stem Cell Centre.
- More information on the Adult Stem Cell Centre is available at http://www.griffith.edu.au//centre/eskitis/home.html

International website links

The following websites provide useful and authoritative information on stem cells, cloning and related issues

- National Institutes of Health (USA) Stem Cell Information website http://stemcells.nih.gov
- BBC World Service Education Home Page (Science and Technology) http://news.bbc.co.uk/1/hi/sci/tech/859672.stm
- American Federation for Aging Research Cloning and Information Centre http://websites.afar.org/site/PageServer?pagename=IA_b_cloning_home

Source: http://www.nhmrc.gov.au/publications/_files/stemcells.pdf [accessed 30.10.06]

APPENDIX 5

LOCKHART REVIEW RECOMMENDATIONS AND EXPLANATIONS

Note: The following summary of the Lockhart Committee's views and recommendations is reproduced from the Legislation Review, pp.162-183.

The Committee concludes that Australia should continue to have national legislation imposing prohibitions on reproductive cloning and some other ART practices, as well as strict control and monitoring, under licence, of human embryo research.

Recommendation — national legislation

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.

17.3 Prohibited practices

The Committee considers that most of the practices that are currently prohibited in the Acts should continue to be prohibited. This includes a total prohibition on reproductive cloning.

The Committee also considers that there should continue to be a total prohibition on the implantation, into the body of a woman, of embryos other than those created by the fertilisation of a human egg by a human sperm.

Furthermore, the Committee also holds the view that the creation of embryos other than by the fertilisation of a human egg by a human sperm should also continue to be prohibited except for the limited circumstances indicated below and in Section 17.4, where the Committee suggests that some such embryos could be created and used for research purposes but never implanted into the body of woman.

These prohibited practices are discussed in detail in the remainder of this section. Prohibitions on import, export and commercial trading of embryos and gametes are discussed in Sections 17.11 and 17.12.

Reproductive cloning

The Committee heard strong agreement between all groups that human reproductive cloning should continue to be prohibited on ethical grounds. The serious health and safety issues associated with the birth of live, cloned animals was also seen as a reason to prohibit this procedure in humans. The Committee’s view is that the prohibition of human reproductive cloning should be maintained because of these ethical and safety concerns.

Recommendation — reproductive cloning

2. Reproductive cloning should continue to be prohibited.

Developing and implanting embryos categorised as 'prohibited embryos'

The Committee considered the 'prohibited embryos' mentioned in the PHC Act. These include:

- embryos created by nuclear transfer
- embryos created by other methods not involving fertilisation of eggs by sperm
- human–animal hybrid or chimeric embryos
- embryos with genetic material from more than two people
- embryos with genetic alterations.

The Committee noted that there was strong community objection to the implantation of such prohibited embryos into the body of a woman or to their development in any other way beyond 14 days. The Committee sees no reason to depart from this strong community objection.

The Committee's view on the creation of embryos by nuclear transfer or other methods not involving fertilisation of eggs by sperm is discussed in Section 17.4.

The Committee noted that the creation of human–animal hybrid or chimeric embryos [44] was only mentioned in a few of the submissions and hearings. However, there was an implicit understanding that the creation of such entities could be of concern to the community. Therefore, the Committee's view is that creation of such embryos for reproductive purposes (that is, development beyond 14 days and implantation of such embryos) should continue to be prohibited.

However, because of the potential benefits, and to avoid the need for obtaining additional human gametes for research purposes, the Committee considers that fertilisation of animal gametes by human gametes should be permitted up to, but not including, the first cell division, to allow testing of human gamete maturity or viability as indicated in Recommendation 17.

The Committee also suggests that, under limited circumstances, human–animal hybrid or chimeric embryos could be used, under licence, for preliminary investigations of nuclear transfer technologies. The Committee reached this view because this procedure could reduce the need for human egg donation (see Recommendation 24).

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44 Embryos created by fertilisation or activation of any combinations of human and animal gametes or cells, or embryos into which an animal cell or part of an animal cell has been introduced (see Glossary)

Similarly, with respect to embryos with more than two genetic parents (including those created using cytoplasmic transfer), embryos using precursor cells from a human embryo or a human fetus, and embryos carrying heritable changes to the genome, the Committee's view is that the creation of such embryos for reproductive purposes should remain prohibited (that is, development and implantation of such embryos should be prohibited) due to the lack of social support for these practices and concerns about safety.

However, the Committee's view is that these methods could be used for research, under licence, to advance knowledge and investigate specific diseases and conditions. Further discussion of these proposed licensed activities is included in Section 17.4.

The Committee also considers that placing any 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 also continue to be prohibited because these practices are repugnant to the community. Similarly, the Committee did not hear any arguments for lifting the prohibition on the collection of viable embryos from a woman and therefore considers that this prohibition should continue.

Recommendations — prohibitions on developing and implanting embryos

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.

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.

5. Implantation into the reproductive tract of a woman of a human–animal hybrid or chimeric embryo should continue be prohibited.

6. Development of a human–animal hybrid or chimeric embryo should continue to be prohibited, except as indicated in Recommendation 17.

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.

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.

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.

10. Implantation into the reproductive tract of a woman of an embryo carrying heritable alterations to the genome should continue to prohibited.

11. Collection of a viable human embryo from the body of a woman should continue to be prohibited

Creating human embryos for any purpose other than to achieve a pregnancy in a woman

During the review hearings, at the discussion forums and through the written submissions, the Committee heard a range of views on the status and potential of a human embryo (see Chapter 8). These views were underpinned by different values and beliefs about the time that human life starts, and the social and moral status of a human embryo. These beliefs, in turn, affected the relative weight placed on the right to life of a human embryo, the potential to help people have children, and the potential to improve or save the lives of people living with incurable diseases or injuries.

Currently, the prohibition of creating a human embryo for any purpose apart from to achieve a pregnancy in a woman prevents the creation and use of fresh embryos for research. The provisions of the RIHE Act for declaring embryos to be excess ART embryos and giving proper consent for research, have also precluded the immediate (fresh) use of any unfit or 'surplus' ART embryos (see Chapter 4).

The Committee therefore discussed the possibility of permitting the creation of embryos for research, particularly because some ART researchers also suggested that relaxation of current laws to allow the production of fertilised human embryos to be used for embryology studies would be beneficial to the further development of safe and successful ART treatments.

In this regard, the Committee noted that, in nature, many embryos fail to implant or to become a viable pregnancy. The Committee also noted that ART embryos that are surplus to reproductive needs are allowed to die. These arguments were used by some to justify the possible creation of embryos for research.

On the other hand, the Committee noted that a human embryo created by gamete fusion is regarded as a significant entity associated with the purpose of having babies.The creation of such embryos is widely accepted for helping people who would otherwise have difficulty having a family, but there is little general support for the creation of such embryos for research purposes. The Committee therefore formed the view that the prohibition on creating human embryos by fertilisation (using human eggs and sperm) for any purpose apart from seeking to achieve a pregnancy should be maintained. However, as noted below, the Committee considers that research on eggs fertilised by sperm should be permitted up until the first cell division.

Recommendations — creation of human embryos by fertilisation

12. Creation of human embryos by fertilisation of human eggs by human sperm should remain restricted to ART treatment for the purposes of reproduction.

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.

17.4 Research and other activities involving human embryos permitted under licence

Use of excess ART embryos

Although some respondents to the reviews thought that all uses of human embryos should be prohibited, the Committee considered that, overall, there was support for the use of excess ART embryos in research under the provisions of the RIHE Act. This view was also heard from ART consumers, many of whom have donated their excess embryos for research.

Excess ART embryos have been used for research and other activities to improve the clinical practice of ART (see below) or for the derivation of embryonic stem cells. Many respondents expressed a view that embryonic stem cells are not required because adult stem cells could be used instead. In terms of this argument, the Committee carefully considered all the submissions on embryonic stem cell research and equivalent research on adult stem cells, and noted the following issues:

- Many of the arguments regarding the clinical utility of embryonic stem and adult stem cell research were based on speculation rather than on established data.
- While the findings of embryonic stem cell research have not yet translated into any clinical trials or treatments, the use of excess ART embryos to derive embryonic stem cell lines has contributed to progress in advancing our understanding of stem cells and research directed to future therapeutic outcomes of stem cell research.
- Although there has been substantial progress in adult stem cell research in the past few years, the developments in adult stem cell research do not remove the need to make progress in embryonic stem cell research. The Committee agrees with the views of the many researchers who consider that both types of research should continue.
- The range of diseases and conditions that may be treated by therapies developed from stem cell research is substantial, and therefore the number of people who may ultimately benefit from such research is high.

Therefore, the Committee's view is that further research on embryonic stem cells is required and that this provides a justification for the use of excess ART embryos for research purposes.

Some respondents suggested that ART clinics produce more ART embryos than required for treatment in order to ensure a supply of excess ART embryos for research. However, the Committee received no evidence that this is the case and therefore rejects this view. Furthermore, ART clinics told the Committee that the number of excess ART embryos that have been donated for research exceeds the number that is required for current research projects.

Information about the number of embryos created, implanted and stored is already provided by each ART clinic in its annual Reproductive Technology Accreditation Committee (RTAC) report(see Chapter 12). In practice, the number of embryos created and implanted per cycle of ART treatment has been decreasing over the past decade as techniques have improved and reduced the risks of multiple births (see Section 4.2).

The Committee also noted that the sunset clause (RIHE Act s46), which has now lapsed, was a response to similar concerns in 2002, and an instrument of government to provide time for the development of an appropriate licensing and inspection system. The licensing system is now in place and the RTAC monitoring and annual reporting mechanisms for ART clinics are well established. Therefore, the Committee concludes that there is no further need to restrict the use of excess ART embryos to those produced before a specified date or for any further mechanism for monitoring of this process.

Recommendation — use of excess ART embryos in research

14. Use of excess ART embryos in research should continue to be permitted, under licence, as under current legislation.

ART clinical practice and ART research

The Committee was concerned to hear that the legislation has had the apparently unintended consequence of preventing research into improved methods for achieving pregnancy in ART clinics. In particular, the legislation has stopped research on culture and maturation of immature eggs ('in vitro maturation of oocytes', or IVM), frozen oocyte storage, various aspects of in vitro fertilisation (IVF), and gamete (egg and sperm) development. The ability to produce mature oocytes in culture provides a way of reducing the use of follicle stimulating hormone and would therefore benefit women undergoing ART. It may also allow the production of mature oocytes from frozen ovarian tissue, such as tissue stored before cancer therapy.

The Committee heard that research on the maturation of eggs has been prevented under the current legislation, because testing the viability of mature eggs requires either fertilisation by sperm, or chemical activation (parthenogenesis). Under the

definitions and prohibitions in the current legislation, both these activities are illegal. The development of methods to freeze oocytes and of better methods of fertilisation has also been prevented for similar reasons. In addition, the prohibition on creation of hybrid embryos, combined with the current definition of an embryo, has further limited IVF research (for example, by preventing tests of sperm quality involving fertilisation of hamster eggs).

The Committee considered several options for changes to the legislation to allow these areas of ART research to resume:

- changing the definition of a human embryo to a slightly later stage in the fertilisation process, in accordance with Victorian and other legislation that was in place before the national legislation was passed in 2002;
- removing parthenogenetic embryos from the definition of a human embryo or human embryo clone, thus allowing oocyte activation; or
- lifting the prohibition on creating embryos by fertilisation of eggs with sperm for research use.

The Committee noted that changing the definition of a human embryo to a slightly later stage in the fertilisation process (the first cell division) would allow much of the research described above to occur without breaking the law, while still maintaining a very broad definition of an embryo in line with all the community views expressed to them during the reviews. This is discussed in detail in Section 17.5.

In connection with the second option, the Committee heard from ART researchers and practitioners that, although parthenogenetic activation can be induced using chemical or other activation methods, it also occurs spontaneously in vitro and in nature. The Committee's view is therefore that intentional parthenogenetic activation of oocytes should be permitted, under licence, for development for up to 14 days, but that implantation of parthenogenetically activated oocytes into a women's reproductive tract should continue to be prohibited (see Recommendation 3).

The third option (permitting creation of embryos by fertilisation for research) is discussed in Section 17.3) and was rejected by the Committee.

The Committee also heard that requiring a licence for training and quality assurance activities has presented an administrative barrier to these necessary aspects of ART clinical practice activities. The current process of applying for a licence is time-consuming and not well suited to these activities, which depend on factors such as staffing requirements. Furthermore, at times, there may be a need for rapid action to resolve a specific quality assurance issue. However, in view of the strong community attitudes supporting the regulation of this sensitive area, the Committee's view is that all research involving human embryos should continue to require a licence. However, it is also the Committee's view that the licensing process for these activities could be facilitated by the Licensing Committee developing a proforma application for training and quality assurance activities in ART clinics.

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

Recommendations — ART clinical practice and ART research

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.

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.

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.

18. The Licensing Committee should develop a simple proforma application for licences to undertake training and quality assurance activities for ART clinics.

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.

Use of fresh embryos, including pre-implantation genetic diagnosis embryos

The Committee heard several arguments in favour of using fresh embryos (rather than frozen embryos) for ART research, training and quality assurance activities, and for the derivation of embryonic stem cells. These procedures cannot occur under the current legislation because of the requirements to first declare an embryo as an excess ART embryo and then complete 'proper consent' procedures. When the research involves damage or destruction of the embryos, 'proper consent' must allow a two-week cooling-off period, during which time those responsible for the embryo can withdraw their consent.

Under current arrangements, embryos that are not suitable for implantation for any reason, including embryos that are found to have a genetic disease using preimplantation genetic diagnosis, are allowed to die and are not available for research. However, ART researchers and practitioners told the Committee that such embryos would be a useful source of fresh (albeit unsuitable for implantation) embryos for research, training and quality assurance activities. Embryonic stem cell researchers would also like to generate stem cells from embryos carrying genetic defects (eg after pre-implantation genetic diagnosis) to study the cause and treatment of genetic diseases.

It appeared to the Committee that the RIHE Act is not clear on whether such embryos could ever be considered to be 'excess ART embryos' (because they are not suitable for reproductive use in the first place), and therefore whether they could ever lawfully be used for research purposes (even if they are first frozen). In Victoria, this ambiguity is removed because freezing embryos that are not suitable for implantation is prohibited under the Victorian Infertility Act 1995. However, this is not the case in other States and Territories.

In view of these ambiguities in the Act, as well as the potential use of embryos that are not suitable for implantation in research, training and quality assurance activities, the Committee considers that there should be clear and unambiguous provisions within the legislation and licensing arrangements for declaring embryos that are unsuitable for implantation as 'surplus embryos', and that such embryos should be permitted to be used for research, training and improvements in clinical practice. However, the Committee acknowledges that, although in some cases the suitability for implantation is an objective decision (eg when the embryo has been diagnosed by PGD to carry a genetic disorder), in other cases it may be subjective (eg when the embryo appears less healthy). Therefore, the Committee's view is that objective criteria should be developed by an expert body, for use in determining whether an embryo is unsuitable for implantation. These criteria could include embryos that have not undergone cell divisions, carry additional pronuclei or show other major chromosomal defects.

Consent arrangements for the use of fresh embryos are discussed in Section 11.2.

Recommendations — use of fresh ART embryos

20. An expert body should formulate objective criteria to define those embryos that are unsuitable for implantation.

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.

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.

Somatic cell nuclear transfer

The Committee heard that research using excess ART embryos, under licence, since 2002 has yielded a number of new embryonic stem cell lines, and that researchers are working with these to refine the methods of cell culture and differentiation that will be needed to develop cellular therapies. However, the Committee also heard from those involved in the field that further development of this area of research requires the creation of human embryo clones to generate embryonic stem cells that are either

patient-matched for development of specific cellular therapies, or of known genotype for disease modelling and other research (so-called therapeutic cloning).

Furthermore, although much publicity to date has been attached to the use of embryonic stem cells to develop cellular transplantation therapies, the Committee noted that, based on the submissions of experts working in the field, embryonic stem cells have potentially useful applications in other areas of medical research, such as for studying cell differentiation in healthy and diseased tissues (disease modelling studies) and for drug screening. Such studies could increase understanding of disease processes and lead to cures for diseases through other means apart from cellular therapies. The Committee's view is that there is scientific merit in the use of embryonic stem cells for this type of research.

The Committee acknowledges the advances that have been made in research into adult stem cells, and that adult stem cells have been used successfully in the treatment of some human diseases, especially bone marrow transplantation. However, to date, the potentiality of adult stem cells, in terms of the number of cell types that can be generated, is still unclear and certainly less than for embryonic stem cells.

The Committee has therefore reached an opinion, based especially on the evidence of experts who work directly in one or both fields of stem cell research (adult or embryonic), that further research involving both adult and embryonic stem cells is required to improve knowledge and to develop effective disease treatments.

The Committee heard that research using human cloning to generate embryonic stem cells is proceeding in several other countries where these technologies are legislatively permitted (eg United Kingdom, South Korea, Singapore) or where no national legislative regulations are in place (eg United States). Therefore, many respondents to the reviews argued that the prohibition of human cloning to generate patient-matched stem cells should be lifted in Australia to allow Australian researchers to continue to contribute to the intellectual and biotechnological developments in this field.

During the reviews, the Committee heard three major objections to the use of somatic cell nuclear transfer (or SCNT) to generate embryonic stem cells (as well as other methods of creating human embryos not involving the fusion of an egg and a sperm). One type of argument, commonly referred to as the 'slippery slope' argument, is that, because the technology is the same as that used for reproductive cloning, allowing cloning to extract stem cells would inevitably lead to its use for reproduction. However, the Committee considers that continuing a ban on reproductive cloning would effectively prohibit the development of human embryo clones beyond 14 days or the birth of a human being using such methods. The Committee therefore rejects the 'slippery slope' argument.

A second argument is that it is wrong to create human embryos to destroy them and extract the stem cells. The Committee agreed that human embryo clones are human embryos and that, given the right environment for development, could develop into a human being. Furthermore, if such an embryo were implanted into the body of a

woman to achieve a pregnancy, this entity would certainly have the same status as any other human embryo, and were this pregnancy to result in a live birth, that child would enjoy the same rights and protection as any other child. However, a human embryo clone created to extract stem cells is not intended to be implanted, but is created as a cellular extension of the original subject. The Committee therefore agreed with the many respondents who thought that the moral significance of cloned embryos that are not implanted is linked more closely to their potential for research developments, including the development of treatments for serious medical conditions, than to their potential as a human life.

Furthermore, the Committee noted that the production and destruction of such embryos is not dissimilar to the production and destruction of excess ART embryos, which is permitted by the legislation and widely accepted by society. Thus, to permit one (production and destruction of ART embryos) but not the other (production and destruction of nuclear transfer and other bioengineered embryos) is inconsistent and appears to attach more importance to the treatment of infertility than to the treatment of other serious diseases and conditions that could be helped as a result of this activity. In view of the wide range of diseases and conditions that stem cell research aims to help, the Committee considers that further research using cloned human embryos should be permitted.

Thus, the Committee concludes that the creation of human embryos by nuclear transfer should be permitted, under licence, according to strict regulatory guidelines, including strong ethical guidelines for egg donation (see Section 11.2) because:

- While reproductive cloning aims to copy a person, SCNT only aims to copy a person's cells; therefore, provided the person consents, there is no objection to this.
- In addition, if the embryo created by SCNT is not intended to be implanted, it does not represent a potential new individual in the way that the product of fertilisation does.
- After nuclear transfer, the new cell needs to develop to the blastocyst stage so the inner cell mass can be removed, and while this entity is indistinguishable from other types of human embryos, it has been created specifically for research purposes (which is currently prohibited under the PHC Act).
- However, this type of embryo is not intended to be implanted, so the production and destruction of such an embryo is not dissimilar to the production and destruction of excess ART embryos, which is permitted by the legislation and accepted by society.
- Therefore, if research on excess ART embryos is permitted, it is not a major additional step to permit SCNT.

However, a significant argument raised by many respondents against the use of SCNT was that it requires the use of donated human eggs. This raises concerns, because ovarian stimulation and egg collection are associated with more risk than the removal of other tissues for research. Because the 'best' eggs are those from young women,

there is also potential for young women to be coerced to donate (such as by payment, through their work or by their families). In this regard, the Committee considers that strict ethical guidelines for obtaining egg donations should be developed and that further research should aim to identify alternative sources of eggs (see Section 17.7). In addition, the Committee considers that the need for human egg donations could be reduced in the early stages of the development of this technology by permitting, under licence, human nuclear transfer into animal egg cytoplasm for the purpose of stem cell research.

The Committee also notes that the majority report of the House of Representatives Standing Committee on Legal and Constitutional Affairs inquiry, chaired by the Mr Kevin Andrews MP in 2001 [45], recommended a three-year moratorium on human cloning to extract embryonic stem cells ('therapeutic cloning') rather than a permanent ban.

Recommendations — use of human embryos created by somatic cell nuclear transfer

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.

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.

Use of human embryos created by activation methods not involving fertilisation of a human egg by a human sperm or SCNT

As discussed in Section17.3, the Committee considers that development of a human embryo created by any method not involving the fertilisation of a human egg by a human sperm beyond 14 days, or implantation of such an embryo into the body of a woman, are important prohibitions to ensure that such embryos are not used for reproductive purposes. However, the Committee proposes that a range of practices involving creation of human embryos by methods other than fertilisation should be allowed, under licence. The Committee considers that all nuclear and pronuclear

45 House of Representatives Standing Committee on Legal and Constitutional Affairs (2001). Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research, Parliament of the Commonwealth of Australia, Canberra (Andrews Report). http://www.aph.gov.au/house/committee/laca/ humncloning/contents.htm

transfer methods (including transfer of stem cell nuclei) should be permitted, under licence, for similar reasons to those already outlined for SCNT above. Similarly, parthenogenetic activation of oocytes should be permitted to allow oocyte maturation research (see above) and for other research and training activities.

Finally, the Committee considered that research involving the use of embryonic precursor cells and gene technology should also be permitted, under licence, to advance knowledge and develop therapeutic applications.

Recommendations — use of human embryos created by activation methods not involving fertilisation of a human egg by a human sperm or somatic cell nuclear transfer

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.

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.

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.

17.5 Definition of a human embryo

During the reviews, the Committee learnt that different people and groups hold differing views about the meaning and use of the term ‘embryo’, both in medical science and as a more general term.

The Committee considers that it is essential that the terminology used in the legislation is biologically accurate, clearly understandable by all stakeholders, and unambiguous to regulators, scientists and the public. Therefore, the Committee has taken the view that a very broad biological definition of ‘human embryo’ should be retained in the Act. This definition covers all stages of development commonly understood by the term ‘embryo’ in either scientific–medical or public–ethical

contexts. The committee suggests, however, that while it is critical to be clear about the terminology used, definitional clarity will not, in itself, resolve moral concerns and it is likely that, whatever language is used, different moral interpretations will be made regarding the status of such entities and the obligations owed to them. The recommendations of the Committee are an attempt to take account of all these views.

As discussed in Section 17.4, the current definition of an embryo sets the starting point of embryonic development as the appearance of two pronuclei. This definition is not based on any precise previous scientific or community definition of an embryo; the Committee was advised that this definition was a compromise between different views and resulted from the legal imperative to have a defined point against which legal judgments could be made. However, the Committee considers that the two pronuclei stage does not represent the formation of a new genetic entity and the use of this definition has had the unintended consequence of impeding or stopping significant areas of ART research (see Chapter 8).

The Committee considers that syngamy is a better definitional starting point for embryonic development because it is at this stage, when the maternal and paternal chromosomes align, that a new genetic entity is formed. However, because the precise point of syngamy is hard to observe in live embryos, the Committee proposes that the definition should refer to the first cell division. Practically, this change would mean that, for example, the biological marker of formation of pronuclei could once again be used as a readily observable marker for fertilisation, which would facilitate ART research on improved methods for treating infertility. This would still prohibit the creation of embryos using human eggs and human sperm for research purposes. Furthermore, this change is consistent with the conclusion of a discussion paper prepared by the National Health and Medical Research Council (NHMRC) on the biological definition of the human embryo. [46]

For embryos created by means other than by fertilisation of a human egg by a human sperm, the NHMRC discussion paper suggests that potential for implantation and future development to a live birth [47] could provide a useful criterion for considering whether such an entity should be included in the definition of a human embryo or not. This criterion was not applied to embryos created by fertilisation, however, because it was considered that all entities created this way should be defined as human embryos, regardless of any chromosomal or other anomalies that may prevent them from future development. These issues are discussed in more detail in Section 8.3.

The Committee considered these issues and has proposed a revised definition of a human embryo, based on the findings of the NHMRC discussion paper.2 In recommending this change, the Committee considers that the revised definition corresponds with the broadest public understanding of a ‘human embryo’, as

46 Discussion Paper: Human Embryo — A Biological Definition (NHMRC December 2005)

47 Where such potential is defined by the appearance of the ‘primitive streak’ (see Glossary)

expressed by the community groups who made representations during the review process.

The Committee acknowledges that obtaining a licence should be a prerequisite for conducting any research with human embryos but considers that this would not be an unreasonable burden for researchers as the Committee's recommendations will allow research that has previously been prohibited.

Recommendation — definition of a human embryo

28. The definition of a 'human embryo' in both Acts should be 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.'

17.6 Consent for embryo research

The Committee was mindful of the care and thought that has gone into the development of the NHMRC National Statement[48] and ART Guidelines.[49] It is essential that practices of consent are consistent across different areas of research and clinical practice. However, new areas of research generate situations that may not have been fully envisaged when guidelines are developed and therefore the Committee considers that the NHMRC should review certain aspects of those guidelines.

Donors of excess ART embryos expressed concerns that the current process for declaration of embryos as excess ART embryos, followed (at a later stage) by consent for a specific research project, is unnecessarily drawn out and stressful. In particular, the second stage of the process, when researchers approach embryo donors for consent to a specific research project, can occur some time (possibly many years) after the initial in-principle agreement to research. This reopens the emotional issue of the fate of the embryos. ART consumers advocated a simplification of the process. However, the Committee noted that there are important distinctions between different purposes or intent of the research that are not known until the embryos are selected for a specific project. Furthermore, some people may wish to be involved in the decision

48 National Statement on Ethical Conduct in Research Involving Humans (NHMRC 1999) see http://www.nhmrc.gov.au/publications/synopses/e35syn.htm

49 Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (NHMRC 2004) see http://www.nhmrc.gov.au/publications/synopses/e56syn.htm

about the particular type of research for which their embryo is used, while for others this may not be the case.

In view of the concerns of ART consumers, the Committee's view is that the NHMRC Australian Health Ethics Committee (AHEC) should review its guidelines for consent in these circumstances. In particular, the Committee considers that AHEC should develop arrangements to facilitate donation of 'excess embryos' to research without further contact at a later stage for those who wish to accept this option (with the involvement of human research ethics committees to determine circumstances where this can occur). These arrangements should take into account any preference of those who donate embryos or gametes for the creation of embryos for the type of research for which the tissue will be used.

However, there is a significant difference between research with human embryos for the purposes of improving ART services (where there is no ongoing, live biological material produced from the embryos), and research with human embryos for the purpose of creating embryonic stem cell lines that are 'immortal' and will be used in various other ongoing research contexts. In this regard, the Committee considers that it is necessary for consent to be obtained and that it is important for people to be fully informed about the commercial potential of their donation and, where possible, appropriate conditions should be put in place for personal use of any products of the research by the donors (such as for the treatment of children who are matched with any stem cell lines derived).

Finally, to facilitate the use of 'surplus' or unfit embryos (including PGD embryos) for research or training, the Committee considers that AHEC should also develop guidelines for consent in these circumstances.

Recommendations — consent arrangements for the donation of embryos

29. The 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.

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).

17.7 Egg donors

The Committee is concerned that changing the legislation to permit nuclear transfer and related technologies would lead to an increased demand for donated eggs (oocytes). The only oocytes presently available for research would be those donated by young women, and the Committee is concerned that this could lead to exploitation of these women. The Committee also noted that oocyte donation for research purposes raises particularly salient ethical concerns, because donors receive no direct medical benefit but are exposed to an increased risk of morbidity or mortality associated with the follicle stimulating hormone treatment required for mature egg retrieval. In addition, the Committee notes with concern the recent publicity about research overseas involving unethical inducement of research staff to donate eggs.50 In the light of this, the Committee's view is that firm guidelines should be prepared to ensure that egg donors give free consent, and have all the appropriate information, including whether or not the eggs may be used to make embryos for research purposes.

The Committee is concerned that women in ART treatment programs may be requested to donate eggs for research and, therefore, to avoid coercion of women in this situation, considers that there should be a clear separation between the obtaining of eggs for ART practice and research. Coercion of other vulnerable people (such as research assistants) and living, related donors should also be discouraged by strict guidelines for preventing or restricting such activities.

The Committee heard the view that the level of reimbursement made to egg donors should be substantial to compensate for the risks. However, the Committee formed the view that payment to donors should not be permitted beyond reimbursement of reasonable expenses, in order to limit the risk of exploitation of women and commodification of tissue.

The Committee considered other ways in which eggs could be obtained, such as after surgical removal of ovaries for conditions such as cancer or polycystic ovary disease, or cadaveric donation (as with other organ donation). Use of such material would avoid the need for individual egg donations.

Finally, the Committee heard of several avenues of research that would overcome the need for eggs in embryonic stem cell research, such as the production of eggs from stem cells in culture or the use of stem cell cytoplasm to incubate adult cell nuclei. Further research on maturing oocytes in the laboratory, and freezing of mature eggs, would also reduce the need for hormone stimulation of women

making individual donations of mature eggs. The Committee's view is, therefore, that these lines of research should all be encouraged to overcome the need for donation of mature eggs as soon as possible. In addition, the Committee has also already suggested that nuclear transfer using animal eggs could be permitted for limited research purposes to establish proof of principle and reduce the need for human egg donation (see Section 17.4).

Recommendations — egg donation

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.

32. The NHMRC should develop guidelines for egg donation.

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.

17.8 Licensing arrangements

Current arrangements

Respondents to the reviews from all stakeholder groups, including researchers, were supportive of the need for strong regulatory oversight of this type of research. The Committee considers that the Licensing Committee fulfils a valuable role in this process and is broadly supported by researchers and by the community.

The Committee notes that delays in issuing of the first licences were an unavoidable consequence of the processes to establish the new regulatory system in this complex area of legislation. As indicated in Recommendations 14–27 above, the Committee's view is that the role of the Licensing Committee should be expanded to include licensing of the additional activities that the Committee has recommended, including creation of human embryo clones by nuclear transfer, parthenogenetic activation of oocytes, experimental fertilisation, and other related research, training and quality assurance activities. However, the Committee notes that institutional human research ethics committees are able to allow or decline specific research proposals for their own institutions.

However, these delays, as well as a lack of clarity in some aspects of the application process, were seen by researchers as inhibiting research, training and quality assurance activities. Conversely, some nonresearchers thought that the licensing process had not been sufficiently rigorous, although the Committee noted that this was, to some extent, due to a lack of public understanding of the licensing requirements (see Section 9.2). The NHMRC itself has observed that there are deficiencies in the legislation relating to the operations of the Licensing Committee, and that amendments to the legislation could improve the efficiency and clarity of the process.

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

The Committee considered that delegation of the powers of the chair, powers to suspend and revoke licences, and other practical issues raised, could be managed under the RIHE Act s15. Similarly, the Committee considered that the issuing of joint licences was a matter for the Licensing Committee to decide, with legal advice, if necessary.

A further area of concern for the Licensing Committee was the need to receive feedback on research outcomes (such as for the derivation of stem cell lines) to inform further decisions relating to whether such research represents a 'significant advance in knowledge or improvement in technology'. The Committee's view is that the Licensing Committee should request reports from researchers using embryonic stem cells derived from licensed activities, and for a reasonable period beyond the conclusion of the licence, as a condition of the issuing of a licence, similar to reporting to HRECs, as a condition of the licence (RIHE Act s24).

The Committee supports the role of the HRECs and the two-stage system of approval of research, with initial approval by the local HREC followed by application for a licence from the Licensing Committee.

The cost of supporting the Licensing Committee and the national compliance system was $3.3 million in 2003–04. To date, no cost-recovery mechanism has been applied to recover these costs (see Section 9.1). However, due to the low number of licences issued, cost recovery from licence applicants would be exorbitant In addition, research organisations already meet the considerable costs of compliance with the national regulatory scheme, including licensing requirements. The Committee's view is that, if cost recovery were to be pursued, it would be likely that research would be severely limited.

Recommendations — licensing arrangements

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.

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).

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.

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.

17.9 Monitoring and compliance

The Committee heard that, under the arrangements set out in the RIHE Act, the Licensing Committee chair has appointed inspectors, and a monitoring and inspection system for facilitation and monitoring compliance with the legislation has been set up and is generally regarded as suitable.

However, the Committee also heard from the Licensing Committee and others that there is a major deficiency in the legislation with regard to the limited powers of the inspectors appointed under the RIHE Act to monitor activities that are not covered by a licence. As a result of this deficiency, suspected breaches by non-licence-holders, including suspected breaches under the PHC Act, cannot be adequately investigated. In terms of licensed premises, the Committee also heard that inspectors do not have the power to make unannounced inspections, which also inhibits their ability to investigate suspected breaches.

The Committee's view is that inspectors should have adequate powers under both Acts to investigate suspected breaches of either Act. There is a legal question whether these powers already clearly exist, notwithstanding s41 of the RIHE Act. The Acts should be amended accordingly if this is necessary.

Recommendations — monitoring powers

38. The Licensing Committee should continue to perform its functions in relation to licences and databases for research permitted by licences under the RIHE Act.

39. Licensing Committee inspectors should be given powers, under the PHC and RIHE Acts, 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.

17.10 Oversight of ART clinical practice and research

Under the RIHE Act, the creation and use of human embryos for ART can only be carried out by an accredited ART centre, defined in the RIHE Act and current RIHE Regulations as a centre accredited by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia. During the reviews, the Committee received information about this accreditation system, which involves accreditation by RTAC against a code of practice developed by the industry (RTAC Code 2005).

Most respondents regarded the current arrangements for oversight of ART services by national and State or Territory bodies as appropriate and effective. There appears to be a cooperative relationship between RTAC, at the national level, and statutory bodies established at the State level. Advantages to the RTAC self-regulatory model include its flexibility to respond to technological change, and its inclusion of a wide range of professional and consumer interests. However, at least in some States, there may be some potential for confusion about the various requirements in legislation, guidelines and codes of conduct.

The Committee received a few comments arguing against industry self-regulation. However, it also received strong endorsement of the current arrangements by ART consumers and heard that ART consumer representatives have been represented on the RTAC Accreditation Board and involved in the development of the RTAC Code 2005.

The Committee noted that an important aspect of the accreditation arrangements is that the ART Guidelines 2004 are mandated in the RTAC Code 2005, a system that ensures compliance with these guidelines, including adherence to the arrangements for declaring ART embryos to be excess and for proper consent for donation of embryos for research. The latter arrangements are also included in the statutory arrangements under the RIHE Act (ss8 and 24). The Committee formed the view that these arrangements are effective and should continue.

Recommendation — oversight of ART clinical practice and research

40. There should be a continuation of the role of the Reproductive Technology Accreditation Committee in the regulation of ART.

17.11 Import and export of human reproductive materials for personal use

During the reviews, the Committee heard that controversy around trade and international exchange of gametes, embryos and embryonic stem cells is related to ethical concerns about the sources and uses of these materials, the commodification of human tissues, and the commercialisation of any therapeutic products derived from them.

However, the Committee heard from ART consumers that the current export prohibitions and custom regulations regarding human embryos have made it difficult

for couples to export their embryos overseas for their own reproductive use. The Committee's view is that the current arrangements, which involve personal application to the Minister for Customs to export embryos for personal reproductive use, are too cumbersome and stressful for users and should be streamlined.

Recommendation — import and export of human reproductive materials for personal use

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.

17.12 Trade and international exchange of human reproductive materials for research use

The PHC Act bans the creation, import and export of human embryo clones, but the import of material derived from human embryo clones (or from any embryos), such as embryonic stem cell lines, is covered by aspects of the Customs Act and Regulations, which prohibit the import of any products of prohibited embryos. However, products that comply with Australian requirements (such as embryonic stem cell lines obtained, under licence, from excess ART embryos) can be imported (under conditions overseen by the Australian Quarantine and Inspection Service).

The Committee heard from some researchers that these arrangements had not affected their research, whereas others noted the importance of Australian researchers having access to further cell lines from overseas. There was general concern about whether such imported cell lines have been derived using practices consistent with Australian legislation. The Committee's view is that the existing requirements for the import and export of human biological materials are satisfactory for ethically derived human embryonic stem cells.

Recommendations — trade and international exchange of human reproductive materials and stem cells

42. The import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority.

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.

17.13 Biotechnology and commercialisation

There is a strong view that gametes and embryos should not be commodified by permitting people to sell their own gametes and embryos. Respondents were also

concerned to see the benefits of altruistic donation translated into public benefit and access to therapeutic applications arising from the research. However, the Committee also notes that stem cell technology is regarded as a useful platform for investment by the biotechnology industry and understands that such investment is needed to develop potential therapies. This would require that the products of the research and development activities are able to be commercialised.

The Committee's view is that there is a necessity to balance commercial interest with recognition of altruistic donation. The Committee strongly supports the current system of monitoring by HRECs to ensure informed consent processes.

Recommendations — biotechnology and commercialisation

44. Trade in human gametes or embryos, or any commodification of these items, should continue to be prohibited.

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.

46. The development of biotechnology and pharmaceutical products arising from stem cell research should be supported.

17.14 The applicability of a national stem cell bank

Stem cell banks offer a way of facilitating research by making the stem cell lines more widely available to the international research community. Other living tissues already banked in Australia for use in transplantation medicine include heart valves, bone, skin, and cord blood. There are also numerous research tissue banks, including banks for various tumour samples and banks for specific diseases and for specific organs.

There are now a number of stem cell registries around the world holding information about the source, characteristics and derivation of stem cell lines, and a number of stem cell banks are either active or planned. The UK Stem Cell Bank, funded by the UK's Medical Research Council and Biotechnology and Biological Sciences Research Council, began operating officially in January 2003 and two Australian embryonic stem cell lines have already been accepted into it.

Although some scientific researchers argued that an Australian stem cell bank may not be necessary because overseas stem cell banks (eg the UK cell bank) were adequate, the Committee heard overall strong support for an Australian national stem cell bank in order to provide improved access to stem cell lines for research and to provide a quality control mechanism for stem cell research. Different models for the administration of a national stem cell bank were suggested. Some recommended that a national stem cell bank be established at the major national research facility at the

Australian Stem Cell Centre (ASCC), which is already capable of storing stem cell lines. Other suggestions were that a national stem cell bank be based on the UK Stem Cell Bank, that such a bank be a decentralised structure incorporating 'nodes' of specific research interest or expertise located in different parts of the country, or that a registry of stem cells would be a better system.

Fair access and equal involvement were the two main concerns about community involvement in a national stem cell bank. There was concern about the potential for exploitation of stem cells from minority groups. Some respondents were also concerned that the driving force behind a national stem cell bank was commercial rather than scientific or medical. While the Committee acknowledged that commercialisation of therapeutic products would be an outcome of stem cell research, it also came to the view that stem cell banks would help to keep research resources in the public domain.

Some respondents commented that a stem cell bank would be expensive to maintain. The Committee has not investigated the financial implications of operating a stem cell bank. However, financial support for this activity would be essential if the stem cell lines are to be made available to the scientific community.

The Committee's view is that an Australian national stem cell bank would make stem cells, including embryonic and adult stem cells, more widely available to researchers and also limit the number of embryos required for further derivation of stem cell lines. As the Australian Stem Cell Centre already has a stem cell banking facility, the Committee considers that this facility could be expanded to accommodate a national bank administered by ASCC. However, ASCC should liaise closely with other stem cell banks overseas and use compatible operating principles.

Many respondents, including both ART consumers and ART clinics, were concerned that, following the decision to make excess ART embryos available for research, there would be no opportunity for these embryos to be used in actual research projects. One IVF clinic suggested that a national embryo bank should be established in conjunction with a national stem cell bank to allow more couples to donate their excess ART embryos for research. It was the Committee's view that such an embryo bank may not have broad community support. However, the Committee considered that there would be considerable potential in the establishment of a national register of donated embryos. This register could be maintained by the Licensing Committee if empowered to do so. This register may serve the function of facilitating embryo donation for research and would provide a transparent account of the number of donated excess ART embryos held. It may also be possible that such a register may facilitate embryo donation to another couple.

Recommendations — national stem cell bank

47. A national stem cell bank should be established.

48. Consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem cell bank.

49. A national register of donated excess ART embryos should be established.

17.15 Regulatory approach to legislation

The Committee noted that both the proponents and opponents of human embryo research would prefer to have legislation in this area, rather than to have no specific regulation. However, the Committee also heard a number of concerns about the capacity of legislation to respond to research needs in a fast-moving area of technology. These included difficulties in anticipating advances in knowledge and potential new uses of the technology, ambiguities and difficulties in interpretation, and unfair exposure of researchers to potential prosecution (see Chapter 16 for further discussion of these issues).

The Committee's view is that some activities should remain entirely prohibited, in order to assuage community concern that practices that are widely condemned will be prohibited. At present, these activities are set out in the PHC Act and include reproductive cloning, creating a human embryo other than by fertilisation, placing certain types of embryos in a woman's reproductive tract and other related offences (see Section 17.3).

To increase certainty and flexibility in the application of the legislation, especially in face of rapidly changing technology, the Committee's view is that the Licensing Committee should be authorised to give rulings on the interpretation of the provisions creating offences under the PHC Act, with a statutory requirement that the Committee must report immediately in detail to the NHMRC and to parliament on its rulings. As with rulings given by the Commissioner of Taxation, people who act on the basis of such rulings should have statutory immunity from prosecution.

In relation to activities that are permitted with a licence under the RIHE Act, the Committee recommends that the Licensing Committee should be empowered to give a ruling that enables it to grant a licence for an activity that may fall outside the literal wording of the Act but seems to fall within its general tenor. If the Committee gives such a ruling, it should be required to report immediately in detail to the NHMRC and to parliament on that ruling and any licence granted on the basis of the ruling. Again, there should be statutory protection for those who act in good faith on such advice.

The Licensing Committee's authority to provide rulings on the interpretation of provisions of both Acts should be specified in those Acts. Section 41 of the RIHE Act appears to give the Licensing Committee powers under both Acts; but, to remove any doubt, it would be preferable for the requisite powers to be specifically conferred under both Acts.

The Committee notes that there are precedents for this approach in other areas of law, such as taxation (where the Commissioner for Taxation can issue 'rulings' on the

applicability and interpretation of various taxation legislation). Also, such an approach would complement the monitoring and compliance procedures that have been set up by the licensing inspectors to assist researchers to comply with the law, and with prosecution seen as an action of last resort (see Chapter 10).

The Committee has not come to any view about whether the two Acts should remain separate or be incorporated into one because, in its view, this is a matter for parliament. However, the Committee notes that the more flexible regulatory arrangements it has recommended would reduce the need for an ongoing review process. Nevertheless, in view of the fast moving developments in the field and the range of amendments proposed in these reviews, it is the Committee's view that the two Acts should be subject to a further reviews, either six years after royal assent of the PHC and RIHE Acts or three years after royal assent to any amended legislation.

Recommendations — regulatory approach to legislation

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.

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.

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.

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.

17.16 Education and public awareness

The Committee found that public knowledge of stem cell research and ART research was limited. A number of respondents expressed surprise and concern about the use of excess ART embryos for ART research and clinical training, because they had formed an opinion based largely on media reports that these Acts were to regulate embryonic stem cell research.

The Committee noted that the scientific community and the public (informed by the media) frequently underestimated the likely timeframes for translation of research

activity into therapeutic outcomes and that this may lead to disappointment and diminished public trust. The Committee therefore suggests that accurate presentation and reporting of research advances is critical for public engagement with this area of research. In particular, emphasis should be given to making realistic assessments of the short-term and long-term benefits of the research.

The Committee noted the current work on stem cell education and endorsed these programs. However, further public education and consultation programs are needed to enable appropriate engagement and understanding of these fields of research and their application. The Committee's view is that the NHMRC, through the Licensing Committee, could play a role in this process.

Recommendation — public education

54. There should be ongoing public education and consultation programs in the areas of science that are relevant to the Acts.