QUALIFYING COMMENTS

PROVISIONS OF THE RESEARCH INVOLVING EMBRYOS AND PROHIBITION OF HUMAN CLONING BILL 2002

EXECUTIVE SUMMARY

- There are a number of fundamental flaws in the Bill raised during the Committee's Inquiry amounting to a failure to justify the need for the legislation with respect to destructive embryo research, and a failure to make the case for the ethically-questionable destruction of human embryos. The flaws we have identified in our Qualifying Comments include:
  - Evidence about extensive but still largely unexamined commercial considerations of the Bill's supporters and the misrepresentation of the relevant science to Senators has raised questions about the possible dubious motivations of those supporting the Bill.
  - There are a range of concerns about the consequences of passage of the Bill and the drafting of its provisions, including:
    - the breadth of the destructive human embryo research that would be allowed;
    - concerns with the utilitarian approach adopted in the Bill and the precedent-setting nature of the Bill; and
    - concerns relating to various provisions of the Bill and their regulatory adequacy.
  - It is questionable whether the Bill is broader than the COAG agreement, upon which it is supposed to be based.
- Supporters of the Bill have argued that the legislation is critical as it offers the hope of a cure to sufferers of a range of disabilities by allowing embryonic stem cell research to continue. That argument is flawed because:
  - Embryonic stem cell research will continue in Australia whether or not this Bill passes the Parliament. The purpose of the Bill has been fundamentally misrepresented – it does not regulate the use of stem cells, rather, it permits the destruction of so-called 'excess' IVF embryos.
  - Research on embryonic stem cells is at a very basic stage, and there is no evidence that embryonic stem cell research offers any hope of a cure to sufferers of various diseases. Many witnesses agreed that existing stem cell lines are adequate for present research purposes.
  - Even if embryonic stem cells did hold promise of treatments for human patients, the number of human embryos to which this Bill grants possible access would be completely insufficient for the creation of therapies for human patients.
  - Present science suggests that embryonic stem cell research offers inferior outcomes to alternative areas of research, which do not pose the same ethical dilemmas, and do not require the destruction of human embryos.

PROVISIONS OF THE RESEARCH INVOLVING EMBRYOS AND PROHIBITION OF HUMAN CLONING BILL 2002

INTRODUCTION

A considerable range of scientific, legal and ethical issues have been raised during this inquiry into the provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002. With some notable exceptions, the Chair's Report generally covers the evidence provided. However an important omission is the lack of serious critical analysis of the evidence, submissions and arguments. All evidence is given equal weight or value in the Chair's Report. Consequently, there are key issues that the Chair's Report fails to highlight despite the fact that the evidence raises issues of considerable concern.

Accordingly, this Report contains analysis of and comments on the evidence presented to the Committee.

The Research Involving Embryos and Prohibition of Human Cloning Bill 2002 was split in the House of Representatives into two separate Bills, the Prohibition of Human Cloning Bill 2002 and the Research Involving Embryos Bill 2002. The reference of the original Bill to the Senate Committee, however, occurred prior to the splitting of the Bill, and so the Committee has inquired into the original Bill in its entirety.

Throughout the Inquiry a number of witnesses before the Committee raised serious concerns about the Bill including:

- the motivation for its introduction;
- the extensive but still largely unexamined commercial considerations;
- the misrepresentation of the relevant science to Senators;
- concerns with the utilitarian approach adopted in the Bill;
- the breadth of the destructive human embryo research that would be allowed;
- the precedent-setting nature of the Bill; and
- concerns relating to various provisions of the Bill and their regulatory adequacy.

The Bill was drafted to implement a nationally consistent approach agreed to by the Council of Australian Governments (COAG) on 5th April 2002. A communiqué setting out the agreed outcomes of the discussions that day stated that the Council had agreed:

- That research be allowed only on existing ART [assisted reproductive technology] embryos, that would otherwise have been destroyed, under a strict regulatory regime including requirements for the consent of donors and that the embryos were in existence at 5 April 2002. It was agreed donors would be able to specify restrictions, if they wish, on the research uses of such embryos.
- The regulatory regime would be reviewed within three years.
- Research would need to have approval from an ethics committee and be in accordance with NHMRC and Australian Health Ethics Committee guidelines.

On that basis, the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 was drafted.

This Inquiry has revealed that there are a number of fundamental flaws in the arguments of the proponents of the Bill. These flaws will be considered in detail in this Report. They raise concerns:

- That there has been a failure to justify the need for the legislation with respect to destructive embryo research, and in particular, a failure to show that the existing regulation and permissible research is inadequate, which amounts to a failure to make the case for the ethically-questionable destruction of human embryos. There is almost unanimous support for the much less contentious part of the Bill which bans human cloning;
- About possible dubious motivations of those supporting the Bill;
- About the consequences of passage of the Bill and the drafting of its provisions;
- About whether the Bill is broader than the COAG agreement.

CHAPTER 1

FLAWS IN ARGUMENTS SUPPORTING BILL

Failure to justify need to destroy human embryos

Our primary concern with the Bill is that the need to permit destruction of so-called 'excess' IVF embryos has not been demonstrated. The issue of destruction of embryos created during IVF processes is a highly controversial one and would require persuasive arguments in its favour. The evidence before the Committee relating to the need for this Bill has been conflicting and contradictory, with many scientists arguing against allowing access to these embryos.

The purpose of the Bill has been fundamentally misrepresented. A large amount of scientific evidence was presented to the Committee supporting the continuation of embryonic stem cell research. In evidence the National Health and Medical Research Council (NHMRC) clearly stated that the Bill:

> …**does not regulate the use of stem cells**. What the Bill does do is provide for the first time a strong national framework for the regulation of research on excess ART embryos that would otherwise have been destroyed.[1] [formatting added].

Those who support this legislation argue that it is critical as it offers the hope of a cure to sufferers of a range of disabilities by allowing embryonic stem cell research to continue. Those arguments are flawed for three main reasons:

a) Embryonic stem cell research is not facilitated by this Bill. Whether or not this Bill passes the Parliament, embryonic stem cell research will continue in Australia. A significant number of witnesses agreed that existing stem cell lines are adequate for present research purposes.[2]

b) There is no evidence whatsoever that embryonic stem cell research offers any hope of a cure to sufferers of various diseases. Research at this stage is very basic.[3] Even if embryonic stem cells did hold the

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1 Prof. Pettigrew, *Committee Hansard*, 29/8/02, p.2.

2 For example: Dr Juttner, BresaGen Ltd, *Committee Hansard*, 17/9/02, pp.32, 38; Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.51, 58-59; Prof. Rowe, *Committee Hansard*, 19/9/02, p.104; Prof. Good, *Committee Hansard*, 19/9/02, p.91; Prof. Bartlett, *Committee Hansard*, 19/9/02, p.95.

3 Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.52; Prof. Rowe, *Committee Hansard*, 19/9/02, p.95; Prof. Hearn, ANU, *Committee Hansard*, 19/9/02, p.95; Prof. Shine, *Committee Hansard*, 19/9/02, p.118.

possibility of some future treatment, it would be up to 30 years before those therapies become available.[4]

c) If embryonic stem cells did, at some stage in the future, hold promise of treatments for human patients, the 70,000 embryos to which this Bill grants possible access would be completely insufficient for the creation of these therapies. Estimates based on existing data on immune rejection suggest that 10 million embryonic stem cell lines would be required to give a 53% possible match of stem cells that would not be rejected, for Caucasians alone.[5] Therefore, the potential treatments that this research will lead to will require the creation and destruction of large numbers of embryos to produce these stem cells, leading to further ethical issues.

The issue of whether arguments in support of the Bill justify its passage take into account the adequacy of existing research. The Committee has received considerable evidence on this issue, particularly from those scientists who question the motivations of the Bill's supporters based on their view that present science does not justify making excess IVF embryos available, or that present science suggests that embryonic stem cell research offers inferior outcomes to alternative research.

Adult stem cells and alternative research

A number of scientists have suggested that adult stem cell research is either adequate at this time, or preferable to embryonic stem cell research. Certainly adult stem cell research is not ethically problematic, unlike embryonic stem cell research, and all other things being equal, would be preferable on that basis.

Arguments to the Committee in favour of alternatives to embryonic stem cell research include:

- Adult stem cell research is presently more advanced.[6]
- Adult stem cells are preferable to embryonic stem cells as therapeutic models based on the use of stem cells from an adult source eliminate any

4 Prof. Tuch: 3,4,5 plus years, *Committee Hansard*, 17/9/02, p.47; Prof. Rowe: 20 to 30 years, *Committee Hansard*, 19/9/02, p.95; Prof. Bartlett, *Committee Hansard*, 19/9/02, p.99; Dr Coulepis: 9, 10, 15 years to get a therapy plus 8-14 years to get therapy on the market, *Committee Hansard*, 19/9/02, p.122.

5 Prof. Good, *Committee Hansard,* 19/9/02, p.98.

6 Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.56; Prof. Rowe, *Committee Hansard*, 19/9/02, p.95; Prof. Good, *Committee Hansard*, 19/9/02, pp.90-1; Prof. Hearn, *Committee Hansard*, 19/9/02, pp.114, 122, 123.

risk of graft rejection by the recipient's immune system.[7] Immunological rejection problems arise if foreign tissue is used in transplantation and derived from embryonic cells.[8] It was even said that animal embryonic stem cell rejection suggests that it is not worth progressing to research with human embryonic stem cells.[9]

- Adult stem cells overcome problems with tumurogenesis when using embryonic stem cells.[10]

- Adult stem cells are preferable to embryonic stem cells because the plasticity of embryonic stem cells is a disadvantage not an advantage.[11] Differentiation and proliferation arguments in support of use of embryonic stem cells are misleading.[12]

- Umbilical cord blood stem cells and somatic or adult stem cells are good alternatives.[13]

- Placing dopamine neurgic cells in the brain can help the motor symptoms of Parkinson's disease.[14]

- Autologous glial cells obtained from the patient's olfactory mucosa is the state of the art prospect for treating paraplegia/quadriplegia.[15]

- It is possible to obtain stem cells which could give rise to the insulin-producing beta cells of the pancreas from a source other than embryonic stem cells – that is, it is possible to use cells created in vitro from pancreatic stem cells.[16]

One alternative which deserves special mention is the use of germ stem cells (those used in the infamous 'rat experiment' used by Prof. Trounson in support of his

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7 Prof. Good, *Committee Hansard*, 19/9/02, p.90; Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.54; Prof. Bartlett, *Committee Hansard*, 19/9/02, p.94.

8 Prof. Good, *Committee Hansard*, 19/9/02, p.89.

9 Prof. Good, *Committee Hansard*, 19/9/02, pp.91, 97; Prof. Bartlett, *Committee Hansard*, 19/9/02, p.95.

10 Prof. Good, *Committee Hansard*, 19/9/02, p.91; Prof. Bartlett, *Committee Hansard*, 19/9/02, p.94.

11 *Committee Hansard*, 19/9/02, p.91.

12 Submission 480; *Committee Hansard*, 19/9/02, p.91.

13 Dr Fleming/Dr Pike, Southern Cross Bioethics Institute, Submission 892.

14 Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.53.

15 Dr McCullagh, Submission 480.

16 Dr McCullagh, Submission 480.

arguments). Germ stem cells are obtained from foetal tissue of aborted foetuses. According to Prof. Trounson:

> Embryonic stem cells from embryos are functionally indistinguishable from embryonic germ cells and will do everything that embryonic germ cells can do in terms of differentiation and tissue colonisation.[17]

Importantly however, the use of germ stem cells does not involve the destruction of human embryos and is therefore not relevant to the Bill.

The question remains that if germ cells and embryonic stem cells are "functionally indistinguishable", as argued by Professor Trounson in defence of his use of the "rat video", why isn't Professor Trounson using germ cells in his research instead of embryonic stem cells?

Motivations of supporters of Bill

A number of witnesses argued that it was too early to say whether any source of stem cells would deliver greater benefits than any other.[18] The consensus of scientific witnesses before the Committee was that there are adequate embryonic stem cell lines available to ensure that research in Australia will continue,[19] without the destruction of additional human embryos, and that will occur whether or not this Bill is passed.

The distinction has been drawn between the number of embryonic stem cells required for therapeutic and research purposes. While there is agreement that embryonic stem cells are still a long way off being used in the production of therapies,[20] and that there are adequate stem cell lines to continue research and establish proof of principle,[21] it is unclear why access is now being sought to excess IVF embryos.

There being no indication of any valid reason why access to these 70,000 or so embryos is required now, the evidence suggests that there are some underlying commercial interests behind the push for access to these embryos. A number of scientists speculated that commercial interests must have motivated the Bill, because

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17 Prof. Trounson, *Committee Hansard*, 24/9/02, p.136.

18 Prof. Hearn, ANU, *Committee Hansard,* 19/9/02, p.114; Prof. Tuch, *Committee Hansard*, 17/9/02, p.35; Ms Royles, CAMRA, *Committee Hansard*, 17/9/02, pp.70, and Mr Turner at p.75; Prof. Bartlett, *Committee Hansard,* 19/9/02, p.95; Ms Hartland, Biotechnology Australia, *Committee Hansard*, 26/9/02, p.228.

19 Footnote 2.

20 Prof. Rowe, *Committee Hansard,* 19/9/02, p.95; Prof. Hearn, *Committee Hansard,* 19/9/02, p.114; Dr Coulepis, *Committee Hansard,* 19/9/02, p.121; Prof. Serjeantson, Australian Academy of Science, *Committee Hansard,* 19/9/02, p.120; Prof. Shine, *Committee Hansard,* 19/9/02, p.118; Prof. Tuch, *Committee Hansard*, 17/9/02, p.40; Prof. Bartlett, *Committee Hansard,* 19/9/02, p.94; Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.53.

21 Prof. Rowe, *Committee Hansard,* 19/9/02, p.104.

there was no scientific basis justifying the need for those embryos.[22] Some scientists raised questions as to the type of research commercial interests sought to perform on embryos.[23]

We can only speculate as to the motivations behind those seeking access to the embryos, however, if there existed a rational and reasonable explanation of the need for them, we are sure it would have arisen in evidence to the Committee. None has arisen.

The only arguments that have been advanced in support of a need for access to IVF embryos have been that new embryonic stem cell lines are needed:[24]

- To create "safer" stem cell lines without using mouse feeder cells that have been used for derivation of existing stem cell lines,[25] except one[26];
- To achieve adequate tissue matching to avoid immune rejection in clinical therapy;[27]
- To produce improved cell lines if there are future improvements to the methodology for initiating and growing cell lines;[28]
- To overcome restrictions to use stem cells derived from commercial funding.[29]

None of those arguments compels immediate access to embryos that will be destroyed for research purposes. Research on embryonic stem cells is at such an early stage that much more research on animal models is required for any of these reasons to justify the destruction of embryos.[30]

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22 Dr Silburn, Parkinson's Australia, *Committee Hansard*, 17/9/02, p.52, Prof. Rowe, *Committee Hansard,* 19/9/02, p.95. See below "Commercial interest in embryos".

23 H51, H91, H96, H98 (Good and Rowe), H99 (Bartlett). See also below "Commercial interest in embryos".

24 Prof. Pera, *Committee Hansard,* 24/9/02, p.135.

25 Prof. Pera, *Committee Hansard,* 24/9/02, p.135; Mr Ilyine, Stem Cell Sciences Ltd, *Committee Hansard*, 17/9/02, p.40; Dr Juttner, BresaGen, 17/9/02, p.38; Dr Simmons, *Committee Hansard*, 19/9/02, p.111 (also to improve stem cell lines if derivation conditions were not optimal). According to Dr Juttner, BresaGen, 100 to 200 stem cell lines would be required for this purpose: *Committee Hansard*, 17/9/02, p.50.

26 Prof Trounson, *Committee Hansard,* 24/10/02, p.153.

27 Prof. Pera, *Committee Hansard,* 24/9/02, p.135.

28 Prof. Pera, *Committee Hansard,* 24/9/02, p.135.

29 Prof. Pera, *Committee Hansard,* 24/9/02, p.135.

30 Dr Silburn, *Committee Hansard*, 17/9/02, p.52; Prof. Good, *Committee Hansard*, 19/9/02, p.102.

Clinical therapy is 20 to 30 years away,[31] if there will ever be any clinical therapy using embryonic stem cells, and that is far from certain.[32] Many scientists have given evidence that existing stem cell lines are adequate for research that will be conducted in the near future given the present restricted state of knowledge.[33] The Committee has also received evidence that excess embryos to which this Bill will permit access will be completely inadequate for the purposes of achieving adequate tissue matching.[34]

The arguments presented to the Committee to destroy excess IVF embryos based on a need to create additional stem cell lines are, therefore, not convincing.

The issue of the number of embryos required for the purposes of "research" was contentious among scientists, and clearly depends upon their interpretation of the definition of "research" in the Bill. Opinions on the number required varied from "tens"[35] to 600-1,000[36] to "up to ten million" embryonic stem cell lines[37] to those not prepared to hazard a guess.[38] Those who based their figures on the number required for basic research (the type of research already being conducted) were at the lower end of the scale, while the higher figure was premised on the possible eventuality of a therapy, and on the number required to develop a therapy which would have a reasonable (greater than 50 per cent) chance of obtaining a match to avoid immune rejection.[39]

There was a further ethical consideration resulting from that analysis of the number of human embryos required. Namely, that if 10 million embryonic stem cell lines were to be required in the future to produce a therapy, then that would involve the creation of human embryos by cloning:[40]

> **Senator HUTCHINS –** How would you get the 10 million stem cell lines?
>
> **Prof. Good –** Under the current legislation before parliament, as I understand it, you would not. I believe there are some 70,000 'surplus'

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31 Footnote 4.

32 Prof. Good, *Committee Hansard*, 19/9/02, p.96.

33 See Footnote 2, especially Dr Juttner, BresaGen, 17/9/02, p.39; Prof. Good, *Committee Hansard*, 19/9/02; p.96; Prof. Tuch, *Committee Hansard*, 17/9/02, p.39.

34 Prof. Good, *Committee Hansard*, 19/9/02, p.98.

35 Prof. Trounson: "20 to 30 or 50 may well be enough", *Committee Hansard*, 24/9/02, p.140.

36 In order to create therapeutic cell lines to provide therapies for a wide range of humanity: Dr Juttner, *Committee Hansard*, 17/9/02, p.39.

37 Prof. Good, *Committee Hansard*, 19/9/02, p.98; Dr Simmons: that estimation "seems perfectly reasonable", *Committee Hansard*, 19/9/02, p.106.

38 Dr Morris and Ms Matthews, NHMRC, 29/8/02, pp.7, 8; Prof. Tuch, *Committee Hansard*, 17/9/02, p.37; Prof. Shine, *Committee Hansard*, 19/9/02, p.116; Dr Coulepis, *Committee Hansard*, 19/9/02, p.125.

39 Prof. Good, *Committee Hansard,* 19/9/02, p.98; Dr Juttner, *Committee Hansard,* 17/9/02, p.39.

40 *Committee Hansard*, 19/9/02, p.98.

> embryos. There are nowhere near 10 million. You would not be able to get 10 million. I do understand that this has already been banned by the parliament, but the alternative that people say is, 'Let's do therapeutic cloning', where you take the nucleus from one of your cells, put it into an enucleated egg of a woman, make a little clone of you and use those cells to make tissue which would be identical to you.
>
> **…**
>
> **Senator HUTCHINS –** But to get 10 million, you would have to think of something like that, wouldn't you?
>
> **Prof. Good –** You would have to make the embryos.

Cloning is the only apparent way to produce the number of embryos that would be required while producing tissue which is compatible with the patient.[41] In order to create embryos, obviously human eggs are required, and while prohibited by the Bill, there will undoubtedly be pressure to remove that prohibition if large numbers of human embryos should be required for a therapy. That raises all manner of ethical concerns about the so-called farming of eggs from women, concerns which have resulted in the prohibition contained in this Bill in the first place. While imposing a prohibition, the Bill potentially creates demand for the removal of that prohibition.

If the destruction of human embryos for research is permitted, the issues that arise will become ever more complicated, and will continue to raise ethical concerns. The obvious ethical concerns that will arise in the foreseeable future are very perturbing. To proceed down this moral and ethical slippery slope is unwarranted when there are so many viable alternatives to the destruction of embryos for research.

Commercial interest in embryos

The question of exactly what the human embryos and embryonic stem cells will be used for has been raised by a number of scientists, as there has been no present demonstrable need for the stem cells for research purposes. There have been a number of suggestions from scientists and industry as to the uses to which they might be put:

> ... these cells will be highly useful for screening drugs for both toxicology and effectiveness.[42]
>
> … this is about commerce , not about science. Let us not kid ourselves.[43]

The breadth of subjective definitions of research permissible using human embryos and embryonic stem cells under the Bill illustrates that the Bill's provisions are open to interpretation and potential abuse if commercial interests are involved. There has

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41 Prof. White, *Committee Hansard*, 19/9/02, p.124.

42 Prof. Trounson, *Committee Hansard*, 24/9/02, p.141.

43 Dr McCullagh, *Committee Hansard*, 24/9/02, p.157.

been considerable evidence about the potential research uses of embryos that might be permissible pursuant to the Bill. The following quotes are examples of that evidence:

> In fairness to companies like BresaGen, they are aware that therapy is 10 to 20 years away. Stem Cell International's CEO has said publicly that therapy, in their eyes, is 10 to 20 years away. *So they have to generate some form of income along the way. To use stem cells for screening and diagnostic purposes is a perfectly understandable use of such cells.*[44] [Italics added]

> My understanding was that the object of the Act was to allow frozen excess embryos in ART labs around the country to be used to derive embryonic stem cells specifically; but that is not specified in this legislation. In fact, any use of human embryos which the NHMRC Licensing Committee feels is worthwhile is approved, under this legislation.[45]

> …as much as I can know, there is no future in cell therapies. There are already ES cell lines which will not be affected by the Act, which could be used for research. … So why do they want the embryos? The only reason I can think of is that drug companies may wish to use them for screening. … there are plenty of embryonic cell line companies that are looking to make lots of money out of getting hold of these embryos.[46]

> For example, you can take embryonic stem cells and make them differentiate into certain tissues, like blood vessels. They would be very good to test certain drugs that you might want to stop this process in, say in tumours, because the approach to many tumour treatments is blocking the growth of blood vessels which support them. That is the sort of thing that you want them for, to be able to approach that sort of treatment in the test tube.[47]

> On reading the research involving embryos Bill, it is fairly clear that the consent provisions do allow, once the embryos are released from parental care, for those embryos to be used for all manner of purposes.[48]

> For me, research is a scientific endeavour aimed at answering questions and moving ahead and improving the way one does things, and my interest is therapeutic, so I am interested in new therapies. For me, research involves everything from where we are now to having products that are being used to treat patients, in the case of cellular transplants. It also includes the possibility of using embryonic stem cell lines for things like drug testing, which I think is actually a proper activity if it saves patients from being exposed to testing of new drugs, but I am not talking about, and absolutely

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44 Prof. Bartlett, 19/9/02, p.99

45 Dr Best, *Committee Hansard*, 24/9/02, p.158.

46 Prof. Good, *Committee Hansard*, 19/9/02, p.98.

47 Prof. Rowe, *Committee Hansard*, 19/9/02, p.98.

48 Dr Pike, *Committee Hansard*, 17/9/02, p.55.

> reject, the concept of using embryos as such for that testing. It is embryonic stem cell lines or the products of them, and actually it is more likely that cell lines that have differentiated into liver cells, kidney cells or heart cells would be wanted for things like drug testing.[49]
>
> My definition of research would include the development of therapies which could be of benefit to humans and the modifications thereof until we have reached the point where we accept them or reject them.[50]
>
> The other thing that sometimes therapeutics is used for is to say, 'Let's establish these lines and test drugs on them.' The argument has been put forward that if you have a muscle cell lines, say, or a liver line you can put chemicals in it and basically see what happens to the liver or muscle before you use it on humans. It is very plausible. Wouldn't it be ideal to get somebody with the disease you are looking at and to establish the line from them and then see what happens to the drug? Number one, you get an idea of whether the drug is going to be toxic to the cell, whether it is a normal cell or a diseased cell, and you might see that it might improve its function.[51]
>
> I do not see anything within the bill which would directly restrict the broader use of human embryos to direct application in pharmaceuticals testing or in toxicological testing.[52]

Professor Hearn on the other hand, did not accept pharmacological testing as an appropriate use of embryos, saying that we need "to restrict the use of embryos to stem cell derivation and not to pharmacological testing-say of teratologic agents"[53] and that "the criteria to allow research need to take that on board".[54] Professor Hearn interpreted "research" in a far more restricted way than many other witnesses:

> My definition of the more basic research and the sort of research I have been engaged in is understanding the fundamental processes—in this context—of how cells behave and the potentials of cells, and our astounding new understanding of how cell nuclei can be programmed and reprogrammed and how cells can be pluripotent. I would not personally put testing of pharmaceuticals on cells or embryos in the realm of basic research.[55]

There is a distinct possibility – as it is not prevented by the legislation – that human embryos could be destroyed for the purposes of pharmacological testing. There have

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49 Dr Juttner, *Committee Hansard*, 17/9/02, p.40.

50 Prof. Tuch, *Committee Hansard*, 17/9/02, p.40.

51 Dr Silburn, *Committee Hansard,* 17/9/02, p.56.

52 Dr Pike, *Committee Hansard,* 17/9/02, p.57.

53 Prof. Hearn, *Committee Hansard*, 19/9/02, p.115. Dr Best agreed with this limitation: *Committee Hansard*, 24/9/02, p.158.

54 Prof. Hearn, *Committee Hansard*, 19/9/02, p.119.

55 Prof. Hearn, *Committee Hansard*, 19/9/02, p.123.

been indications that there is commercial interest in obtaining embryos for such purposes.

The research permissible under the legislation is left at the discretion of the NHMRC. We consider it important that if this Bill is to become law it should include more restricted prescription of permissible research, in line with COAG's apparent intention and agreement.

Conclusion

Given the ethical sensitivity associated with the destruction of excess human embryos created in IVF procedures, we consider it important that there be some degree of consensus on the scientific consequences of agreeing to or rejecting this Bill. Given the considerable variation of opinion, it is up to those who support the Bill to justify its existence. This has patently not been achieved. Indeed, more reasons have been advanced supporting rejection of the Bill than have been advanced in support of it. This is not adequate for such a contentious issue.

We believe that for Parliament to mandate the expansion of ethically contentious research, involving the destruction of human life, there must be compelling reasons. We do not find any of the reasons presented to the Committee compelling.

For example, the Australian Academy of Science sought the flexibility contained in this legislation because the scientific knowledge underpinning it is flawed.[56] While the knowledge underpinning the legislation is so flawed there should be no decision to permit the destruction of embryos in order to improve that knowledge, especially when that course of action is unnecessary to improve the knowledge.

56 Prof. Serjeantson, *Committee Hansard*, 19/9/02, p.120.

CHAPTER 2

ETHICAL AND MORAL CONSIDERATIONS

Definition of "embryo" – moral considerations

The destruction of a human embryo is a destruction of human life, in our moral judgement.

> Either it is permissible to destroy human embryos in the name of science or it is not. … We are concerned that the harm may affect us and future generations if we come to regard the early stages of human life as raw material for use in exploitation. We contend that the human embryo is just that – human. This is supported by embryology and agreed on by scientists on both sides of the debate. That is why people want to use them. The question is not "Are they human?' but 'How are we going to treat them. ... The moral status of an embryo is not a fact but a value.[57]

The issue then, is that the Bill contains a value judgement about how we are going to treat embryos. To our minds, that value judgement should not involve commercial considerations above all else. In view of the underwhelming evidence in support of the destruction of embryos and the divergence of views among scientists as to the need for embryos to be destroyed in the name of research, we cannot reach the conclusion that embryos should be destroyed in these circumstances.

The assumption underpinning this Bill is that parents have absolute proprietorial rights over their progeny – including embryos. In fact, this is not the case because there are broader social values which override parental interests, whether they be derived from religious views or from commonly held social views. It is inconsistent with accepted policies and ethical arguments to give parents proprietary rights over embryos.[58]

Allowing to succumb v destroying an embryo

This Bill represents a move away from established principles by rejecting the ethical distinction between letting life succumb and killing or destroying a human life.

It may be true that:

> … no embryos would be saved by defeating the legislation.[59]

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57 Dr Best, *Committee Hansard*, 24/9/02, p.155.

58 See also, Dr Pike, *Committee Hansard,* 17/9/02, p.55.

59 Dr Elefanty, *Committee Hansard*, 24/9/02, p.138.

However, if it is believed that a human embryo is human life, then there is a distinct difference between letting an embryo "succumb" and destroying it for research. The end outcome should not be confused with how that outcome is achieved.

> … we have tried to clarify what we see as a distinction which in one respect we hoped would never have to be made, and that is the distinction between intentional killing and allowing to die. It is a difficult one, but one recognised in ethics in several different arenas. What concerns me most about this particular application of the 'they're going to die anyway, so let's use them' approach is that that line of reasoning has been used in other arenas in the past and some of those have been quite disturbing. As often happens in ethics and philosophy, what is a consistent argument in one arena gets transferred into another arena. So it is quite possible that if this distinction is not recognised here, whereas it is at other places and times—for example, end of life, which is one of the best examples we have of that particular distinction—if we lose it here we may lose it elsewhere.[60]

Some witnesses stated that the Bill was dealing with embryos that would otherwise be destroyed.

> What the Bill does do is provide for the first time a strong national framework for the regulation of research on excess ART embryos **that would otherwise have been destroyed**.[61]

> … the proposed legislation will permit the use of surplus embryos from in vitro fertilisation procedures **that would otherwise be destroyed**…[62]

In fact, the embryos, would not "otherwise be destroyed", they would, rather, be allowed to succumb. To our minds, active destruction is ethically quite a different proposal.

> ... there is no proof of principle for destructive embryonic stem cell research. … This is no basis for legislation which sets the precedent for the deliberate destruction of human life.[63]

As noted by Dr Pike, this issue has serious implications for how we treat human beings in the future where people are 'going to die anyway'. We are concerned at this change in our present approach to forbidding experimenting on and putting an end to a human life, irrespective of the subject's consent.

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60 Dr Pike, *Committee Hansard*, 17/9/02, p.55.

61 Prof. Pettigrew, *Committee Hansard*, 29/8/02, p.2.

62 Dr Elefanty, *Committee Hansard*, 24/9/02, p.137.

63 Dr Neville, *Committee Hansard*, 26/9/02, p.217.

CHAPTER 3

SPECIFIC CONCERNS WITH BILL AND REGULATORY REGIME

Omissions from Bill

Number of embryos

The number of embryos required for research is not a requisite consideration of the NHMRC's Licensing Committee in this legislation. That is a serious inadequacy. The NHMRC stated:

> One of the criteria that the Licensing Committee must examine is the number of embryos necessary to achieve the goals of the project … That is one of the criteria that COAG set.[64]

That criterion is not, however, enshrined in legislation, and we believe that it is appropriate that it be an object of the Act. The concept that it is desirable to minimise the number of embryos has been removed from the Bill, and even though the licensing process is to take account of the number of embryos proposed to be used, there is no objective to limit the number.

Clearly there is dispute over the number of embryos that will be required to be destroyed for research purposes, if any are in fact required.[65] We believe that it should be an object of this legislation to minimise the number of embryos destroyed, so that embryos are not unnecessarily destroyed.

We suggest amendment of the Bill to include such a limitation, as this should be a critical consideration for the NHMRC Licensing Committee.

There have been suggestions that the approach in the UK of establishing a "stem cell bank" so that there are no intellectual property rights over stem cell lines would better achieve a purpose of minimising the number of embryos used than the approach in this Bill.

> In the UK they have taken a decision … to establish a national stem cell bank which will be managed independently of academic research institutes and commercial companies. … in trying to minimise the number of embryos destroyed for that purpose [producing stem cell lines], the UK government saw that it would make sense to hold all of the stem cell lines in a central

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64 Ms Matthews, NHMRC, *Committee Hansard*, 29/8/02, p.8.

65 See above "Number of embryos".

> point where there would be free and unencumbered access to those stem cell lines to qualified researchers.[66]

In Europe, the prohibition of patents on unmodified human stem cell lines, also reduces the destruction of embryos:

> So there could be no encumbrance of research being conducted on the human stem cell lines, no patents were granted for their isolation or their development. But for discoveries made when using those cells which are beneficial for one matter or another … those discoveries would indeed become patentable.[67]

There is merit in these international approaches, and this Bill takes a very different approach which we do not believe will restrict the number of embryos destroyed. Alternative approaches should be investigated.

There is a distinct possibility, as it is not prevented by the legislation, that embryos could be destroyed for the purposes of pharmacological testing. There have been indications that there is commercial interest in obtaining embryos for such purposes.

The research permissible under the legislation is left at the discretion of the NHMRC. We consider it important that if this Bill is to become law it should include more restricted prescription of permissible research.

Revocation of license not automatic

One other concern that was raised during Committee hearings was that there is no automatic revocation of license by NHMRC if a person commits an offence:[68]. The NHMRC should not have, nor is it likely to desire any discretion in such circumstances, and the license should be automatically revoked.

Definition of "proper consent"

The Bill requires consent of the 'owners' of the embryo. The adequacy of the requirements have been brought into question. AHEC has stated that it has concerns that the definition of "proper consent" is open to interpretation, and does not reflect the strict regulatory regime that COAG approved.[69]

The submission from ACF GeneEthics Network expressed the concern that:

> It is important that advance informed agreement (with evidence of full notification and maybe even counselling) be required before an embryo is

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66 Mr Ilyine, *Committee Hansard*, 17/9/02, p.36.

67 Mr Ilyine, *Committee Hansard*, 17/9/02, p.45.

68 NHMRC, *Committee Hansard*, 29/8/02, p.17.

69 *Committee Hansard*, 26/9/02, p.251.

> used for any purpose other than pregnancy, rather than mere consent sufficing as that is too passive.[70]

It is important that proper procedures for the obtaining of consent from the 'owners' of the embryo is obtained before any embryo is destroyed. This needs to be prescribed in the legislation.

Assessment of research

It was suggested to the Committee that in order to address concerns that research may be carried out without sufficient evidence-based justification, there should be mechanisms in the legislation that require assessment and review of the research conducted under licenses and re-assessment of the potential of future research based on developments and contemporary community standards.[71]

We agree that there should be regular assessment of the outcomes of research conducted under the Bill, and that this should be included in the Licensing Committee's reports to the Parliament.

Concerns with regulatory regime

The importance of proper mechanisms for scrutiny and adequate transparency of decisions of NHMRC licensing committee were issues raised with the Committee.[72] It has been suggested that there are some possible deficiencies in public scrutiny and accountability under the Bill.

The NHMRC gave evidence to the Committee that:

> there are various other reporting requirements, as established in the bill, which prescribe reports that the licensing committee should provide both to parliament and to the NHMRC. In addition, certain data will be publicly available on the web site so that there is free access to relevant information. … the information that we make publicly available is the best that we can do, given the requirements of the Privacy Act and the obligations in handling commercial-in-confidence information.[73]

There is the prospect here (in Clause 45 of the Bill) as Senators frequently encounter when seeking information, that claims of commercial-in-confidence restrict access to information. As stated in a submission:

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70 Submission 1843, ACF GeneEthics Network.

71 Submission 1843, ACF GeneEthics Network.

72 Prof. Hearn, *Committee Hansard*, 19/9/02, p.115; Prof. White, *Committee Hansard*, 19/9/02, p.118.

73 Prof. Pettigrew and Dr Morris, NHMRC, *Committee Hansard*, 29/8/02, p.28.

> The amount of "confidential commercial information" withheld from publication should always be minimised. The public's right to know has at least equal status with commercial interests.[74]

We believe that this is particularly so in the present circumstances where there is considerable public interest in the ethical issues involved. The reporting requirements of the NHMRC should be strengthened, and the NHMRC Licensing Committee should be required to table in the Senate a six-monthly report on the operation of the Bill and details of licenses provided pursuant to this Bill.

The question has been raised whether the Parliament has the power to directly require a report from the Licensing Committee.[75] That certainly should be a reporting requirement of the Committee and we intend to pass a motion in the Senate to this effect.

Additionally, the openness of NHMRC has been brought into doubt, raising questions about the appropriateness of NHMRC control of the regulatory (licensing) regime:

> The NHMRC is impenetrable and effectively answerable to no-one outside. GTRAP and AHEC are examples of NHMRC with whom we have attempted to engage over many years, with very little success. We propose that this licensing function be vested in the Office of 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.[76]

We believe that alternatives to the regulatory arrangements in the present Bill need to be considered.

Appeal rights

We consider that it is appropriate that as well as applicants for licences and licence holders, any other interested party should have standing to appeal decisions of the NHMRC Licensing Committee including present or former "owners" of the embryos, interest groups and the public at large.[77]

In this Bill there are so many ethical concerns that it is proper that decisions made in the licensing process be subject to appeal.

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74 Submission 1843, ACF GeneEthics Network.

75 Submission 1843, ACF GeneEthics Network.

76 Submission 1843, ACF GeneEthics Network.

77 See Submission 1843, ACF GeneEthics Network.

Grants of funding

Given the division within the scientific community on many issues, the potential for bias and conflict of interest in decision-making, in particular where funding is concerned, it is recommended that in the future, there be greater accountability to the Parliament of committees appointed to distribute research funding, and greater oversight by the Parliament of significant funding grants.

Sunset clause and review

Sunset clause

Clause 60 of the Bill provides for repeal paragraphs 36(3)(b) and 39(1)(c) and subsection 39(3) on 5 April 2005 or, if COAG declares, an earlier date. Those provisions that are to be repealed prevent the use of embryos created after 5 April 2002. Therefore after 5 April 2005 (or earlier if so declared) there will be no restriction on the date of creation of the embryo to be used for research.

Concerns have been expressed, which we share, that this sunset clause could result in the de facto production of human embryos (through IVF procedures) deliberately for the purposes of research.

Review

Clause 61 of the Bill provides for a review of the legislation within three years of its commencement. We consider review of the legislation developed by COAG[78] and coordinated by the NHMRC, which has significant regulatory responsibilities in this area, to be inappropriate in these circumstances.

The ACF GeneEthics Network stated in its submission that:

> An inhouse committee of the NHMRC is not open to public scrutiny, communication, or participation and cannot be therefore assured of acting in the public interest.[79]
>
> Without full public participation the object of the Act "to address concerns, including ethical concerns …" cannot be realised. The Bill, as drafted fails to enable full public participation.[80]

Rather, we consider review by a joint house parliamentary committee, comprising representative numbers of members of each party to be more appropriate.

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78 Ms Matthews, NHMRC, *Committee Hansard*, 29/8/02, pp. 14-15.

79 GeneEthics Network, Submission 1843.

80 Ibid.

There are serious ethical issues that this review needs to take into account, and not only are members of parliament appropriate representatives of community concerns, but furthermore, it is appropriate that legislators have a role in the review of contentious legislation such as this.[81]

Constitutional issues

Advice from the Australian Government Solicitor raises serious doubts about the constitutionality of the legislation.[82] Clearly, the legislation would be open to challenge if individuals were prosecuted for an offence under this legislation, as there is no apparent Commonwealth head of power in the Constitution. Consequently, the States will need to enact empowering legislation in order to give full effect to this legislation.[83] If there is national agreement on the content of legislation by each of the States and Territories, why are they not left with responsibility when they have complete constitutional power?

It is of concern that this Parliament is being asked to knowingly pass legislation that is not constitutional and offences that are unenforceable unless or until the States and Territories confirm transfer of their constitutional power to the Commonwealth. There is no clear rationale for this action.

81 Prof. White, *Committee Hansard*, 19/9/02, p.118.

82 Ms Matthews, NHMRC, *Committee Hansard*, 29/8/02, p.11.

83 Ms Matthews, NHMRC, *Committee Hansard*, 29/8/02, pp. 11-13, 17.

CHAPTER 4

COMMENTS ON CHAIR'S REPORT AND CONDUCT OF INQUIRY

Australian concepts

The Chair's Report refers to a Morgan poll indicating that 72 per cent of Australians surveyed have indicated their approval of research using excess IVF embryos for the development of therapies, assuming the informed consent of donors.[84]

We do not believe that this poll reliably represents the views of Australians on this Bill because:

- The poll refers to "the development of therapies", not mentioning that the development of a therapy involves up to 30 years of research using human embryos, and even then a positive therapeutic outcome is still an unlikely consequence.
- This poll does not relate to the Bill, as the Bill is not about "developing therapies", the Bill is about using excess human embryos for destructive research, and even permits pharmacological testing.
- It is probable that those responding to this question were not properly informed about the likelihood of successful therapies being developed using alternate methods and were influenced by media reports overstating the possibility of cures resulting from embryonic stem cells for Parkinson's and Motor Neurones diseases, spinal cord and brain injuries, juvenile diabetes and the like. It is not likely that respondents were well informed about the true nature of this Bill.
- The poll contradicts other evidence that shows 56% of Australians responded 'definitely yes', 'probably yes', had 'mixed feelings' or were 'undecided' when asked if an embryo is a human being at the moment of conception.[85] These figures clearly show that the majority of people at the very least had mixed feelings or were undecided about whether an embryo is a human being at conception. In that case, we need to give very careful consideration to the ethical issues surrounding the destruction of human embryos.

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84 Chair's Report, para [3.104].

85 Melbourne Institute of Applied Economic and Social Research, "When human life begins: Public perceptions", *Australian Social Monitor*, Vol. 5, No. 1, February 2002, pp.15-16.

There is evidence that there is a mixture of views internationally on this issue, and that mixture is likely to be evident in a properly informed Australian public.

The Chair's Report, in Chapter 5, considers the variety of international approaches to the destruction of embryos for research purposes. Clearly, the ethical issue is not as clear-cut as some witnesses would have us believe, with a range of approaches being adopted by governments across the modern world. This represents the ethical element of decision-making where the destruction of embryos is concerned, and the different ways parliaments have exercised their judgement in that situation indicates the diversity of views and conclusions on the available evidence.

Approach to ethical issues

The Chair's Report, in Chapter 3, describes "third way" approach to ethics. We draw attention to this because we are unaware of any substance to or support for that ethical position. In fact, we believe that this approach is a creation of the Chair.

Important questions arise if this approach to ethics is to be used to justify the ethical position represented in the Bill. For example, no evidence is provided that there are any ethicists who support this approach. It also seems that there is no theological or ethical basis for this "third way" concept.

It is a dangerous situation ethically when you need to create a new approach to ethics to justify ethically contentious legislation.

Equally bewildering is the conclusion to Chapter 3 where the possibility that the research would continue unregulated is a greater evil than passage of a Bill, even given ethical concerns. This argument fails to take account of the fact that the Bill does not regulate stem cell research, and the embryos would only be available for destruction if States permit such action.

Incorporation of guidelines into Bill

Several areas of the Bill are given effect by the incorporation of material for which the Parliament is not responsible. This is cause for concern considering the breadth of legislative delegation by the Bill.

As noted in the Chair's Report, in the past, the Senate Scrutiny of Bills Committee has drawn attention to provisions of Bills 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.[86]

The Chair's Report states that "On this occasion, the Senate Scrutiny of Bills Committee considered the Bill and found no cause to comment".[87] The unusual omission to comment on this issue when there is such a considerable degree of delegation of legislative power dictates that the Parliament seek to amend the Bill to establish a sufficient regime of scrutiny over the exercise of that power.

The Australian Health Ethics Committee of the NHMRC has expressed some dissatisfaction with the drafting of the Bill:[88]

> **Senator JACINTA COLLINS-** Let me characterise for you my understanding of the way those concerns have been described. AHEC raised the concern that, without further describing the parameters of significant gain in knowledge or other similarly grey areas of the draft bill- for instance, those terms open to interpretation such as 'proper consent'-the proposed regulatory system will not deliver the strict regulatory regime required by the COAG decision.
>
> **…**
>
> **Dr Breen-** It is in our notes from 16 May.

It is recommended that the Bill be amended to include scrutiny of the legislative power extended by the Bill.

AHEC review of ART guidelines

One instance where guidelines are incorporated into the Bill is of particular concern. As noted by the Chair, Paragraph 36(4)(c) of the Bill requires that the Licensing Committee have regard to any relevant guidelines issued by the NHMRC. Pursuant to that paragraph, the Licensing Committee would need to have regard to the Ethical Guidelines on Assisted Reproductive Technology.

However, those guidelines are under review and the revised draft is not available for Senators to take into account in their deliberations on the Bill.

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

86 Chair's Report, para [4.126] referring to the Senate Scrutiny of Bills Committee, Work of the Committee during the 38th Parliament, chapter 6.

87 Chair's Report, para [4.130]

88 *Committee Hansard*, 26/9/02, p.251.

> 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.[89]

This is an important aspect of the regulatory regime, and contrary to AHEC's comments, work should have continued on those guidelines even when this Bill was introduced. The guidelines involved important ethical considerations, and should have been ready for the parliament's consideration of this Bill. AHEC stated that:

> 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 ... 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.[90]

Furthermore, in the review of those guidelines, information on how institutional ethics committees reached their decisions, what they saw as extraordinary circumstances, what types of research were regarded as perhaps extraordinary will not be available. Dr Breen of the Australian Health Ethics Committee of the NHMRC conceded this during public hearings:

> They are valid criticisms, and we do not have access to that information.[91]

It is not appropriate that AHEC does not have access to this very relevant information in its review process. This lends further support to arguments for parliamentary review.

It is not proper that Parliament delegate such a critical part of the licensing regime without the ability for proper parliamentary scrutiny of the substance of the Bill during our Inquiry.

Recommendation: that the revised guidelines should be referred to the Parliament – tabled in parliament and be disallowable by either House.

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89 NHMRC, Submission 23, p. 21.

90 Dr Breen, *Committee Hansard*, 26/9/02, p. 251.

91 *Committee Hansard*, 26/9/02, p.249.

Conduct of Inquiry

There are a few comments that remain to be made about the conduct of the Inquiry. There has been undue haste in the process, the period in which submissions could be made was very short, yet over 1800 submissions were received. In spite of the clear community interest in the process, public hearings were only held in Canberra, on sitting days (not typical for a Senate Inquiry). Time was regularly an issue for witnesses and Senators alike. It was an issue of considerable interest among Senators, and there were seemingly unnecessary time restrictions imposed.

The question needs to be asked why the passage of this legislation is so pressing an issue for some States and the Commonwealth Government. Embryonic stem cell research is occurring and will continue to occur, irrespective of the passage of the legislation.

It is disappointing to say the least, and does not help the perception that there are vested commercial and political interests at play.

CONCLUSIONS

In our consideration of this Bill we conclude:

- That human embryos surplus to ART purposes should not be exploited in destructive research. No persuasive argument has been put forward that justifies the destruction of human life.
- That research on pre-existing human embryonic stem cells lines can continue, as this research is not dependent upon the passage of the Bill.
- That research should use available resources without destroying human life. There are clearly very viable research alternatives open to scientists that will not result in the destruction of embryos.
- That there are a number of amendments to the Bill which we foreshadow, to address the inadequacies in the Bill that have been considered in these qualifying comments. Those inadequacies are particularised in Chapters 3 and 4.

SIGNATORIES

Full Members

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Senator Guy Barnett (Liberal Party, Tasmania)

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Senator Bill Heffernan (Liberal Party, N.S.W.)

_____

Senator Stephen Hutchins (A.L.P., N.S.W.)

Participating Members

_____

Senator Mark Bishop (A.L.P., W.A.)

_____

Senator Ron Boswell (National Party, Queensland)

_____

Senator Jacinta Collins (A.L.P., Victoria)

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Senator Brian Harradine (Independent, Tasmania)

_____

Senator John Hogg (A.L.P., Queensland)