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.