CHAPTER 4

THE BILL

4.1 The provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 (the Bill) as referred to the Committee were not altered by the House of Representatives procedure of dividing the provisions into two separate bills. This chapter will discuss the provisions of the Bill in the order they were originally introduced.

Part 1 - Preliminary

4.2 Clause 2 provides that the various provisions take effect on various specified dates. Clauses 25 to 27 dealing with offences will commence 6 months after the day on which the Bill receives Royal Assent. Clause 25 provides that a person must not use an excess ART embryo unless that use is an exempt use or is authorised by a licence. Clause 26 provides that a person must not use a non-excess ART embryo unless it is part of an ART program carried out by an accredited ART centre. Clause 27 provides that a person must comply with any conditions of a licence.

4.3 The explanatory memorandum explains that the delay of commencement for these clauses is to allow time for the establishment of the new NHMRC Licensing Committee and for applications for licences to be made. During this 6-month transitional period researchers and others will continue to have to comply with existing State legislation and the NHMRC *Ethical Guidelines on ART* (1996).[1]

4.4 The delay will also allow States and Territories to introduce complementary legislation and, where necessary, repeal existing provisions of State legislation that ban the use of excess ART embryos.

4.5 Clause 3 sets out that the object of the Bill is to 'address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos'. This provision gives a general understanding of the purpose of the legislation and sets out general aims and principles that are intended to help users interpret the detailed provisions of the legislation.

4.6 Several submissions expressed dissatisfaction with this objects provision, preferring an express reference to be made to the various ethical considerations and international conventions.[2] For example, the Australian Catholic Bishops Conference submitted that:

---

1 Explanatory memorandum, p.3.

2 For example, *Submissions* 1, 156, 282, 285, 981, 1031, 1033 and 1053.

> There ought be basic, preambular provisions which at least refer to some ethical parameters, such as found in the Victorian and WA legislation, and/or taken from the Declaration of Helsinki. This may assist some members of the licensing committee to focus on appropriate ethical considerations and provide a source for further ethical reflection.[3]

4.7 The definitions contained in Clause 7 of the Bill were commented upon in a number of submissions.

4.8 Several submissions noted that the Bill contains no specific definition of 'embryo'[4]. Instead, it defines the terms, 'chimeric embryo', 'human embryo', 'human embryo clone', 'hybrid embryo', 'prohibited embryo' and 'excess ART embryo' by reference to the undefined concept of an 'embryo'. These submissions argued that the circularity in these definitions created uncertainty as to the fundamental scope of the Bill. Possible meanings for the term 'embryo' were proposed in a number of submissions including the Catholic Archdiocese of Melbourne which suggested that:

> ***embryo*** means a cell whose self-directed development is begun by the fertilisation of an ovum by a sperm, or such an organism as it subsequently develops, or any cell or organism produced in another way which has a similar developmental potential in favourable conditions.[5]

4.9 Other submissions were concerned with the definition attributed to a 'human embryo'. Subsection 7(1) of the Bill defines a 'human embryo' as a 'live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means'. Dr Tonti-Filippini advised the Committee that:

> In fact an unfertilized ovum also has two pro-nuclei. […] Thus the first appearance of two pro-nuclei is actually prior to fertilisation with the appearance of the ovum.
>
> This problem could be rectified by adding the words 'after sperm penetration' following the word 'pro-nuclei' in the definition of 'human embryo'.[6]

4.10 An alternative view was offered by Professors Jansen and Pera, and Dr Pope, who each told the Committee that unfertilised eggs do not have 2 pro-nuclei. Dr Pope and Professor Jansen outlined the difficulties in defining an 'embryo'. Professor Jansen advised that:

> Defining embryos is problematical in many ways, not least of which is that embryo-like development can arise from an egg without fertilization at all.

---

3 *Submission* 981, p.15 (ACBC).

4 For example, *Submissions* 86, 870, 876, 884, 981 and 1061.

5 *Submission* 876, p.11 (CAM). *Submissions* 981, p.16 (ACBC); 86, p.2. (Dr Tonti-Filippini); and 870, p.10 (Qld Bioethics Centre) endorsed or proposed substantially similar definitions.

6 *Submission* 86, p.2 (Dr Tonti-Filippini).

> The pronuclear stage, at which the presence of 2 pronuclei generally indicates fertilization of the egg by a single sperm (there are exceptions), lasts only a few hours and might be missed by observers.
>
> In summary, there is no easy way of defining an embryo and defining an embryo as having or having had 2 pronuclei is neither necessary nor sufficient in principle and also has additional limitations in practice…
>
> Incidentally, pronuclei can form from parthenogenesis and from self-fertilization, which appears to be what happens in the natural initiation of an ovarian germ cell tumour such as a dermoid cyst, the commonest ovarian tumour in young Australian women, research into which will be jeopardised as an unintended consequence of the legislation.[7]

4.11 Dr Pope made similar comments noting that:

> The definition of an "embryo" is quite difficult as it is based on an individual's religious and moral opinions of when life begins. Scientifically, I feel an embryo is defined when the embryonic genome is activated at around the 8 cell stage. Syngamy is often used as a marker for an embryo. This is the time at which the 2 pronuclei fuse and the cell divides into two cells. This marker does overcome the concerns relating to failure of 2 pronuclei oocytes/zygotes to divide.[8]

4.12 Professor Pera added a note of caution indicating that 'many definitions use the point of syngamy meaning mixing of the maternal and paternal chromosomes, but this is a difficult point to determine experimentally'.[9]

4.13 The Catholic Archdiocese of Melbourne also commented on the definition of 'human embryo clone':

> The reference in this definition to "genetic copy" is problematical given that clones created by the 'Dolly the Sheep Technique' are not precisely 'genetic copies' of the genetic parent from whom the nucleus was taken. This is because some genetic material from the egg donor survives in the cytoplasm even after the nucleus is removed to be replaced with the nucleic material from the genetic parent.[10]

4.14 However, the explanatory memorandum explains that Subclause 7(2) clarifies that the definition will cover the case of somatic cell nuclear transfer.[11] The Subclause provides that to establish that a human embryo clone is a 'genetic copy' it is sufficient

---

7 *Submission* 897, Additional information 15.10.02 (Professor Jansen).

8 *Submission* 1001, Additional information 15.10.02 (Dr Pope).

9 *Submission* 873, Additional information 11.10.02 (Professor Pera).

10 *Submission* 876, p.11 (CAM).

11 Explanatory memorandum, p.6.

that the set of genes in the nuclei of the cells has been copied and it is not necessary that the copy is an identical genetic copy.

4.15 The Catholic Archdiocese of Melbourne and Dr Tonti-Filippini submitted that the definition could still permit a variety of forms of asexual reproduction, that is, embryos formed other than by fertilisation. While they noted the ban on this activity provided in Clause 12, they submitted that the Bill could still allow fertilisation using genetically altered sperm or ova.[12]

4.16 They also submitted that the definition of 'hybrid embryo' would seem to allow researchers to create an organism that was part human and part animal by fusing segments of the human nucleus with segments of an animal nucleus. They addressed this issue by suggesting that:

> ***Hybrid embryo*** means an embryo which contains genetic material substantially derived from an animal source and genetic material substantially derived from a human source.[13]

Part 2 - Prohibited practices

4.17 Part 2 of the Bill contains a number of offences relating to human cloning and the creation and use of human embryos.

4.18 The Committee received several submissions that addressed the terms of these offences generally. For instance, the Australian Catholic Bishops Conference suggested all of the offences in Part 2 be extended to include acts or omissions that are done recklessly, noting that only the offence created under Clause 21 (importing, exporting or placing a prohibited embryo) currently includes this element.[14] In all other provisions in the Part, a person will not commit an offence, despite the fact that they have engaged in the offending conduct, if they did not intend, but were merely reckless as to whether, they acted in the offending way.

Human Cloning

4.19 Clause 8 of the Bill makes it an offence to intentionally create an embryo that is a genetic copy of another human, that is, a human embryo clone.

4.20 As discussed in chapter 2, current technology presents two methods of cloning–nucleus substitution and embryo splitting. Nucleus substitution (also known as somatic cell nuclear transfer) basically involves removing the nucleus from an egg cell, and substituting the nucleus of another cell. Embryo splitting is a technique of fertilising an egg with sperm, and dividing the newly formed embryo into two or more. The Bill provides that it is an offence to intentionally create a human embryo

---

12 *Submissions* 876, p.11 (CAM) and 86, p.2 (Dr Tonti-Filippini).

13 *Submissions* 876, p.11 (CAM) and 86, p.2 (Dr Tonti-Filippini).

14 *Submission* 981, p.16 (ACBC). The NHMRC responded to this point in additional information dated 18.10.02.

clone, whether by either of these methods or by any other method that may be developed in the future.

4.21 However, the offence does not apply where a human embryo is created by the fertilisation of a human egg by human sperm. In this way, where a human embryo created by assisted reproductive technology spontaneously divides into two or more identical embryos (commonly known as identical twins, triplets, etc.) no offence is committed under Clause 8.

4.22 Clause 9 creates an offence for intentionally placing a human embryo clone in the body of a human or the body of an animal. The Queensland Bioethics Centre submitted that this offence should be much broader, to instead prohibit all uses of a human embryo clone.[15]

4.23 Clause 10 creates an offence for intentionally importing or exporting a human embryo clone. It was submitted that the offence created under Clause 10 should be extended to apply to all products derived from a clone. In the absence of this further restriction, those submissions suggested that the Bill may be circumvented by the importation of products derived from a human embryo clone.[16]

4.24 Dr Clive Morris, of the NHMRC advised the Committee that:

> There would be a prohibition on the import or export of prohibited embryos under the legislation. In relation to the import of embryos which are not prohibited embryos–that is, embryos which are part of an IVF program or embryos which were part of an IVF program and which perhaps have been declared to be excess–if they are part of an IVF program then the import or export would be for the purposes of the IVF program. If they were embryos which were declared to be excess to an IVF program, to import them for other purposes–for example, research–under the Quarantine Act you would, firstly, need to get an import permit from the Director of Quarantine. You would also need to get a licence from the NHMRC Licensing Committee…
>
> In relation to the import and export of embryonic stem cell lines, there is general legislation relating to the import and export of tissue.[17]

4.25 Dr Morris also advised the Committee that there is no prohibition in the Bill on a person from taking stem cells from a human embryo and then selling them for profit overseas:

> The legislation does not extend to the use of stem cell lines…The use of cells derived from any tissue would be permitted to be sent overseas…[The legislation] does not prohibit any uses of embryonic stem cell line.[18]

---

15 *Submission* 870, p.10 (Qld Bioethics Centre).

16 *Submissions* 86, p.3 (Dr Tonti-Filippini); 876, p.14 (CAM); 981, p.16 (ACBC).

17 *Committee Hansard*, 26.9.02, p.262 (Dr Morris).

18 *Committee Hansard*, 26.9.02, p.256-257 (Dr Morris).

4.26 Ms Matthews, a consultant to the NHMRC added:

> The Customs regulation provides that approval must be sought in certain circumstances for the export of tissue…
>
> It would not prevent it; it just provides that a permit is required for the export under certain circumstances.[19]

4.27 Mr Rocco Mimmo, of Don't Cross the Line spoke about the possibility that disaggregated embryos are being stored either in Australia or overseas. He suggested, that if this were the case, 'it would seem to me that the bill itself would not prevent the importation of such material to Australia'.[20]

4.28 Clause 11 provides that it is no defence to any of these offences that the human embryo clone did not survive, or could not have survived.

4.29 The maximum penalty for each of these offences is imprisonment for 15 years, though the explanatory memorandum notes that a court may, at its discretion, either supplement the imprisonment term with a monetary penalty or convert it into a monetary penalty.[21] The NHMRC explained that:

> While the Bill only mentions imprisonment terms, the effect of this is the same as if monetary penalties had also been included. This is because of the operation of the Commonwealth *Crimes Act 1914*. The *Crimes Act 1914* provides that if a piece of Commonwealth legislation includes an imprisonment term then this can be converted, by the courts, to an equivalent monetary penalty or a combination of imprisonment term and monetary penalty, in accordance with a formula included in that Act.[22]

Other prohibited practices

4.30 The Bill also creates a number of offences relating to the creation of human embryos and other prohibited activities.

4.31 Clause 12 provides that an offence is committed when a person intentionally creates a human embryo by a process other than fertilisation, or develops an embryo that has been created in such a way. This ensures that if such an embryo was imported into Australia (an offence under clause 21) it could not be developed by the person who imported it or by any other person without an offence being committed.

4.32 The explanatory memorandum explains that a human embryo intentionally created outside the body of a woman must only be created by the fertilisation of a human egg by human sperm. As such, an embryo must not be created by embryo

---

19 *Committee Hansard*, 26.9.02, p.262 (Ms Matthews).

20 *Committee Hansard*, 24.9.02, p.181 (Mr Mimmo).

21 Explanatory memorandum, p.7.

22 *Submission* 23, p.15 (NHMRC).

splitting, by nucleus substitution or by any other technique that does not involve fertilisation of a human egg by human sperm.[23]

4.33 The NHMRC noted that some IVF clinicians have argued that, since parthenogenesis (where an unfertilised egg starts to divide in the same manner as a fertilised egg) may be a causal factor in the development of ovarian tumours in Australian women, the clause may jeopardise research into the cause of these ovarian tumours. The NHMRC advised the Committee that:

> The Bill does not impose a different regulatory approach from that which currently applies under the requirements of the Reproductive Technology Accreditation Committee (RTAC), the NHMRC's Ethical Guidelines on ART and existing legislation. Under the existing system of regulation, embryos may only be created for the purposes of ART treatment and the creation of parthenogenetic embryos for research is not allowed.
>
> The Bill will not prevent research on ovarian tumours, ovarian tissue or human eggs, or the investigation of disease models and proof of concept research using animal models.[24]

4.34 Subclause 13(1) makes it an offence for a person to intentionally create a human embryo outside the body of a woman, unless it was created in an attempt to achieve pregnancy in a particular woman. That is, it is an offence to create human embryos specifically for other purposes such as for use in research or to derive embryonic stem cells for potential therapeutic use. However, the explanatory memorandum explains that this is not to limit the creation of multiple embryos in ART to bring about a pregnancy in a particular woman or to prohibit the creation of embryos that may not be ultimately used, and so become excess.[25]

4.35 Professor Jansen, of Sydney IVF, considered that this provision could restrict the research currently undertaken by IVF clinics. He claimed that the Clause:

> …prevents the fertilisation of eggs in the investigation of a scientific question unless the embryo is for the particular woman whose egg it is…
>
> It will not necessarily be in the interests of that person but it will be in the interests of infertile women generally. There are several areas where these questions are very important for improving IVF. I should preface this by saying that the area where IVF fails to make an impact on socially important infertility is the infertility that occurs in women as they get older, well before the menopause, and which is from the mid-30s and on.[26]

4.36 In response to this argument the NHMRC noted that:

---

23 Explanatory memorandum, pp.8 and 9.

24 *Submission* 23, Additional information 15.10.02, p.5 (NHMRC).

25 Explanatory memorandum, p.9.

26 *Committee Hansard,* 26.9.02, p.200 (Professor Jansen).

> Research involving the *in vitro* fertilisation of human eggs, when this is not carried out in conjunction with the ART treatment of a particular woman, is not allowed in Australia under existing legislation nor the NHMRC's Ethical Guidelines on ART, which are required to be observed as a condition of accreditation of ART clinics by RTAC. The proposed legislation does not alter this situation.[27]

4.37 Subclause 13(2) clarifies that the prosecution (and not the defendant) bears the evidential burden in relation to an offence under Subclause 13(1).

4.38 Clause 14 provides that a person commits an offence if they intentionally create or develop a human embryo containing genetic material provided by more than two persons. In particular, the explanatory memorandum explains that this will prohibit the ART technique of cytoplasmic transfer, which involves the transfer of the cytoplasm (the part of the cell outside the nucleus) from one egg to another. Under this procedure mitochondrial DNA (which is thought to have no impact on the physical characteristics of a child) from a third party would be introduced into a recipient patient's egg.[28]

4.39 However, the explanatory memorandum acknowledges that cytoplasmic transfer has been reported to be particularly valuable in assisting older women to achieve pregnancy. Professor Robert Jansen submitted to the Committee that, while the efficacy of the procedure has not yet been proven, it should be further investigated and that Clause 14 'is a significant set-back for improving the fertility of women over 35'. Professor Jansen added that:

> …the alternative to a probably unimportant admixture of non-coding mitochondrial DNA to the genome is to donate an entire nuclear and cytoplasmic genome (in the form of egg donation), disenfranchising the woman from all genetic endowment to her children.[29]

4.40 The NHMRC commented that:

> Cytoplasmic transfer is a relatively new and controversial technique, which involves the injection of cytoplasm from a healthy donor egg into a recipient patient's egg. Because of the presence in the cytoplasm of mitochondria, which contains small amounts of DNA, embryos created through cytoplasmic transfer will have DNA from three separate people. The clinical safety and efficacy of this practice has not, to date, been established and therefore the impact of the third party mitochondrial DNA is not known.
>
> The Bill implements the cautious approach adopted by COAG by banning the creation of an embryo that contains genetic material from more than two

---

27 *Submission* 23, Additional information 15.10.02, p.5 (NHMRC).

28 Explanatory memorandum, p.10.

29 *Submission* 897, p.6 (Professor Jansen).

> persons. This is subject to review within three years when more may be known about the safety and efficacy of this technique.[30]

4.41 It is an offence under Clause 15 for a person intentionally to develop a human embryo outside the body of a woman for more than 14 days, not including any time that the development is suspended (e.g. while the embryo is frozen). This means that human embryos created by ART must be implanted, stored or allowed to die (if unsuitable or excess) before the 14th day of their development. It is standard ART clinical practice for embryos to be implanted when they have reached between three and seven days of development. The explanatory memorandum explains that this Clause must be read subject to Clause 12, which provides that a human embryo created by embryo splitting or nucleus substitution, cannot be created or developed to any stage.[31]

4.42 The NHMRC advised that the 14-day limit is based on a clear policy direction in the COAG Communique and is consistent with Australian and international standards. The NHMRC explained that Clause 15 conforms with:

- NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996);
- Reproductive Technology Accreditation Committee (RTAC) Guidelines;
- South Australian legislation (*Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995*);
- Western Australian legislation (*Human Reproductive Technology Act 1991*);
- United Kingdom legislation (*Human Fertilisation and Embryology Act 1990*); and
- proposed Canadian legislation (Bill C-56).[32]

4.43 In addition, the NHMRC provided further information on the scientific evidence that determined 14 days as the appropriate time to mark the offence for inclusion in the Bill. It advised the Committee that:

> The prohibition on maintaining an embryo *in vitro* for longer than '14 days' is based on scientific evidence, which indicates that beyond 14 days development *in vitro*, an embryo is unlikely to have the capacity to implant in a woman's uterus.
>
> *In vivo*, the second week of embryonic development is marked by continued blastocyst development and implantation. Rapid growth and differentiation of the extra-embryonic tissue leads to development of the placenta. During the second week the cavity within the blastocyst and the inner cell mass, consisting of embryonic stem cells that form the embryo, begin early differentiation. Implantation is necessary to ensure the viability of the

30 *Submission* 23, Additional information 15.10.02, p.6 (NHMRC).

31 Explanatory memorandum, p.11.

32 *Submission* 23, Additional information 13.9.02, p.15 (NHMRC).

> embryo and has normally completed by the end of the second week (14 days).
>
> If implantation occurs, this is shortly followed by the next phase of embryonic development known as gastrulation. The term gastrulation describes the series of events that leads to the formation of the trilaminar (three layered) embryo and is characterised by the appearance of the 'primitive streak'.
>
> Hence, guidelines for clinical practice in the application of ART require that embryos must be implanted, stored or allowed to succumb before the 14th day of their development.[33]

4.44 As discussed in chapter 3 there is dispute over this point. For example, several submissions argued that there was no real significance behind the 14-day limit, and that this period was purely an arbitrary line drawn by the UK Warnock committee.[34] Dr Gregory Pike of the Southern Cross Bioethics Institute told the Committee that:

> The Warnock committee also acknowledged that it was dealing with a continuum of development and that 14 days was indeed an arbitrary time and that it had to choose for extrinsic rather than intrinsic reasons on a time– 'to allay public anxiety' was the wording used by the Warnock committee, yet it is a scientific fact that it is a continuity of development. We are talking about quite an arbitrary point of time. Arguments based on twinning or the appearance of the primitive streak are in my view quite thin.[35]

4.45 Under Clause 16 it is also an offence to use precursor cells taken from a human embryo or a human fetus to intentionally create a human embryo, or develop an embryo so created. A precursor cell is one that has the potential to develop into a human egg or sperm. This provision will prevent the situation where a child may be born never having had a living genetic parent.

4.46 Clause 17 prohibits the alteration of a human genome that is intended to be heritable, that is, able to be passed on to subsequent generations. This would ban germ line gene therapy, which modifies the genome of embryo, egg or sperm cells that would then be passed on to subsequent generations. However, the GeneEthics Network advocated that this prohibition should also apply to all non-heritable gene manipulations in embryos, arguing that the repeal of sections 192B, 192C and 192D of the *Gene Technology Act 2000* 'may leave a legislative vacuum unless this is done'.[36]

---

33 *Submission* 23, Additional information 13.9.02, p.16 (NHMRC).

34 Baroness Mary Warnock was invited by the UK Government in July 1982 to chair a Committee of Inquiry into the 'social, ethical and legal implications of recent, and potential developments in the field of human assisted reproduction'. The report of that committee is the *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (1984).

35 *Committee Hansard*, 17.9.02, p.35 (SCBI).

36 *Submission* 1843, p.1. (GeneEthics Network).

4.47 It is an offence under Clause 18 if a person removes a human embryo from the body of a woman, intending to collect a viable human embryo. This bans the practice of 'embryo flushing' where viable embryos are removed after fertilisation has taken place *in vivo*.

4.48 Clause 19 makes it an offence to intentionally create a chimeric or hybrid embryo. The explanatory memorandum explains that this provision prohibits the creation of transgenic human embryos, but not transgenic animals, which are regulated under the *Gene Technology Act 2000.*[37] However, the GeneEthics Network submitted that:

> The claim that such procedures are regulated under the *Gene Technology Act 2000* as a genetically modified organism is not strictly correct. Transgenic animals are categorised as Notifiable Low Risk Dealings by the OGTR [Office of the Gene Technology Regulator] and need only be notified to the office. They are not assessed, monitored or regulated by the OGTR provided they remain in enclosed environs.[38]

4.49 Clause 20 prohibits the placement of:

- a human embryo into an animal;
- a human embryo into the body of a human, other than a woman's reproductive tract;
- an animal embryo into a human for any period of gestation.

4.50 Under Clause 21 a person commits an offence if they import, export or place in the body of a woman, a prohibited embryo (broadly one prohibited under Clauses 12 to 19), where the person knows, or is reckless as to whether, it is a prohibited embryo. The current practice of importing or exporting embryos (created by fertilisation of a human egg by human sperm) for the ART treatment of a particular couple, will be permitted to continue, subject to other legislation such as the *Quarantine Act 1908* and the *Customs Act 1901*.

4.51 Clause 22 prohibits the commercial trading in human eggs, sperm or embryos. A person commits an offence if they give or receive valuable consideration (not including reasonable expenses) for the supply of human eggs, sperm or embryos. Valuable consideration is not limited to monetary rewards and includes any inducement, discount or priority in the provision of a service. Reasonable expenses may relate to the costs of collection, storage or transport. However, as noted earlier, the Bill does not prohibit commercial trading in embryonic stem cells.

4.52 The Committee heard evidence from Professor Michael Good and Professor Peter Rowe, that excessive handling fees had been offered within the United States to

---

37 Explanatory memorandum, p.13.

38 *Submission* 1843, p.2. (GeneEthics Network).

escape provisions equivalent to Clause 22.[39] In response to this suggestion, the NHMRC advised the Committee that:

> The legislation prohibits the giving or receipt of valuable consideration for the supply of a human egg, human sperm or human ovum. Valuable consideration is further defined to include any inducement, discount or priority in provision of a service, and it is intended that this would include such things as a handling fee.[40]

4.53 Many submissions supported the creation of this offence. BresaGen added that Clause 22 should be strengthened to further reduce any risks of financial inducement to donate embryos for embryonic stem cell research. In particular, BresaGen suggested that the following two points from the United States NIH guidelines for embryonic stem cell research be included:

> (a) the donors must recognise that any ES cell lines resulting from embryo donation may result in the development of cell therapy products which may be used for human therapy;
>
> (b) if this should happen, the embryo donors should have no commercial rights to financial benefit from these products.[41]

4.54 Dr Megan Best of the Anglican Church, Sydney Diocese informed the Committee that:

> We would like clarification on the buying and selling of stem cells and embryos. We were looking at the Canadian legislation–which is similar to this bill–and it has limitations on payments for embryos or stem cells, direct or indirect. Researchers are asked to disclose actual perceived or potential conflicts of interest to the equivalent of the NHMRC. Copies of contracts between researchers, institutions and industry sponsors and any relevant budgetary information are provided to the licensing body so that any actual or potential conflict of interest can be detected by examination of these documents.[42]

4.55 Although the current Bill does not directly address the issue of intellectual property rights in relation to human embryos and stem cells, this was an issue that was repeatedly raised during the course of this inquiry.[43]

---

39 *Committee Hansard*, 19.9.02, p.104 (Professors Good and Rowe).

40 *Committee Hansard,* 26.9.02, p.246 (Dr Morris); see also *Submission* 23, Additional information received 16.10.02, p.6 (NHMRC).

41 *Submission* 1030, p.12 (BresaGen).

42 *Committee Hansard*, Tuesday, 24 September 2002, p.170 (Dr Best).

43 For example *Submissions* 37, 100, 282, 285, 362, 480, 540, 614, 805, 869, 871, 872, 880, 981, 1012, 1027, 1030, 1031, 1035, 1041, 1072, 1074, 1099, 1239, 1250, 1263, 1300, 1409, 1484, 1542, 1561, 1600 and 1833.

4.56 Biotechnology Australia submitted to the Committee that one reason existing embryonic stem cell lines are insufficient for continued research and further development of therapies is that many existing stem cell lines are subject to patent protection, restricting researchers' freedom to operate. It identified that this inability to gain access to cell lines is likely to hamper scientists' work in this field.[44]

4.57 *Australian Biotechnology News* has since reported that:

> Singapore-based company ES Cell International (ESI) is changing the marketing strategies for its human embryonic stem cell lines because of researchers' reluctance to part with intellectual property. The company is dropping its previous demand to share in any IP flowing from research using its lines and instead is attaching a straight dollar value to the lines…
>
> The company does not believe its cell line sales will contravene any clauses on the Bill on research into human embryonic stem cells being readied for debate in the Senate. The Bill does outlaw trade in human embryos but that is not the same thing as human embryonic stem cells.[45]

4.58 Many submissions suggested that the regulation of embryonic stem cell research was being driven by the prospect of profits that could be derived under a patent. Those submissions claimed that the potential for scientific and medical advances, which may also exist in adult stem cells, was secondary to the financial bounties that could be secured by asserting intellectual property rights that may only be claimed over embryonic stem cell lines.[46] Professor Silburn also commented in the Committee hearings that patents inhibit the sharing of research information.[47]

4.59 Dr Warwick Neville argued that the commercial emphasis of the Bill provides a flawed basis for research. He suggested that:

> Firstly, empirical research suggests only a weak correlation between patent rights and innovation. Secondly, there is substantial doubt whether the traditional equilibrium that patent law seeks to strike between private monopoly and public accountability works to maximise innovation in the biomedical field. Thirdly, patent law is centred on economic or market values and has difficulty dealing with ethical and social issues.[48]

4.60 Others opposed the commercial control and exploitation of embryonic stem cells on the grounds that they represent a fundamental biological resource. For

---

44 *Submission* 1263, p.7 (Biotechnology Australia).

45 *Australian Biotechnology News,* vol.1 No.29, 4 October 2002, p.5.

46 For example *Submissions* 37, 100, 282, 285, 362, 540, 869, 872, 981, 1027, 1031, 1049, 1250, 1409, 1484, 1487, 1542 and 1600.

47 *Committee Hansard,* 17.09.02, p.52 (Professor Silburn).

48 *Committee Hansard*, 26.09.02, p. 215 (Dr Neville, ACBC).

instance, Stem Cell Sciences suggested the adoption of the European Union's Ethics Group recommendation to prohibit patenting of unmodified human stem cells.[49]

4.61 In addition, Stem Cell Sciences advocated the establishment of a National Stem Cell Bank, within an independent government organisation, to distribute human stem cell lines to researchers. This would be similar to the recent United Kingdom announcement to establish such a bank, operating independently of research institutions and commercial organisations.[50]

4.62 However, others saw the creation of such a bank, in the IVF context, as the very reason as to why there are many excess embryos in existence today. They asserted that a bank of embryonic stem cells would itself promote the creation of further embryos.[51] Professor Michael Good submitted that for any stem cell collection to be comprehensive many more embryos would need to be created:

> To make such a tissue bank from 'all human ES cell lines' would be virtually beyond the bounds of possibility. Furthermore, women would have to undergo super-ovulation in order to provide the large number of eggs that would be needed to generate such a vast bank of cell lines.[52]

Part 3 - Regulation of certain uses involving excess ART embryos

4.63 Broadly, the Bill provides that a human embryo may only be used in the course of routine IVF practice, if the couple for whom the embryo was created decide that it is excess to their needs, and the use is an exempt use, or a use that has been licensed.

Interpretation

4.64 Clause 23 defines a number of terms for the purposes of Part 3 of the Bill. In particular, the clause defines an 'accredited ART centre' as one accredited by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia. The GeneEthics Network expressed their opposition 'if this were to take over the legally mandated roles of statutorily established organisations such as the Vic Infertility Treatment Authority' adding that '[v]oluntary self-regulation is not appropriate here'.[53]

4.65 Clause 24 defines an 'excess ART embryo' as a human embryo that was created by assisted reproductive technology and is excess to the needs of those for whom it was created. Furthermore, those people must have determined that the

---

49 *Submission* 1012, p.2 (Stem Cell Sciences).

50 ibid.

51 For example *Submissions* 86, 210, 369, 1036 and 1071.

52 *Submission* 614, p.2 (Professor Good).

53 *Submission* 1843, p.2 (GeneEthics Network).

embryo is excess and given their written authority for its use for purposes other than their own ART treatment.

4.66 This definition is seminal as it defines the scope of the regulation provided in the Bill. An important element of the definition is that of the consent required before an human embryo is regarded as 'excess'. Several submissions expressed concern as to which parties were required to give consent, and as to whether that required consent had to be fully informed.[54]

4.67 During public hearings an issue was raised as to whose consent should be required before an excess ART embryo may be used. In particular, the question was asked whether the consent was required of an anonymous gamete donor before an embryo may be used.[55]

4.68 Paragraph 24(1)(b) of the Bill provides that an excess ART embryo is one that is excess to the needs of a woman and her spouse (if any). In the case of an anonymous gamete donor, the donor will almost certainly not be the spouse of the woman for whom the embryo was created. As such Subparagraph 24(1)(b)(ii) would not apply to the donor and the authorisation and determination of the donor would not be required under Subclause 24(2).

4.69 Therefore the consent of an anonymous gamete donor will not be required for an embryo to meet the definition of an 'excess ART embryo' under the Bill. However, there is a further issue as to whether consent of the anonymous gamete donor is required for that excess ART embryo to be actually used.

4.70 Clause 25 of the Bill provides that an excess ART embryo may be used:

- as authorised by a licence (discussed below under 'Licensing system'); or
- for an exempt use.

4.71 Under Subclause 25(2), an exempt use of the excess ART embryo may be made without requiring the further consent of any other parties. That is, it seems that the consent of an anonymous gamete donor will not be required for an exempt use of a human embryo.

4.72 The Catholic Archdiocese of Melbourne opposed this situation, explaining that:

> Justice would surely require that both the couple for whom the embryo was intended and the donors (if any) should be consulted. The donor(s) (and their spouses if any) might prefer to receive the embryo themselves or have the embryo used in another way.[56]

---

54 For instance, *Submissions* 216, p.1 (K Seager); 876, p.11 (CAM); and 1020, p.5 (I Hamilton).

55 *Committee Hansard,* 17.9.02, p.52 (Senator Barnett).

56 *Submission* 876, p.11 (CAM); see also *Submission* 1061, p.1 (Dr Joshua).

4.73 For an exempt use of an embryo to be authorised in accordance with paragraph 24(2)(b), consent must be given 'for the use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned'. In particular, the authorisation required does not need to specify the particular exempt uses for which the consent is given, only that it is given for an exempt use of that embryo. It was argued that greater steps to inform the consent of embryo donors should be provided:

> Given the moral and emotional importance of these decisions, the Bill should explicitly provide that those concerned must be given detailed information about the proposed research before they are asked for consent to the use of their embryos, are given an opportunity to restrict consent to particular research, and are advised of their right to withdraw or vary their consent up to the time that their embryo is used for research.[57]

4.74 Another suggestion was Stem Cell Sciences' proposal that a 'cooling-off' period be imposed to ensure that potential donors have the opportunity to fully consider whether they wish to authorise the exempt use of their embryos.[58]

4.75 The Catholic Archdiocese of Melbourne called for the legislation to explicitly provide that the donors may withdraw their consent up to the time that their embryo is used for research.[59] In addition, Salt Shakers, a Christian ethics group, suggested that an independent counsellor should give any counselling leading to consent for the exempt use of embryos.[60]

4.76 Each of these matters is discussed further in relation to the licensed use of an embryo under the heading 'Licensing System' below.

Offences and exempt uses

4.77 As mentioned above, Clause 25 outlines the exempt uses to which an excess ART embryo may be put, that is, uses for which a licence is not required. Subclause 25(2) lists the various exempt uses of an excess ART embryo as:

- storage, removal from storage and transport of an excess ART embryo (Paragraph 25(2)(a));
- observation of an excess ART embryo (Paragraph 25(2)(b)), which includes photographing or recording an embryo (Subclause 25(4));
- allowing the excess ART embryo to succumb (Paragraph 25(2)(c));
- diagnostic investigations on embryos that are not suitable to be placed in the body of the woman (Paragraph 25(2)(d));

---

57 *Submission* 876, p.11 (CAM).

58 *Submission* 1012, p.2 (Stem Cell Sciences).

59 *Submission* 876, p.11 (CAM).

60 *Submission* 1502, p.6 (Salt Shakers – a Christian Ethics Group).

- using the excess ART embryo the purpose of achieving pregnancy in another woman (Paragraph 25(2)(e)); and
- any other use prescribed in the regulations (Paragraph 25(2)(f)).

Diagnostic investigations

4.78 The Committee received a number of submissions commenting on the term 'diagnostic investigations' in Paragraph 25(2)(d). In particular, several submissions noted that the term is undefined in the legislation, and expressed concern that it could allow a wide range of experiments on embryos which otherwise would be prohibited under the legislation.[61]

4.79 Addressing the concerns that this might create a loophole, the NHMRC reiterated that the investigations can only be carried out on embryos that are unsuitable for implantation and may only be carried out for the purposes of diagnostic investigations for the particular woman for whom the embryos were created. It also advised that significant penalties apply in the event of non-compliance (up to 5 years imprisonment) and the regulatory framework requires the collection of significant data and close monitoring of license holders. In response to calls for the exemption to be removed the NHMRC noted that:

> Without an exemption for diagnostic investigations, clinics would be required to obtain a licence from the NHMRC Licensing Committee to carry out such diagnostic tests. The following concerns have been expressed regarding licensing requirements for diagnostic investigations:
>
> - although the embryo is unsuitable for implantation, some of these investigations may damage the embryo. Under the legislation, no licence could be granted for any such investigation to be carried out on embryos created after 5 April 2002. This would effectively prohibit such diagnostic investigations being carried out for women who commenced their treatment after 5 April 2002. These women would be disadvantaged relative to those whose treatment commenced prior to 5 April 2002; and
>
> - the timeframes for applying to a Human Research Ethics Committee and then to the NHMRC Licensing Committee would limit the capacity of ART clinics to provide a timely and appropriate treatment for patients. For example, if the embryo is unlikely to survive freezing, the clinician may only have a narrow window of time (ie 1 or 2 days) when the diagnostic investigation can be carried out on the embryo.[62]

4.80 Although the term 'diagnostic investigations' is undefined in the legislation, the explanatory memorandum expands on its intended meaning:

---

61 See *Submissions* 876 (CAM), 981 (ACBC), 1035 (Australian Youth Alliance (Vic)) and 1843 (GeneEthics Network).

62 *Submission* 23, Additional information 15.10.02, p.3 (NHMRC).

> In some cases, as a part of routine clinical practice, it may be beneficial to the woman for whom the embryo was created for diagnostic tests to be undertaken on ART embryos that are unsuitable for implantation to determine the reason why they are not suitable for implantation so as to improve the likelihood of successful pregnancy in the next attempt.[63]

4.81 The NHMRC also advised the Committee as to the intended scope of 'diagnostic investigations'. It advised that where an embryo fails to develop properly and is unsuitable for implantation:

> The exemption allows these embryos to be used by the ART clinic, with the consent of the couple, to try to work out why the embryos are abnormal or not developing properly…The exemption enables work of a purely diagnostic type (that is part of an ART treatment program) to be undertaken in order to try to increase the chance of suitable embryos being developed in a particular couple's subsequent round of treatment. The exemption does not allow such embryos to be used for general research or general quality assurance activities – any such use must be licensed.[64]

IVF clinical practice and training

4.82 The NHMRC also noted that the Bill does not create an exempt use for the purposes of ART training. It advised the Committee that:

> During consultations on the Bill, many ART clinics noted that, with the consent of the couple, they currently use many abnormal or unsuitable embryos for training purposes. For example, to train technicians in micro-surgical sperm injection techniques, to train people to take individual cells from embryos so that the cells can be tested for genetic illness.
>
> Following detailed consideration of the issues, it was considered that including an exemption for training could create a loophole in the legislation because it would be very difficult to distinguish between training, quality assurance activities and research. For example, it could be argued that a person was 'training' in the derivation of stem cells.
>
> The legislation therefore requires that the use of embryos in ART clinics for training purposes must be licensed by the NHMRC Licensing Committee.[65]

4.83 In this way the Bill would regulate activities of IVF clinics. The Committee heard from several witnesses who were concerned that the delivery of IVF clinical services could be impeded. Dr Adrianne Pope, of Monash IVF, gave evidence that:

> The IVF community has undertaken varying degrees of research or investigation on embryos as part of the evolving nature of the infertility treatment for the last 24 years. During that time both Government legislation

63 Explanatory memorandum, p.17.

64 *Submission* 23, p.20 (NHMRC).

65 *Submission* 23, pp.20 and 21 (NHMRC).

> and self-regulation have unfolded and worked well hand in hand The [Bill] will have an impact on material available to IVF researchers and to couples wishing to donate embryos in the future.[66]

4.84 In addition, Dr Pope submitted that:

> It would be a tragedy to all those people who have embraced the need to utilise assisted reproductive technologies as the only way to achieve a family, to see the limitations placed by the Bill, prevent the use of this material for the common good of so many. I would hope that society can accept the benefits associated with the use of abnormal embryos, fated to succumb, in the beneficial techniques aimed at assisting those couples desiring their own children.[67]

4.85 Accordingly, Dr Pope proposed that a distinction should be made between viable and non-viable embryos, with all non-viable embryos being available for 'diagnostic investigations' rather than just those created before 5 April 2002. Dr Pope commented that:

> As the Bill stands abnormal embryos created after the 5th April 2002 would not be available for training or development of techniques as these would result in the destruction of the fresh abnormal embryos. I would ask the [Committee] to make an exception to the Bill and allow abnormal material available at the time of IVF, to be used for techniques and training which would aid couples in future treatments.[68]

4.86 Professor Illingworth estimated that 40 000 non-viable embryos were created annually as part of clinical IVF in Australia.[69] This number referred to an approximation of the number of embryos per year that were unsuitable (by virtue of their appearances) for either freezing or for transfer. The Professor clarified his comments made at the hearing:

> I need to emphasise that these are embryos that are not suitable for freezing, cannot be held in storage and are therefore outside the terms of this act. My response did not in any way intend to suggest that this number is currently being used for research. On the contrary, the value of such embryos for research would be extremely limited.[70]

4.87 ACCESS, a consumer-based infertility network, submitted that:

> Consumers of ART services are extremely concerned about the way in which the [Bill] goes substantially beyond the COAG communique by

---

66 *Committee Hansard,* 26.9.02, p.204 (Dr Pope).

67 *Submission* 1001, p.1 (Dr Pope).

68 *Submission* 1001, p.2. (Dr Pope).

69 *Committee Hansard*, 26.9.02, p.205 (Professor Illingworth).

70 Professor Illingworth, Additional information, 8.10.02

> targeting clinical IVF practice, which is already governed by several layers of accountability[71]

4.88 The Queensland Government stated that it did not support any further increase in the regulatory and administrative burden on the IVF clinical sector. It submitted:

> Queensland is concerned that the recent separation of the original Bill and the capacity for separate consideration of the new Bills and their further amendment will negatively impact on the IVF clinical sector.[72]

4.89 In response to these concerns, the NHRMC emphasised that the legislation does not regulate routine IVF clinical practice, although the legislation could impact on some IVF clinics, particularly in relation to the use of excess ART embryos for research, training and quality assurance purposes. The ethical and scientific considerations (including the requirement for informed consent and ethics committee approval) are the same irrespective of how an excess ART embryo is used. Therefore, IVF clinics will be subject to the same regulatory approach as applied to all institutions proposing to use excess ART embryos. The NHMRC advised:

> The legislation has been drafted so that an even regulatory hand is applied to all types of excess ART embryos, all types of research and all persons. The Bill does not prevent the continuation of ART clinical practices, including training of ART clinicians and quality assurance testing to ensure that culture and pre-implantation testing is optimal. By requiring a licence for these practices, the Bill takes a consistent approach to the treatment of embryos that may be damaged or destroyed, whether the use of the embryos is for training an ART clinician or for the derivation of stem cells.
>
> …
>
> The Licensing Committee will consider options to streamline the administration of the legislation, where it is satisfied that the use of the excess ART embryos will not damage or destroy the embryo. For example, ART service providers could apply for one licence to undertake quality assurance work using an approved list of techniques and a defined number of excess ART embryos. It may also be appropriate to consider similar arrangements for certain uses of excess ART embryos that may damage the embryo but are part of routine ART clinical practice, such as the use of embryos for training people in specific techniques of assisted reproductive technology. This would ease the administrative burden on ART clinics but still enable close regulatory oversight by the NHMRC Licensing Committee.[73]

4.90 Clause 26 makes it an offence to knowingly use a human embryo that is not an excess ART embryo where the use is not part of an ART program carried out by an accredited ART centre, and the person knows, or is reckless as to that fact.

---

71 *Submission* 1047, p.2 (ACCESS).

72 *Submission* 1500, p.3 (Qld Government).

73 *Submission* 23, Additional information 15.10.02, pp.1, 4 (NHMRC).

4.91 Finally, under Clause 27 it will be an offence to intentionally or recklessly breach the condition of a licence issued under the Bill.

Embryo Research Licensing Committee of the NHMRC

4.92 Clause 28 establishes the NHMRC Licensing Committee. As a Principal Committee of the NHMRC, many provisions of the NHMRC Act will apply in respect of its operations. For example, as a Principal Committee of the NHMRC, the Licensing Committee must comply with the statutory requirement that the NHMRC promulgate ethical guidelines for research developed by AHEC.[74]

4.93 The GeneEthics Network argued that the NHMRC was not the appropriate body to be responsible for licensing activities and that this licensing function should be vested in the Office of the Gene Technology Regulator 'who has statutory responsibilities and authority commensurate with the importance of this licensing work, and has processes and mechanisms to engage with the interested and general publics'.[75]

4.94 Clause 29 sets out the functions of the Licensing Committee, which are essentially to administer the licensing system, monitor compliance with the legislation and where necessary take enforcement action.

4.95 Under Clause 30 the Licensing Committee has the power to do all things necessary or convenient to be done in connection with its functions.

4.96 Under Subclause 31(1) the membership of the Licensing Committee is to comprise:

- a member of AHEC (Paragraph 31(1)(a));
- a person with expertise in research ethics (Paragraph 31(1)(b));
- a person with expertise in a relevant area of research (Paragraph 31(1)(c));
- a person with expertise in assisted reproductive technology (Paragraph 31(1)(d));
- a person with expertise in a relevant area of law (Paragraph 31(1)(e));
- a person with expertise in consumer health issues as they relate to disability and disease (Paragraph 31(1)(f));
- a person with expertise in consumer issues relating to assisted reproductive technology (Paragraph 31(1)(g));
- a person with expertise in the regulation of assisted reproductive technology (Paragraph 31(1)(h)); and

---

74 The Committee received several submissions that expressed concern with references the Bill makes to guidelines issued by the NHMRC and other bodies. These concerns are discussed below in relation to clauses 36 and 39 under the heading 'Licensing System'.

75 Submission 1843, p.2 (GeneEthics Network); See also *Committee Hansard*, 24.9.02, p.165 (Dr Tonti-Filippini).

- a person with expertise in embryology (Paragraph 31(1)(i)).

4.97 BresaGen submitted that given the differences and lack of overlap between ART research and embryonic stem cell research it is very important that there be adequate representation of both broad fields. It proposed that the third committee member should be 'a person with expertise in embryonic stem cell research' rather than merely 'a person with expertise in a relevant area of research' under Paragraph 31(1)(c).[76]

4.98 The members of the Licensing Committee must be appointed by the Minister after seeking nominations from the organisations described in regulations. The explanatory memorandum explains that placing the list of organisations in the regulations enables the list to be updated relatively simply as organisations change their name or as new organisations are formed that should be consulted. The Minister must also seek nominations from all States and Territories, consult the States and Territories on proposed appointments and have regard to their views (Subclauses 31(2) and (3)).[77]

4.99 The AHEC member must not be appointed as the Chair of the Licensing Committee, thus ensuring the position cannot also be held by the Chair of AHEC (Subclause 31(4)).

4.100 Subclause 31(5) provides that before appointing the Chair of the Licensing Committee, or the member with expertise in the regulation of assisted reproductive technology, the Minister must have the agreement of a majority of the States and Territories.

4.101 Subclause 31(6) provides that in appointing members to the Licensing Committee the Minister must also have regard to the desirability of ensuring that the Licensing Committee as a whole comprises members from different States and Territories.

4.102 Despite these safeguards, several submissions suggested that the membership of the Licensing Committee might be unrepresentative. For instance, the Catholic Archdiocese of Melbourne submitted that:

> The membership of the Licensing Committee could easily be stacked with those who have a particular interest in the embryo industry. There is no attempt to minimise this conflict of interest. Nor is there any attempt to ensure a broad spectrum of opinion or representation. Even with the inclusion of positions (b), (f), (h) and (i) there is no representative of the churches and no provision for a member with expertise in philosophical ethics, women's issues or other social issues.[78]

---

76 *Submission* 1030, p.12 (BresaGen).

77 Explanatory memorandum, p.21.

78 *Submission* 876, p.12 (CAM); See also *Submission* 1843, p.3 (GeneEthics Network).

4.103 The Australian Catholic Bishops Conference added that:

> The Bill provides nothing with respect to 'conflict of interest'. Only in the Explanatory Memorandum is one referred to certain sections of the *National Health and Medical Research Council Act 1992* (Cth) which summarily states (s.38 (b)(vi)) that it is the Council which determines 'the disclosure of members' interests in matters being considered by the Committee'. Given the vast sums of money at stake in embryo research, conflict of interest of researchers, decision-makers and commercial interests with respect to licences must be dealt with comprehensively in the legislation.[79]

4.104 As noted by the Australian Catholic Bishops Conference, under the NHMRC Act, the NHMRC may determine the procedure to be followed by the Licensing Committee (as a Principal Committee) in relation to the disclosure of members' interests in matters being considered by the Licensing Committee.

4.105 The terms of appointment to the Licensing Committee may be on a part-time basis and may last for terms of up to 3 years (Clause 32).

4.106 Clauses 33 and 34 provide that the Licensing Committee must provide details of its operations to the NHMRC for inclusion in the NHMRC Annual Report and may report to Parliament at any time that it considers necessary.

Licensing system

4.107 An application for a license authorising the use of excess ART embryos is required to be made in accordance with Clause 35. The Licensing Committee will be able to specify the requirements for an application, and the regulations may require a fee to be paid.

Determination of application

4.108 Clause 36 describes the matters that must be considered by the Licensing Committee when deciding whether or not to issue a license. Particular matters that the Licensing Committee must have regard to include:

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

---

79 *Submission* 981, p.17 (ACBC).

4.109 The explanatory memorandum lists a number of the uses for which a license may be granted, including using excess ART embryos:

- for research, e.g. to derive stem cells or to improve ART clinical practice;
- to train people in ART techniques;
- for Quality Assurance testing to ensure that pre-implantation diagnostic tests give accurate results; and
- to examine the effectiveness of new culture media for growing human embryos.[80]

4.110 A number of submissions commented that the provisions of Clause 36 were vague and indeterminate. For example, the National Civic Council (WA) noted that there is no specification of the kinds of 'knowledge' that may be sought or of the 'technologies for treatment' that may be improved:

> The inclusion of 'training people in ART techniques' and 'quality assurance testing' is significant. It is hard to see how these lead to a 'significant advance in knowledge' or 'improvements in technologies for treatment'.
>
> This suggests that the drafters of the Bill and the explanatory memorandum may be reading down Section 36 (4), which only requires the NHMRC Licensing Committee to 'have regard to' various matters, including 'the likelihood of significant advance in knowledge, or improvement in technologies for treatment'. This wording does not require the Committee to reject license applications for uses that do not have any likelihood of advancing knowledge or improving technologies for treatment.[81]

4.111 The NHMRC advised the Committee that:

> The Australian Health Ethics Committee (AHEC) is currently reviewing the NHMRC *Ethical Guidelines on ART* and a consultation draft of these revised guidelines is likely to be released shortly. It is anticipated that these guidelines will include information about the types of matters that should be considered in order to establish that certain uses of excess ART embryos are likely to result in a significant advance in knowledge, or improvement in technologies for treatment as a result of the use of excess ART embryos.[82]

4.112 As noted above, Paragraph 36(4)(c) specifically states that the Licensing Committee must have regard to any relevant guidelines issued by the NHMRC, which would include the *Ethical Guidelines on Assisted Reproductive Technology*.

---

80 Explanatory memorandum, p.18.

81 *Submission* 282, p.9 (NCC-WA). See also *Submissions* 870 (Qld Bioethics Centre); 981, p.19 (ACBC); and 1235 (Don't Cross the Line (NSW)).

82 *Submission* 23, p.21 (NHMRC).

4.113 Several submissions noted that these guidelines are currently under review and commented on the Bill being considered while Parliament cannot predict what the new guidelines will ultimately contain.[83] Dr Kerry Breen, Chair of AHEC, described the process that was being undertaken to prepare the revised guidelines. He advised that the revision was foreshadowed in AHEC's strategic plan in mid-2000, and was initially deferred to await the House of Representatives Standing Committee on Legal and Constitutional Affairs report. Dr Breen informed the Committee that:

> During the time from which parliament commenced debate of the bill, AHEC considered carefully the timing of the release for consultation of the revised guidelines, which are presently entitled *Ethical guidelines on the use of reproductive technology in clinical practice and research*. It is the belief of AHEC that, even if the draft were ready for release for public consultation, it would be inappropriate for AHEC and the NHMRC to release the document before parliament has completed its current task. This belief has been formed out of respect for parliament and because some aspects of the draft guidelines are premised on the decision of COAG.[84]
>
> [Dr Breen added]
>
> We have not set a date for completion of the draft. We had originally hoped to conduct our public consultation and complete this by the end of the year. As we have made the decision to wait for parliament to complete the legislation, it may be later than that.[85]

4.114 Clause 37 requires the Licensing Committee to notify the applicant, the HREC and the relevant State authority of its decision on an application and to provide copies of any licence that is issued.

4.115 Clause 38 provides that a licence may be issued for the period specified in that licence. The GeneEthics Network noted that this provision appears to give the Licensing Committee discretion to issue long term licences and suggested that the term of a licence should be capped with an annual review and renewal for longer periods.[86]

'Proper consent' to authorised use of excess embryo

4.116 Under Clause 39, before an excess ART embryo may be used, each 'responsible person' must have given 'proper consent' to the use authorised under the licence. This is in addition to the donor's determination that the embryo is excess and their written authority for its use for purposes other than their own ART treatment. The definition of 'responsible person' in Clause 23 is:

---

83 *Submissions* 282, p.8 (NCC-WA); 981, p.19 (ACBC); and 1015, p.2 (Dr Piercy).

84 *Committee Hansard*, 26.9.02, p.248 (Dr Breen).

85 *Committee Hansard*, 26.9.02, p.251 (Dr Breen).

86 *Submission* 1843, p.3 (GeneEthics Network).

- any woman who provided the egg (and any spouse of that woman at the time it was provided); and
- any man who provided the sperm (and any spouse of that man at that time it was provided); and
- the woman for whom the embryo was created (and any spouse of that woman at that time it was created).

4.117 This would suggest that the licence holder requires the consent of at least two people, and at most six people, before the embryo may be used as authorised under the licence. That is, it seems that the consent of an anonymous gamete donor will be required before an excess ART embryo may be used as authorised under a licence.

4.118 Professor Jansen of Sydney IVF confirmed that any donor would be able to find out what general type of research has been performed on donated embryos. He gave evidence that:

> Every embryo that passes through our laboratory can be traced–its location is accounted for. …
>
> I may not, for example, be able to tell a patient whether the medium was designed to test magnesium concentrations compared with calcium concentrations. I would be able to inform them that the embryos were used in the development of culture medium. Likewise, I would be able to tell them to what extent their cells were developed along ES cell development lines.[87]

4.119 However, the Committee heard evidence that the instance of anonymous donors in Australia is very low. Professor Jansen informed the Committee that Sydney IVF does not deal with anonymous donors at all. He added that:

> In a research context, I do not think that one would ever use embryos that had been conceived as a result of sperm donation. The ethics are just too complex for that and the numbers involved are exceptionally small in any case.[88]

4.120 'Proper consent' is defined in Clause 23 to mean consent obtained in accordance with:

- the *Ethical Guidelines on Assisted Reproductive Technology* (which as noted above are currently under review); or
- other guidelines issued by the NHMRC, if specified by notice in the *Gazette*.

4.121 The *Ethical Guidelines on Assisted Reproductive Technology* provide direction on what sorts of information should be given to ensure informed decision-making. For instance, the guidelines currently require all information which may be of

---

87 *Committee Hansard*, 26.9.02, p.194 (Professor Jansen).

88 *Committee Hansard,* 26.9.02, p.194 (Professor Jansen).

significance to the participant to be given in a way that is appropriate to, and sufficient for, informed decision-making. That is, full, accurate and objective information must be given.[89]

4.122 In addition, that information must be explained orally, supported by written material in plain language that is provided to participants with enough time for it to be taken away and considered. This aspect of the guidelines would seem to approach Stem Cell Sciences' proposal for a 'cooling-off' period to be imposed to ensure that potential donors have the opportunity to fully consider whether they wish to authorise the use of their embryos for research.[90]

4.123 Under the guidelines, informed decision-making is required of all participants, including the donors of gametes and embryos.[91] However, as noted above, informed consent was still raised as a concern in several submissions.[92]

4.124 The guidelines also state that '[c]ounselling may be provided within, or independently of, the clinic. It should be incorporated into the routines of the clinic and be available as part of long-term follow-up'.[93] This does not fully address Salt Shakers' proposal that an independent counsellor should be required to give counselling leading to consent for the licensed use of embryos, which they support with this cautionary comment:

> If the IVF staff counselling the couple are supportive of the embryonic stem cell research and aiming to obtain as many embryos for research we need to ask if they would give unbiased and accurate information.[94]

4.125 Aside from the contents of the guidelines referred to in the Bill, several submissions expressed concern that areas of the Bill are given effect by incorporating material for which the Parliament is not responsible. In particular, a number of submissions were concerned that 'proper consent' is defined by reference to the *Ethical Guidelines on Assisted Reproductive Technology* and other NHMRC guidelines rather than being comprehensively defined within the Bill.[95] The Australian Family Association argued that:

> It is the responsibility of government to be more directly involved in the control and direction of this industry.[96]

---

89 *Ethical Guidelines on Assisted Reproductive Technology*, p.5, paragraph 3.1.1.

90 *Submission* 1012, p.2 (Stem Cell Sciences).

91 *Ethical Guidelines on Assisted Reproductive Technology*, p.5, paragraph 3.1.3.

92 For instance, see *Submission* 1036, p.5 (FINRRAGE).

93 *Ethical Guidelines on Assisted Reproductive Technology*, p. 8, paragraph 4.1.

94 *Submission* 1502, p.6 (Salt Shakers – A Christian Ethics Group).

95 *Submissions* 282, p.8 (NCC-WA); 981, p.19 (ACBC); 1015, p.2 (Dr Piercy) and 1843 (GeneEthics Network).

96 *Submission* 1029, p.1 (Australian Family Association, Newcomb Branch).

4.126 The Senate Scrutiny of Bills Committee has in the past drawn attention to provisions which give power to a particular person or body to issue guidelines, directions or similar instruments which determine the way authority given under an Act of Parliament is to be exercised. It usually suggests that such instruments be tabled in Parliament and, where appropriate, be disallowable by either House.[97]

4.127 There are a number of reasons for imposing such a standard. Without it, a person or organisation outside the Parliament may change the obligations imposed without the Parliament's knowledge, or without the opportunity for Parliament to scrutinise and (if so minded) disallow the variation. In addition, such a rule also encourages more certainty in the law, and ensures that law-makers bear the onus of ensuring that those obliged to obey a law have adequate access to its terms.

4.128 However, the distinction has long been drawn between delegated matters that are legislative in nature, and those that bear some administrative character. This distinction was drawn by Latham CJ in *Commonwealth of Australia v Grunseit*.[98] In that case, his Honour held that legislation determines the content of the law as a rule of conduct or a declaration as to power, right or duty, whereas executive authority applies the law in particular circumstances.

4.129 Where the power delegated is administrative in nature, the delegation is generally considered acceptable. Where the power delegated is legislative in nature, the Senate Scrutiny of Bills Committee has generally expected that legislation should establish a sufficient regime of scrutiny over the exercise of that power.[99]

4.130 On this occasion, the Senate Scrutiny of Bills Committee considered the Bill and found no cause to comment.[100]

4.131 Under Subclause 39(5), the Licensing Committee may also impose a number of conditions upon a license. These may include conditions relating to reporting and monitoring. The GeneEthics Network suggested that these matters should be mandated, rather than imposed only on the discretion of the Licensing Committee.[101]

4.132 Clauses 40 to 43 provide that the Licensing Committee may vary, suspend or revoke a licence and in so doing must notify the licence holder, the HREC and relevant State bodies. A license holder may surrender a licence.

4.133 Under Clause 41, the Licensing Committee has a discretion to suspend or revoke a licence if it believes, on reasonable grounds, that a condition of the licence

---

97 Senate Scrutiny of Bills Committee, Work of the Committee during the 38th Parliament, chapter 6.

98 (1943) 67 CLR 58.

99 Senate Scrutiny of Bills Committee, Work of the Committee during the 38th Parliament, chapter 6.

100 Senate Scrutiny of Bills Committee, Alert Digest No. 7 (21.8.02), p.36.

101 *Submission* 1843, p.4. (GeneEthics Network).

has been breached. During the public hearings the NHMRC were questioned as to why the breach of a licence (which is an offence under Clause 27) or the commission of another offence would not lead to the automatic revocation of that licence. In particular, it was noted that a corporation that has committed an offence may be liable only for a monetary penalty and would not necessarily lose its licence.[102]

4.134 The NHMRC responded:

> The public and the parliament would have very little confidence in a licensing committee that could continue to uphold a licence granted to someone who had been prosecuted for a criminal offence under the legislation. Our assumption had certainly been that the licence would be revoked by the NHMRC licensing committee.[103]

4.135 The explanatory memorandum explained that this Clause enables the Licensing Committee to suspend or revoke a licence that has been issued if they believe, on reasonable grounds, that a condition of the licence has been breached. Importantly, this permits the Licensing Committee to take immediate action in the event of apparent non-compliance without the need to establish a conviction of an offence. The explanatory memorandum further explained the advantages to the Licensing Committee of having the flexible powers:

> The NHMRC Licensing Committee has the power to re-instate the licence should the suspected breach of condition fail to be established or should the licence holder rectify the situation and the Committee is convinced that the work can continue without risk of further breaches. Whether or not the licence is suspended, cancelled or subsequently reinstated would depend on the individual circumstances of the case and the extent, severity and importance of the alleged breach.
>
> It is important that the NHMRC Licensing Committee has a degree of discretion in this respect given that breaches of licence can range from fairly minor infringements (for example, late submission of annual reports to the NHMRC Licensing Committee) through to very serious breaches such as using more embryos than has been authorised by the licence.[104]

Reporting and confidentiality

4.136 Clause 44 of the Bill requires the Licensing Committee to keep a publicly available database that contains information relating to licences it has issued including the name of the licensee, the nature of the uses of the embryos authorised by the licence (e.g. whether the embryos are proposed to be used for the derivation of stem cells, for testing culture medium, for training of technicians etc.), the number of embryos proposed to be used and the conditions of licence.

---

102 *Committee Hansard*, 29.8.02, p.17 (Senator Barnett).

103 *Committee Hansard*, 29.8.02, pp.17-18 (Ms Matthews).

104 Explanatory memorandum, pp.25-26.

4.137 While agreeing with the creation of the database, the GeneEthics Network argued that it should contain more information than is proposed. GeneEthics referred to the OGTR process to maximise information available on its website and commented that this process may be a good model for the NHMRC database as it will make the maximum amount of information available in a form that is accessible to all interested people.[105]

4.138 An important constraint on the information that may be disclosed by the Licensing Committee under Clause 44, or by any person, is that confidential commercial information must not be disclosed. The term 'confidential commercial information' is defined in Clause 23 to mean 'information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed'.

4.139 Several submissions noted that the legislation provides no protection for 'whistle-blowers', that is persons who may disclose information in the public interest. For example, the Australian Catholic Bishops Conference considered that the Bill gives undue protection to commercial interests without balancing those against the public interest:

> 'Confidential commercial information', as defined (cl.23), is so broad, and so subjective, as to defy any relevant meaning (e.g. 'Or other value' - to whom?). 'Whistle-blowers' are not protected under the legislation. As the legislation presently stands, they are likely to be the principal source of information to the public. Accordingly, they should be protected. Combined with the effect of cl.45, there is abundant protection for commercial interests but precious little either for embryos or whistle-blowers.[106]

4.140 In response to suggestions that the commercial-in-confidence provisions will inappropriately inhibit public access to information about the licences granted by the Licensing Committee, the NHMRC stated:

> Firstly, the bill makes a lot of information publicly available in relation to the determinations of the licensing committee. Secondly, in relation to what would be deemed commercial-in-confidence information, that sort of information may not be relevant to the determination of the committee. There is always an obligation to maintain the privacy of the people putting in applications. There has to be a balance between making a decision, having a transparent process and protecting confidentiality.[107]

Review provisions

4.141 Applicants and licence holders may apply to the Administrative Appeals Tribunal (AAT) for a review of certain Licensing Committee decisions including a

---

105 *Submission* 1843, p.4. (GeneEthics Network).

106 *Submission* 981, p.17 (ACBC).

107 *Committee Hansard,* 26.9.02, p.267 (Dr Morris).

decision not to issue a licence, decisions about licence conditions, and decisions about varying, revoking or suspending a licence (Clauses 46 and 47).

4.142 The inclusion of provision for review by the AAT of the Licensing Committee's decisions was considered by governments as important given the nature of the decision making process proposed for the Licensing Committee and the fact that a licence will be the only means by which a person would be allowed to undertake research or other activities involving excess ART embryos.

4.143 However, the GeneEthics Network argued that:

> Restricting appeal rights over NHMRC Licensing Committee decisions to the applicants and licensees alone removes important democratic and legal checks and balances on the proper administration of this law. Any interested party should have standing to appeal, including the present or former 'owners' of the embryos, interest groups and the public at large.[108]

Part 4 - Monitoring powers

4.144 Under Clause 48, the Chair of the Licensing Committee may appoint Commonwealth or State employees as inspectors to monitor compliance with the Bill. Clauses 49 to 55 provide inspectors with the power to enter premises and having entered premises, specify the range of monitoring powers that they may exercise.

Part 5 - Commonwealth/State arrangements

Operation of State laws

4.145 Clause 56 provides that the Act is not intended to exclude the operation of State and Territory laws except where the State or Territory laws are inconsistent with the Act and cannot operate concurrently. The explanatory memorandum notes that one of the intended effects of this clause is that if a State has existing legislation that, for example, bans the use of excess ART embryos, such a law would not be capable of operating concurrently with the Act and as such it is intended that the Act override the State law to the extent that it is inconsistent. Three States – South Australia, Victoria and Western Australia – have laws which attempt to ban human reproductive cloning and regulate, to differing extents, research on human embryos.[109]

4.146 Some argued that for a federal law to override 'inconsistent' State laws was neither democratic nor warranted by the COAG agreement. It was noted that the existing State laws regulating aspects of human reproductive technology had only been passed after thorough debate in the respective State parliaments, and therefore the Commonwealth Bill should leave existing State laws intact until the State

---

108 *Submission* 1843, p.4. (GeneEthics Network).

109 Parliamentary Library Bills Digest No.17 2002-03, p.10 and House of Representatives' report on human cloning, pp.132-145.

parliaments considered whether they supported national uniform legislation and, if so, amended their laws accordingly.[110]

4.147 An amendment was moved in the House of Representatives proposing that the operation of State law prohibiting the use of excess ART embryos should not be affected whether consistent or inconsistent with this Act. In response, the Attorney-General emphasised that the COAG agreement was quite clear that a nationally consistent approach to the regulation of research involving embryos was required. The effect of the amendment would be to create differences across jurisdictions that would be inconsistent with one nationally consistent single licensing regime.

4.148 The Attorney also stressed that as part of the COAG agreement the States would introduce corresponding legislation to establish a comprehensive and effective national scheme. He noted that South Australia, Victoria and Western Australia are currently in the process of amending their existing legislation so that it will mirror the Commonwealth legislation. Therefore the States that currently have legislation to ban research on excess ART embryos will be lifting those bans, consistent with the Commonwealth legislation.[111] The amendment was defeated.

Constitutional issues

4.149 A further issue raised in relation to the COAG agreement on nationally consistent legislation concerned the Commonwealth's constitutional powers to legislate with respect to human cloning and related unacceptable practices.

4.150 Clause 4 describes the constitutional powers that the Commonwealth is relying on to support the legislation. As there is no express power in the constitution relating to human cloning and the use of embryos, the Commonwealth is relying on a range of powers to support the legislation, including the corporations power, the trade and commerce power and the external affairs power.[112] The NHMRC referred to advice from the Australian Government Solicitor that stated:

> Under the Constitution, the Commonwealth Parliament has reasonably extensive powers in this area. However these powers would not support comprehensive legislation to regulate human cloning, assisted reproductive technology or the proposed unacceptable practices…
>
> As a result of the Commonwealth's lack of comprehensive legislative power in relation to this subject, it would, for example, be difficult for the Commonwealth to prohibit or control human cloning and related unacceptable practices carried on within a State by a natural person or persons, alone or in partnership. Other limits might include the prohibition

110 *Submissions* 282, p.11 (NCC-WA), 764 (CNI-WA), 1073, p.6 (Festival of Light).

111 *House of Representatives*, *Hansard*, p.6866, 24.9.02 and p.6888, 25.9.02 (Mr Williams).

112 The Parliamentary Library Bills Digest No.17 2002-03, pp.10-14, provides a detailed outline of the heads of constitutional power that might support the legislation.

> or control of research and development related to human cloning and related unacceptable practices by private research institutes in the States.[113]

4.151 In recognising the limitations of the Commonwealth's constitutional powers, the Commonwealth legislation forms part of a national legislative scheme, which will include corresponding laws in each State and Territory. Once all jurisdictions have enacted corresponding State and Territory laws, the legislation will apply equally to all persons and all activities in Australia. The NSW Government explained the importance of nationally consistent legislation:

> As the Commonwealth does not have a constitutional power directly relating to this matter, it has primarily relied upon the corporations' power, the trade and commerce power and the external affairs power. However this does not provide complete coverage. The advantage of having corresponding State and Territory legislation is that it gives complete coverage of all people and activities relating to the subject matter of the Bills, thereby ensuring that a truly national scheme can be implemented.[114]

4.152 Clauses 57 and 58 provide for the effective operation of the national scheme relating to the regulation of uses of excess embryos. Corresponding State laws will provide that the NHMRC Licensing Committee will undertake the licensing functions exercised under a State law. The intention is that there would not be dual licensing systems in any jurisdiction. Rather, anyone wishing to undertake work using excess ART embryos would need to apply for a licence from the NHMRC Licensing Committee whether or not they are technically organisations that come within the scope of the Commonwealth's constitutional powers or State powers.

Part 6 - Sunset clause, review provision and regulations

Sunset clause

4.153 Clause 60 gives effect to the COAG decision that the regulation restricting the use of excess ART embryos created after 5 April 2002 will cease to have effect on 5 April 2005, unless an earlier date is agreed to by COAG. Removing the restriction in three years time is aimed at ensuring the adequacy of the supply of excess ART embryos for research.

Numbers of embryos required for research

4.154 The question as to the actual number of excess ART embryos required for research was the subject of considerable debate during the inquiry. However, answers to questions put by the Committee were not always consistent, some referring to human embryos and some to embryonic stem cells.

---

113 *Submission* 23, Additional information 13.9.02 part 2 (c). Copies of the AGS advice dated 13 February and 30 April 2002 were provided to the Committee through the Committee Chair.

114 *Submission* 891, p.3 (NSW Government).

4.155 The figure of over 71 000 available embryos was regularly referred to in evidence. It should be noted that this figure is the total number of embryos in storage. Many of these embryos are currently in storage because the couples for whom they were created either still want them, have not yet decided that they are no longer required, or if they have decided they are excess, do not yet know what they want done with them. Professor Illingworth has also estimated there are a further 40,000 non-viable human embryos created each year in Australia, though these are not suitable for freezing, cannot be held in storage and are therefore outside the terms of this act.

4.156 The Australian Catholic Bishops' Conference notes the rapid rise in the number of embryos, observing that:

> …the latest statistics from the Australian Institute of Health and Welfare confirm that there has been a more than threefold increase in the number of embryos frozen between 1994 (22,280) and 2000 (71,176). To so manipulate the production of human life is an affront to human dignity and fosters a view of life which is more akin to the embryo as "property", able to be bought and sold as a commodity, than as a member of the human family.[115].

4.157 Nevertheless, Professor Illingworth gave evidence to put these numbers in context, stating that there were:

> 3,695 embryos in storage in our clinic. However, the vast majority of these embryos are in active clinical use. In 2001 we stored 1,708 embryos and thawed 1,210 embryos. In other words, the turnover every year is over 60 per cent of the total number of embryos in storage at any one time. Only six per cent of the embryos stored in our unit have ever been actively disposed of. Another six per cent have been in storage longer than five years.[116]

4.158 Accordingly, the number of embryos that would be an 'excess ART embryo' in conformity with the definition in the Bill would be considerably less than the figure of 71 000. However, the number of embryos estimated to be required for research has varied widely according to different sources and depending upon the use to which they are to be put. It is necessary to differentiate within the estimates the number of embryos required as distinct from the number of stem cell lines derived from embryos.

- 'My own view is that, if we were able to be successful with methodologies such as the induction of tolerance, we would not really need a large number of embryonic stem cells – around 20 to 30 or 50 may well be enough' – Professor Trounson;[117]

---

115 *Submission* 981 (ACBC).

116 *Committee Hansard,* 26.9.02, p.190 (Professor Illingworth); see also additional information from Professor Illingworth, 16.10.02.

117 *Committee Hansard,* 24.0.02, p.140 (Professor Trounson).

- 'In the development of culture medium for meaningful results then we are talking about hundreds [of embryos]' – Professor Jansen;[118]
- 'BresaGen believes that only 600-1000 such therapeutic ESC lines will provide adequate immunological tissue matching' – BresaGen;[119]
- 'The view of our members, though, is that, because we are at such an early stage of the research, anyone who wants to hazard a guess at the number is purely crystal-balling – we really do not know' – AusBiotech.[120]

4.159 The lack of a precise number was commented upon in evidence.[121] Dr McCullagh submitted:

> The number of embryos actually used in Australia is likely to be determined by the extent to which the requirement is met after a finite time when a certain number of cell lines are available or, alternatively, exciting new prospects continue to necessitate an indefinite continuation. I believe that it would be extremely naive to expect that the former outcome is the more likely…[122]

4.160 Professor Good argued that proponents of this research were trying to 'sell a story' and suggested that "to hear these numbers differ vastly between different people just tells me that this is an afterthought: 'We hadn't really thought about cell therapy, but we had better put some numbers up because we want to find some numbers that'll fit under the legislation'."[123] Professor Good had his own estimate:

> I believe that to get a bank suitably large enough to guarantee you a reasonable chance of finding a correct tissue typing match, you would need a bank of approximately 10 million, of that order, for each of the major human races: Caucasian, Asian, African and Hispanic.[124]

4.161 The contrary argument proposed that rapid developments in research and the constantly changing science involved made it difficult to provide a definitive number. Professor Hearn remarked that 'I think we are talking here about a moving field, in terms of the knowledge of what stem cells can do, and indeed how one can derive them and how few or many embryos might be needed'.[125]

4.162 The NHMRC noted that arising out of their consultations with IVF clinics:

---

118 *Committee Hansard,* 26.9.02, p.211 (Professor Jansen).

119 *Submission* 1030, p.1 (BresaGen).

120 *Committee Hansard,* 19.9.02, p.125 (AusBiotech).

121 For example *Committee Hansard* 17.9.02, p.58 (Professor Silburn).

122 *Submission* 480, p.9 (Dr McCullagh).

123 *Committee Hansard,* 19.9.02, p.99 (Professor Good).

124 *Committee Hansard* 19.9.02, p.90 (Professor Good).

125 *Committee Hansard,* 19.9.02, p.123 (Professor Hearn).

> It appears that, based on current practices and proposed future practices, it is possible that more excess ART embryos will be required for ART related research, quality assurance and training than for the derivation of stem cells. However…the precise numbers that may be required for ART related research or for the derivation of stem cells is not clear at this time and is dependent on future developments in research.[126]

Implications of the 5 April 2002 restriction and its proposed removal

4.163 Several submissions referred to the implications that the 5 April 2002 restrictions would have for potential research. BresaGen argued that the 5 April 2002 'sunset' date is incompatible with the need for safe therapeutic ES cell lines:

> While those embryos developed and frozen before 5 April will be satisfactory for basic research, they will not necessarily meet adequate current Good Manufacturing Practice (cGMP) safety requirements for therapeutic product development. These cGMP requirements are different from the standards required in IVF programs and are more stringent. The legislation should therefore allow derivation of more ES cell lines under cGMP conditions. These conditions can only be fully applied prospectively, and thus to ART embryos that come into existence after 5 April 2002, embryos currently prohibited from use by the new legislation.[127]

4.164 The banning of research involving fresh and frozen excess embryos produced after 5 April 2002 was also pointed to by Monash IVF as severely compromising embryology training programs, laboratory quality assurance process and embryo culture system improvements and techniques.[128]

4.165 Conversely, the Southern Cross Bioethics Institute claimed that 'if embryos created at any time and excess to requirements are available to researchers, it would not be difficult to create an excess of embryos by simple changes to practices in IVF clinics'.[129]

4.166 A response to this comment was provided on both medical and regulatory grounds. Professor Jansen noted that 'it is not medically possible to vary the number of eggs that respond to stimulation upwards at all and it is not possible downwards without compromising the chance of success for the woman'.[130] RTAC guidelines specifically prohibit the practice of deliberately super ovulating patients in an attempt to generate excess embryos for use in stem cell research or stem cell based product development. If any clinic did opt for such an unethical and unacceptable practice it would be readily apparent to RTAC due to the data reporting process for IVF clinics

---

126 *Submission* 23, Additional information 13.9.02, p.12 (NHMRC).

127 *Submission* 1030, p.9 (BresaGen).

128 *Submission* 1007, p.1 (Monash IVF).

129 *Submission* 892, p.9 (SCBI). A similar view was put by the Catholic Archdiocese of Melbourne in *Submission* 876, p.13 (Professor Jansen).

130 *Submission* 897, Additional information 1.10.02 (Professor Jansen).

to the National Perinatal Statistics Unit being extended this year to include a requirement for every clinic to report quite specific information about the number of eggs collected and the number of embryos stored in every treatment cycle.[131]

4.167 The Bill provides that it is an offence to create human embryos specifically for other purposes such as for use in research or to derive embryonic stem cells for potential therapeutic use.

4.168 As noted earlier, the Bill also includes requirements that the NHMRC develop and maintain a comprehensive, publicly available database containing information on all licences issued by the NHMRC Licensing Committee. The database will ensure that the public will have access to detailed information about the number of embryos used for research each year and the nature of such research.

Reviews of 'sunset' date

4.169 The need to retain the restriction will be considered as part of two reviews commissioned by COAG to report by 5 April 2003. These reviews, to be undertaken by the working committee of the Australian Health Ethics Committee that is revising the Ethical Guidelines on ART and by the NHMRC, were referred to in the COAG communique (see Appendix 3):

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

4.170 The Attorney-General has stated that 'these reviews will ensure that strong ethics and research protocols and appropriate safeguards are in place prior to the sunset clause coming into effect'.[132]

Review of Act

4.171 Clause 61 provides for an independent review of the Act to be commissioned by the NHMRC as soon as possible after the second anniversary of Royal Assent. The Clause describes the nature of the review and stipulates that the review report must be submitted to COAG before the third anniversary of Royal Assent.

---

131 *Submission* 1047 (ACCESS) and Professor Illingworth, Additional information 27.9.02.

132 *House of Representatives*, *Hansard*, p.6896, 25.9.02 (Mr Williams).

4.172 In the House of Representatives an amendment was moved to Clause 61 seeking to establish a parliamentary joint committee to review the Act. Proponents of the amendment argued that allowing the NHMRC to establish the review lacked independence and removed from the Parliament its role in reviewing the operation of the legislation. The amendment sought to 'establish the authority of the democratic process on making difficult decisions'.[133] Pro-Life Victoria in its submission also supported the amendment.[134]

4.173 In response the Attorney-General argued that the amendment:

- risked losing a nationally consistent approach by limiting the role of the States in helping to choose appropriate persons to undertake the review and by not providing a report back to COAG; and
- it did not preserve the integrity of the original bill before it was split, that is the concurrent review of both Bills by the same persons.

4.174 The Attorney-General also noted that Parliament's role would not be subverted or supplanted through the review process proposed by Clause 61 as it would consider any amendments to the Act arising from the review. Furthermore, the NHMRC would not itself be undertaking the review, rather it must appoint an independent review and may only choose the reviewers with the agreement of all States and Territories. The Attorney-General indicated that the arrangement was in accordance with the COAG agreement for national consistency.[135] The proposed amendment to Clause 61 was not agreed to.

4.175 Following the splitting of the original Bill, the NSW and Queensland Governments raised concerns about the impact that this may have on the original review provisions. Under the new Cloning Bill, the Minister must cause an independent review to be undertaken and the review is to be undertaken by persons chosen by the Minister with the agreement of each State and be provided to COAG by the third anniversary of Royal Assent. The Research Bill provides for the NHMRC to cause an independent review to be undertaken by the same persons who conduct a review of the Cloning Bill. The research review must be undertaken concurrently with the cloning review and must accompany the report of that review to COAG.

4.176 The NSW Government stated that the new provisions 'represent an unnecessary and problematic departure' from the original provisions 'which more accurately reflected the spirit and intention of the COAG agreement'.[136] The Queensland Government argued that the amendments had implications for the implementation of a meaningful review of the Bills.[137]

---

133 *House of Representatives*, *Hansard*, p.6905, 25.9.02 (Mr Cadman).

134 *Submission* 1570, Attachment 2, p.5 (Pro-Life Victoria).

135 *House of Representatives*, *Hansard*, p.6907, 25.9.02 (Mr Williams).

136 *Submission* 891, p.6 (NSW Government).

137 *Submission* 1500, p.4 (Qld Government).

4.177 Both Governments supported the NHMRC as the appropriate body to cause the independent reviews to be undertaken. The Queensland Government regarded the original review clause as superior with the NHMRC 'well-placed to ensure the delivery of an evidence-based, rigorous and objective evaluation of the functional operation of the two statutory instruments for both the prohibition and regulation regimes'.[138]

4.178 The Governments voiced concern that under the new provisions it was possible for a person or body other than the NHMRC appointees to undertake the reviews. The Queensland Government argued that:

> For example, the reviews might be undertaken by a parliamentary committee. The Queensland Government regards this as a further risk to the objectivity of the review process because the complex subject matter and objective evaluation of the operation of the licensing committee necessitates a high level of expertise and familiarity with the content area.[139]

4.179 It was noted that because of the relationship between the activities to be reviewed in both Bills, the reviews should be undertaken concurrently. Both Governments pointed to the impact of delays between the Bills coming into operation on concurrent reviews and noted that these would be minimised if the Senate considered and voted on the Cloning and Research Bills together.[140]

4.180 In response to State concerns, the Minister's Second Reading Speech for the Prohibition of Human Cloning Bill, stated that:

> The Prime Minister also expressed the hope that the States and Territories would remain committed to the vision of national consistency. The Prime Minister disagreed with statements of three of the Premiers that splitting the bill would not be consistent with the spirit of the COAG Agreement. The agreement dealt with a series of matters to be incorporated into a nationally consistent legislative scheme. Those matters will still be addressed as agreed, albeit in two separate pieces of legislation.
>
> Nothing has been lost by implementing the agreement reached at COAG through two pieces of legislation rather than one. The two bills give effect to the COAG agreement in exactly the same way as the one consolidated bill would have done. The bills must, however, be preserved without further amendment.[141]

---

138 *Submission* 1500, p.4 (Qld Government).

139 *Submission* 1500, p.4 (Qld Government); see also *Submission* 891, p.8 (NSW Government).

140 *Submission* 891, p.9 (NSW Government); *Submission* 1500, p.6 (Qld Government).

141 *Senate*, *Hansard,* 18.9.02, p.4324.

Regulations

4.181 Clause 62 empowers the Governor-General to make regulations prescribing matters required to be prescribed by the Act or necessary for giving effect to the Act. Before the Governor-General makes regulations, the Minister must be satisfied that the States and Territories have been consulted in relation to the proposed regulations and that there was regard to the views of the States and Territories in the preparation of the proposed regulations.