12

Proposed regulation of human cloning

INTRODUCTION

12.1 This chapter outlines the Committee's proposed framework for the regulation of human cloning and related research in Australia. The Committee has drawn on the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* and the existing legislative regulation of these matters in Victoria, South Australia, Western Australia and the United Kingdom in developing its proposal.

12.2 As reported in Chapter 7, Committee members recognise the potential benefits of human cloning, but they have differing views about using stem cells, depending on the source of the material. Whilst the majority of members believe that it should be permissible for surplus embryos from assisted reproductive technology programs to be used in clearly defined, limited circumstances,[1] other members believe that procedures that involve the destruction of embryos are unethical and should be rejected.[2]

12.3 All members recognise, however, that the final decision about cloning in Australia will be made by Commonwealth, State and Territory Parliaments.[3] If Australian Governments and Parliaments decide to

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1 See Chapter 7, paragraphs 7.110-7.111

2 See Chapter 7, paragraph 7.112-7.115

3 The Council of Australian Governments (COAG) decided (on 8 June 2001) to develop nationally consistent provisions in legislation to prohibit human cloning. COAG agreed that jurisdictions would work towards nationally consistent approaches to the regulation of assisted reproductive technology and related emerging human technologies. Health Ministers are expected to report back to COAG by the end of the year on technical issues arising from this decision with the aim of a nationally consistent approach being in place in all jurisdictions by June 2002. Council of Australian Governments' Meeting, *Communique*, 8 June 2001

regulate human cloning involving stem cells derived from embryos surplus to assisted reproductive technology programs, all Committee members agree upon the proposed system of regulation outlined in this chapter. Those members of the Committee who believe the use of embryos in research is unethical, nevertheless agree that if such research is permitted it should be regulated in the way outlined in this chapter.

A SYSTEM OF REGULATION

12.4 The Committee proposes the following features of a regulatory framework:

- a national uniform legislative approach;
- a ban on cloning for reproductive purposes;
- one system of regulation for privately and publicly funded research;
- legislation regulating human cloning and stem cell research to be separate from that governing artificial reproductive technologies (ART);
- any attempt to undertake cloning for reproductive purposes to be subject to criminal penalty and the withdrawal of a licence to undertake research in this area;
- research using cloning techniques be subject to clear legislative parameters, including (subject to the moratorium referred to in paragraph 12.42) a complete ban on the deliberate creation of embryos for research purposes;
- a national licensing body be established to regulate human cloning and research using cloning techniques;
- individual researchers be licensed for each research project that involves the use of an embryo;
- the import and export of embryonic stem cells should be permitted within the framework of principles outlined in this report, that is, it should be permissible to import or export embryonic stem cell lines that are already in existence or have been created using embryos that are surplus to the requirements of assisted reproductive technology programs. The import or export of embryos for the purposes of cloning related research need not occur. As there is no evidence to suggest that this is required, the Committee is not convinced that it is appropriate or necessary; and

- the regulatory framework must be transparent, accountable and responsive.

12.5 These features are discussed in detail below.

12.6 The Committee supports the continued development of adult stem cell research but does not believe it should be subject to the regulatory framework outlined in this report. Such research should be governed by existing regulatory schemes.

12.7 The clinical application of the results of research involving cloning technologies will not occur for some time. The Committee did not examine the regulatory framework that should govern such clinical application in detail. The regulatory issues arising from the clinical application of the results of cloning related research should be considered if and when the research yields results that may be applicable in the clinical context.

A National Approach

12.8 As was noted in the previous chapter, the evidence overwhelmingly supported national uniform regulation covering both public and private sectors.

12.9 The AHEC report recommended that the way to achieve this would be for those States and Territories without specific legislation governing this area to proceed to enact such legislation. This recommendation was premised on the view that the Commonwealth did not have sufficient constitutional power to legislate on its own.

12.10 These recommendations by AHEC found little support among those giving evidence to the inquiry. In the Committee's view simply following AHEC's recommendations would not do justice to the fundamental importance of the issues. Past experience inspires little confidence that AHEC's recommendations would be implemented expeditiously if left to individual states and the end result of such an approach would be likely to be further jurisdictional inconsistency.

12.11 Other alternatives for regulation include the:

- passage of uniform legislation by the Commonwealth, States and Territories;
- use of available constitutional powers to support Commonwealth legislation; or
- Australian Academy of Science proposal which builds on the existing system.

12.12 In the Committee's view the Commonwealth must take the lead in regulating this area of research because:

- of its inherent importance, involving as it does fundamental and sensitive issues concerning the possible development of human life and the creation and use of embryos. This is a matter so significant as to require a national response;
- the international as well as national dimension of the research requires consistent national regulation within Australia;
- the Commonwealth has legislative power in many areas that impinge upon the conduct of research involving the use of cloning techniques such as the import and export of human material, patenting, trade and commerce, corporations, external affairs and higher education;
- Commonwealth leadership is required to ensure the necessary uniformity; and
- some of the States and Territories have been tardy in developing legislation.

12.13 The Committee considers it would be preferable for the Commonwealth to take the lead in developing national legislation. The legislation, developed in cooperation with the States and Territories, would establish a national licensing body to regulate research involving human cloning and related technologies.

12.14 This matter requires urgent action. It is the Committee's view that if the will for immediate action on the part of the States and Territories is not apparent the Commonwealth should develop and enact legislation in reliance on the full extent of its constitutional powers and work with the States and Territories to seek to ensure that they enact legislation consistent with that of the Commonwealth in order to fill any gaps in coverage that remain.[4]

12.15 In the Committee's view the Commonwealth has the constitutional power to legislate to regulate human cloning and its related research.

12.16 The clear preference of the Committee is for the Commonwealth Government to enact legislation to regulate cloning and its related research. It should rely on the full range of its constitutional powers in relation to matters such as corporations, trade and commerce, quarantine, territories, import and export, patents, statistics, external affairs, actions by

4 See discussion in Chapter 11 at paragraphs 11.42-11.46

the Commonwealth or Commonwealth authorities and its capacity to attach conditions to its funding of activities or institutions.[5]

Recommendation 1

12.17 **The Committee recommends the enactment of legislation by the Commonwealth to regulate human cloning and stem cell research.**

12.18 The Committee has noted the Council of Australian Governments' (COAG) decision of 8 June 2001 to develop a consistent national approach to the regulation of these issues.[6] Should the enactment of legislation by the Commonwealth not prove to be feasible, the Committee recommends, in light of the decision by COAG**,** the enactment of national uniform legislation at both the Commonwealth and the State / Territory level to achieve a cooperative uniform national scheme to regulate these matters. The Committee considers it is crucial that the national regulation of these issues be uniform across jurisdictions. While the alternative regulatory proposal of COAG is not the Committee's preferred approach, it has the potential to appropriately regulate human cloning and its related research if the Committee's proposals in the rest of this chapter are incorporated in its national scheme.

Public And Private

12.19 The Committee proposes that the legislation cover both privately and publicly funded research involving cloning techniques.

12.20 The AHEC report expressed concern that privately funded organisations in those States and Territories without legislation governing cloning might consider cloning a human being or human parts without the approval of an institutional ethics committee (IEC) under National Health and Medical Council (NHMRC) guidelines. The AHEC report noted that ' … [w]ithout

5 See Constitution; section 51(i)–trade and commerce; section 51(ix)– quarantine; section 51(xx) – corporations; section 51(xi)–statistics; section 51(xviii)–patents; section 51(xxix)–external affairs; section 122-Territories. Commonwealth legislation in reliance on these powers would lead to significant Commonwealth control particularly in relation to research conducted by corporations and Commonwealth funded institutions as well as over the import and export of research material

6 Council of Australian Governments' Meeting, *Communique*, 8 June 2001

legislation the NHMRC cannot stop private institutions conducting such work'.[7]

12.21 The evidence to the Committee overwhelmingly supported one regulatory framework for both privately and publicly funded cloning related research.

12.22 Professor Chalmers, then Chairman of AHEC, reiterated that AHEC's '…feeling is that much of this work could be done in the private sector'[8] and that the private sector needs to be regulated.[9]

12.23 Dr Mayo, of the Australian Academy of Science, sought uniform national legislation that 'would apply equally to both the public and private sector'.[10] In the Academy's view the right regulatory tool is not the withholding of funds from research (as is currently the case in relation to the NHMRC).[11]

12.24 The view that any regulatory framework must apply to both the public and private sectors was supported by the Human Genetics Society of Australasia which supported the creation of a national statutory body to review:

> … all proposals and policies relating to the use of new reproductive technologies for human cell or tissue cloning in any context …[and] ensure that this policy applies both to the public and private sectors.[12]

12.25 Professor Williamson also took the view that any regulation must cover both publicly and privately funded research.[13] Dr Nicholas Tonti-Filippini argued that the lack of regulation of private sector cloning related research in many of the States and Territories is '… really creating a pressure for this work to go into the private institutions and private companies' and urged that private sector research in this field be regulated.[14]

12.26 The Committee agrees with these concerns. It also agrees with the comment of a private citizen, Dr David Elder, who argued that the sort of

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7 AHEC report, Chapter 4, paragraph 4.34
8 Professor Donald Chalmers, *Transcript*, p.3
9 Professor Donald Chalmers, *Transcript*, p.52
10 Dr Oliver Mayo, *Transcript*, p.78
11 AAS, *Transcript*, p.78
12 Human Genetics Society of Australasia, *Submissions*, p.S509
13 Professor Robert Williamson, *Transcript*, p.9
14 Dr Nicholas Tonti-Filippini, *Transcript*, p.46

'double standard' that operates in the United States in the regulation of public and private research was 'highly unacceptable'.[15]

12.27 As was noted in Chapter 10 research that occurs in the private sector in the United States is virtually unregulated. The Australian Academy of Science also made this point. In the Academy's view this has resulted in an element of secrecy whereby the information being gained as the result of research is not in the public domain.[16]

Recommendation 2

12.28 **The Committee recommends that legislation regulating human cloning and stem cell research cover all research in this area, both publicly and privately funded.**

Separate From Legislation Governing Assisted Reproductive Technologies (ART) and Other Legislation

12.29 The Committee proposes that legislation governing human cloning and stem cell research be separate from legislation pertaining to artificial reproductive technologies (ART).

12.30 Current regulation of cloning and research involving the use of embryos was developed in the context of assisted reproductive technology and fertility treatment. While aspects of research involving the use of cloning technologies (such as for reproductive purposes) may still have some connection with these areas, the focus of the research is currently in areas that potentially will be applicable to all in society and involve fundamental changes in medical and social practices.

12.31 Further, while at present reproductive medicine is a comparatively discrete area, the future development of research involving cloning technologies will involve large biotechnology interests and major research projects. The products of the research could potentially be applicable in broad areas of clinical and medical practice that go a long way beyond reproductive technologies. Hence it is important that the regulation of this research be separated from the regulation of assisted reproductive technologies.

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15 Dr David Elder, *Submissions*, p.S194. See Chapter 10 for a discussion of regulation of human cloning and its related research in the United States. Others to stress the importance of covering both the public and private sectors included the Country Women's Association of NSW, *Submissions*, p.S160 and *Transcript* p.95; Consumers Health Forum, *Submissions*, p.S792

16 Australian Academy of Science, *Transcript*, p.78

12.32 The Committee reiterates that its proposed regulatory framework applies only to the conduct of research and not its clinical application.

Recommendation 3

12.33 **The Committee recommends that the regulation of research involving the use of cloning technologies should be separate from that governing assisted reproductive technologies.**

12.34 The Committee also emphasises that only research involving humans should be regulated under this proposed new system. Research and commercial applications involving plants and animals should continue to be subject to current regulation. In the Committee's view it is both inappropriate and inadequate to include provisions concerning human cloning in the *Gene Technology Act 2000*.[17]

THE CONTENT OF THE LEGISLATION

Ban On Cloning for Reproductive Purposes

12.35 For the reasons set out in Chapter 6, the Committee proposes that any legislation contain a ban on cloning for reproductive purposes.

12.36 The Committee further proposes that any attempt to undertake cloning for reproductive purposes should be subject to criminal penalty and the withdrawal of a licence to undertake research by the individual concerned.

Recommendation 4

12.37 **The Committee recommends that the legislation regulating human cloning and stem cell research contain a ban on cloning for reproductive purposes. Any attempt to undertake cloning for reproductive purposes should result in a criminal penalty and the withdrawal of a licence to undertake research in this area for the individual concerned.**

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17 The *Gene Technology Act 2000* was discussed in Chapter 8 at paragraphs 8.21-8.22, 8.37- 8.38 and 8.76

Provisions Relating To Research

12.38 The Committee emphasises that the following discussion concerning the regulation of research involving the use of embryos is not intended to affect the existing regulation applicable to assisted reproductive technology programs.

12.39 Hence a person may produce a human embryo by achieving the fertilisation of a genetically unaltered human ovum by genetically unaltered human sperm through natural conception or artificial conception (by means of, for example, IVF, GIFT etc).

12.40 The Committee proposes that research involving the use of cloning technologies and requiring the use of embryos should be subject to clear parameters.

12.41 The Committee proposes that, with the exception of embryos created by means of somatic cell nuclear transfer, which is dealt with specifically in paragraph 12.42, the legislation should ban the deliberate creation of an embryo for research purposes as well as any selling or trading in embryos, sperm or eggs. The term 'embryo' should include an entity with a genome that is human or substantially human and that has a capacity for development similar to a human zygote or embryo normally produced by the fertilisation of a human ovum by human sperm.

12.42 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. If, at any time, AHEC forms the view that research has progressed to a point which necessitates that the moratorium be lifted it should report to the Council of Australian Governments. The creation of embryos by means of somatic cell nuclear transfer should not be permitted at this stage although this need not necessarily form part of the legislative ban on the deliberate creation of embryos. Currently, there is no therapeutic purpose to be served by the creation of such embryos as research has identified no specific opportunities that require the deliberate formation of embryos.

12.43 The legislation should permit the licensing body to issue a licence for a person to use a surplus embryo from an assisted reproductive technology program for research or therapy that damages or destroys the embryo where that project has the approval of both an institutional ethics committee (IEC) established, composed and conducted in accordance with

NHMRC guidelines and the national licensing body proposed in this report, and that the approval is given on the basis that:

- there is a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed procedure;
- the significant advance in knowledge or improvement in technologies could not reasonably be achieved by other means;[18]
- the procedure involves a restricted number of embryos and a separate account of the use of each embryo is provided to the IEC and the national licensing body (as is the case with animal research);
- all tissue and gamete providers involved and their spouses or domestic partners, if any, have consented to the specific form of research for each embryo used;
- no animal tissue or animal gametes are used to form a human-animal hybrid embryo;
- no embryo that has been the subject of cloning technology, or produced other than by fertilisation of a human ovum by a human sperm is ever transferred to the body of a woman or otherwise allowed to survive beyond the stage at which a blastocyst forms or the age by which a blastocyst would normally have formed;
- no human embryo is ever allowed to be transferred to the body of an animal or to be artificially gestated;
- no attempt is made to form embryos using stem cells or stem cell cultures; and
- a licence has been granted for the use of the embryo (see below).

18 The inclusion of such a criterion should not be able to be used as a means of reopening the issue of embryonic stem cell research. It would simply require, in the case of an individual application to conduct research involving a surplus embryo gained from assisted reproductive technology programs, that the applicant demonstrate that the individual project for which approval is sought could not be conducted without the use of a surplus embryo. This is similar to the requirements established under legislation in the United Kingdom. Paragraph 3 (6) of Schedule 2 of the *Human Fertilisation and Embryology Act 1990 (*UK) provides that research licences for research involving the use of embryos may only be granted if the Human Fertilisation and Embryology Authority is satisfied that any proposed use of embryos is necessary for the purposes of the research. See Chapter 10, paragraphs 10.76-10.85 and 10.92-10.96 for a more detailed discussion of the United Kingdom regulatory regime

Recommendation 5

12.44 **The Committee recommends that the Commonwealth regulate human cloning and stem cell research within the strict parameters outlined in paragraphs 12.41-12.43.**

National Licensing Body

12.45 The legislation should also establish a national body to license research involving the use of cloning and associated technologies.

Recommendation 6

12.46 **The Committee recommends that a national licensing body be established to regulate any research involving the isolation, creation and use of embryonic stem cells.**

A Licensing Scheme

12.47 The Committee proposes a national licensing body to regulate human cloning and stem cell research. This would be comparable to the regulatory approach used in the United Kingdom.

12.48 A licensing approach to the conduct of this research would enable decisions to be made in an open and transparent way that is easily understood by all. It would apply consistent rules across the country and serve to reassure the community that fundamental values are being protected. It would also provide certainty to researchers and to industry.

12.49 Regulation in this form should also ensure effective access to knowledge of scientific and clinical developments with a view to protecting the public interest. The legislation should provide sufficient discretion to the licensing body to enable it to respond to developments and implement changes in response to discoveries in the areas of science and medicine and the growth in community understanding.

12.50 The legislation should incorporate a sunset clause to enable its operation to be reviewed in five years.

12.51 The legislation could also incorporate a mechanism similar to the Ministerial Council used in the *Gene Technology Act 2000* to engage the

States / Territories in the regulation of the issues.[19]

Recommendation 7

12.52 **The Committee recommends that a licence issued by the national licensing body should be required to undertake any research involving the isolation, creation and use of embryonic stem cells.**

Structure Of The Licensing Body

12.53 The legislation should provide that a licence from this body is required to undertake any research involving the use of cloning technologies. It should be an offence to conduct such research without a licence. Furthermore, only a holder of a current licence should be eligible to receive Commonwealth research funding to undertake research involving the use of the listed technologies.

12.54 The licensing body should be established by the legislation. In the Committee's view the licensing body should have a good balance of membership across relevant sectors such as science, medicine, law, ethics and the social sciences. Its membership should include a scientist with knowledge of human cloning technologies.

Powers Of The Licensing Body

12.55 The licensing body would:

- grant research licences in accordance with the legislation as set out in paragraphs 12.35-12.37 and 12.40-12.43;
- develop and issue guidelines concerning various aspects of the conduct of research. Such guidelines could be used by States and Territories;
- ensure transparency and accountability by reporting annually to Parliament outlining all licences granted, the purposes for which they were granted and the outcome of such research;
- conduct inspections;
- monitor compliance with the conditions of the licence;

19 The Ministerial Council is established under the Gene Technology Agreement made between the Commonwealth and the States and Territories in relation to the regulation of gene technology. The *Gene Technology Act 2000* (sections 21-24) enables the Ministerial Council to issue policy principles or guidelines or codes of practice

- impose sanctions for the breach of licence conditions. These sanctions should include withdrawal or non-renewal of a licence or fines;
- consult with scientists, researchers, other regulatory bodies, industry and the general public; and
- consult regularly with AHEC on ethical, scientific and other issues arising from research applications.

Recommendation 8

12.56 **The Committee recommends that the national licensing body have the responsibilities listed in paragraph 12.55.**

Role of AHEC

12.57 AHEC should have a continuing role. It should monitor scientific developments in this area in Australia and overseas, analyse their potential impact and provide advice to Commonwealth, State and Territory governments on future directions in research, anticipated challenges, strategic priorities for research and the potential implications of research. Such a role would provide an integrated advisory and policy capacity that is currently lacking. In order to carry out this function AHEC would need to involve a person(s) with direct scientific experience in this area of research.

12.58 AHEC should also be responsible for developing and implementing a strategy to consult and involve the public in consideration of the issues arising from this research and encourage debate on the potential and implications of the research.

Recommendation 9

12.59 **The Committee recommends that the Australian Health Ethics Committee (AHEC) be responsible for monitoring scientific developments in this area, analysing their potential impact and providing advice to Commonwealth, State and Territory governments on these matters.**

Type Of Licence

12.60 The Committee proposes that individuals and organisations be licensed to undertake cloning related research. Individuals should also be licensed for each research activity involving cloning related research they intend to undertake. Issuing general licences to organisations to undertake research of this kind should increase the efficiency, speed and responsiveness of the licensing process for research activities.

12.61 The *Human Fertilisation and Embryology Act 1990* (UK) establishes a similar system in the United Kingdom. The Human Fertilisation and Embryology Authority has comprehensive authority and jurisdiction over all laboratories dealing with gametes or embryos whether those laboratories are in the public or the private sector. All centres and individuals in the United Kingdom that carry out research involving the use of human embryos must be licensed by the Authority and individual research projects must also be licensed. Premises to which a licence relates may be subject to an annual inspection. *The Human Fertilisation and Embryology Act 1990* (UK) makes it a criminal offence to bring about the creation of an embryo outside the human body or to keep or use an embryo without a licence from the Authority. The parameters within which the Authority may issue licences are provided for in the *Human Fertilisation and Embryology Act 1990 (*UK).[20]

Recommendation 10

12.62 **The Committee recommends that individuals and organisations be licensed for each research activity involving the isolation, creation and use of embryonic stem cells they intend to undertake.**

Parameters Of A Licence

12.63 The legislation should prohibit the issue of a licence to do any of the following:

- engage in cloning for reproductive purposes;
- manipulate the germ line;

20 For further information concerning the regulatory framework in the United Kingdom see Chapter 10 at paragraphs 10.75-10.85 and 10.92-10.96

- insert a human somatic nucleus into the cytoplasm of a non-human mammal, or fuse cells (adult and eggs or other) from humans and animals;
- purchase or sell human embryos, sperm or eggs;
- harvest human material or cells for cloning without express permission in writing from the person from whom such material originates (not the family); or
- create an embryo outside the body of a woman by means of somatic cell nuclear transfer for any reason (noting the moratorium set out in paragraph 12.42).[21]

Recommendation 11

12.64 **The Committee recommends that the matters listed in paragraph 12.63 be prohibited. Such a prohibition would mean that the licensing body would not have the authority to issue a licence for research involving any of the items listed in paragraph 12.63.**

Issuing A Licence

12.65 The licensing body would be able to issue licences for research involving the use of embryos within the parameters outlined in this chapter. The legislation should provide that the following may only be undertaken in pursuance of a licence:

- the extraction of embryonic stem cells from any embryo; and
- the use of embryos surplus to fertility treatments for the purposes of research.[22]

Recommendation 12

12.66 **The Committee recommends that research using cloning technologies and involving the use of embryos may only be undertaken pursuant to a licence.**

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21 The deliberate creation of embryos for research is not permitted under the Western Australian, South Australian and Victorian legislation. It is also not permitted under the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*

22 The regulation of assisted reproductive technology practice would remain with the States and Territories. The licensing body would need to liaise with State and Territory authorities where these exist

12.67 In order to grant a licence for one of the above the licensing body must be satisfied of the matters listed in paragraph 12.43.

Recommendation 13

12.68 **The Committee recommends that a licence for research using cloning technologies and involving the use of embryos only be granted if the licensing body is satisfied of the matters listed in paragraph 12.43 and that informed consent has been granted by all relevant persons.**

Consent

12.69 The licensing body must be satisfied that proper arrangements are in place to ensure that all relevant persons have given the consent necessary for embryos to be used in the course of research. The licensing body must also issue guidelines outlining the steps licensees must follow to ensure that consent is properly informed. Suggestions for matters to be included in such guidelines are outlined below.

12.70 The number of persons from whom it may be necessary to obtain consent may be quite large. For example, stored embryos may be formed for a couple:

- using their own genetic material;
- using the woman's ovum and donor sperm;
- using a donated ovum and the man's sperm;
- using donated ovum and donated sperm; or
- in any of the above scenarios and donated to another couple.[23]

12.71 In relation to the use of embryos for the extraction of embryonic stem cells, the licensing body should consider the use of the United States National Institutes of Health (NIH) *Guidelines for Research Using Human Pluripotent Stem Cells.*[24] The application of those guidelines in this context would require: only using stem cells from frozen embryos created for the purpose of fertility treatment and in excess of clinical need; prohibiting the use of inducements (monetary or otherwise) for the donation of the embryo and a clear separation between the fertility treatment and the decision to

23 NSW Government Discussion Paper, *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies*, p.6.4

24 See discussion of these guidelines in Chapter 10 at paragraphs 10.61-10.69

donate; that the informed consent specify whether or not information that could identify the donor(s) will be retained; the donation must be made without any restriction as to the individual(s) who may be the recipient of any derived cells and informed consent must have been obtained (see below).[25]

12.72 Establishing suitable guidelines for adequate disclosure of information and properly informed consent and ensuring that these are implemented conscientiously is a primary safeguard against pressure, coercion or undue influence being placed upon women to donate eggs or for couples to donate embryos for research purposes.

12.73 The potential for pressure to be applied to women to agree to the donation of eggs or for people to be pressured to agree to the formation of additional embryos and to donate them for research is a matter of great concern to the Committee and will require intensive monitoring by the licensing body. Further legislation on this matter may be necessary.

12.74 The licensing body should develop guidelines in relation to the disclosure of information and the gaining of informed consent. Compliance with these guidelines should be a condition of a licence to undertake any research involving cloning technologies. Because of the number of people potentially involved in decisions to donate material for research involving cloning techniques certain consents need to be mandated.

12.75 Current provisions[26] relating to disclosure and consent specify that consent must be in writing and not withdrawn or varied. The consent may specify conditions subject to which an embryo may be used. Consent must be given by the gamete providers whose gametes constitute the embryo and the consent must be to the use of the embryo in a particular procedure. Prior to giving consent a person or couple must have been given a suitable opportunity to receive proper counselling and detailed information about the proposed research.

12.76 Consent should also be given by the spouses and partners of donors of embryos or gametes in accordance with the current requirements of the *Infertility Treatment Act 1995* (Vic).[27] As is currently the case in South

25 See paragraph 12.77

26 See generally the *Infertility Treatment Act 1995* (Vic), the Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 (SA) and the *Human Fertilisation and Embryology Act 1990* (UK)

27 The *Infertility Treatment Act 1995* contains detailed requirements relating to consent (see sections 27-30 and sections 34-38). These sections contain provisions relating to consent by spouses and partners of donors and matters such as withdrawal of consent or objections by a later spouse

Australia, consent provisions should also specify that a woman must consent not only to the donation of ova (eggs) but also to the use of drugs to stimulate their production and the medical or surgical procedure associated with their removal.[28]

12.77 The Committee also suggests that, in relation to the donation of embryos for embryonic stem cell research, the following informed consent requirements of the NIH *Guidelines for Research Using Human Pluripotent Stem Cells* should form the basis of guidelines issued by the licensing body. The Guidelines state that the informed consent process should include discussion of the following information with potential donors:

- a statement that the embryos will be used to derive human pluripotent stem cells for research that may include human transplantation research;
- a statement that the donation is made without any restriction or direction regarding the individual(s) who may be the recipient(s) of transplantation of the cells derived from the embryo;
- a statement as to whether or not information that could identify the donors of the embryos, directly or through identifiers linked to the donors, will be removed prior to the derivation or the use of human pluripotent stem cells;
- a statement that derived cells and / or cell lines may be kept for many years;
- disclosure of the possibility that results of research on the human pluripotent stem cells may have commercial potential and a statement that the donor will not receive financial or any other benefits from any such future commercial development;
- a statement that the research is not intended to provide direct medical benefit to the donor; and
- a statement that embryos donated will not be transferred to a woman's uterus and will not survive the cell derivation process.

Recommendation 14

12.78 **The Committee recommends that the licensing body develop detailed guidelines specifying the requirements for informed consent and take**

28 This is currently provided for in Regulation 15 of the Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 in South Australia

into account the matters discussed in paragraphs 12.69-12.77 in developing these guidelines.

Role Of Institutional Ethics Committees

12.79 The criticisms that were made of institutional ethics committees (IECs) during the course of the inquiry were outlined in Chapter 9.[29] Associate Professor Thomson, the Deputy Chair of AHEC, accepted that there are inadequacies in the transparency and accountability of IECs. He also stated that there:

> … is presently some extensive work on the notion of compliance and better methodology in seeing that the processes of [IECs] do conform and that there is some way of assuring that quality happens.[30]

12.80 A review of the structure and operation of IECs is beyond the scope of this inquiry but the Committee is concerned about their operation and believes that there should be greater transparency and accountability in relation to IECs.[31]

Recommendation 15

12.81 **The Committee recommends that the Government establish an independent review of the institutional ethics committee system in Australia.**

Other Matters

12.82 The licensing body should also have regard to the potential commercialisation of the products of cloning related research and issue guidelines to other Commonwealth agencies, such as the Australian Quarantine and Inspection Service (AQIS), concerning material that should be permitted to be imported or exported.

12.83 All Commonwealth Departments should refer to the licensing body for guidance where a matter arises that involves the use of human reproductive material, embryonic stem cell research or cloning research.

29 See Chapter 9 at paragraphs 9.24-9.36

30 Associate Professor Colin Thomson, *Transcript*, p.199

31 In March 1996, the *Report of the Review of the Role and Functioning of Institutional Ethics Committees* to the Minister for Health and Family Services was released.That review was undertaken some time ago and for present purposes is not adequate

Examples of occasions on which such guidance would need to be sought include the granting of funds for research or the consideration of research and development grant applications.

Recommendation 16

12.84 **The Committee recommends that all Commonwealth Departments refer to the licensing body for guidance where a matter arises that involves the use of human reproductive material, embryonic stem cell research or cloning research.**

Kevin Andrews MP
Chairman