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.